# MEDICALTHERAPIES ()

### Prospectus 2005

MEDICAL THERAPIES LIMITED ACN 111 304 119 For the offer of 25,000,000 Shares at an issue price of A\$0.20 to raise A\$5,000,000 (with the ability to accept oversubscriptions for up to a further A\$5,000,000).

#### Summary of important dates

Lodgement of Prospectus with ASIC	3 June 2005
Opening Date	11 June 2005
Closing Date	26 July 2005
Expected date of dispatch of Holding Statements	3 August 2005
Expected date of listing on ASX	12 August 2005

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

#### Important information

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

#### Important notice

This Prospectus is dated 3 June 2005 and was lodged with ASIC on that date. ASIC and its officers take no responsibility for the contents of this Prospectus nor the merits of the investment to which the Prospectus relates. The expiry date of this Prospectus is 5.00pm WST on that date which is 13 months after the date this Prospectus is lodged with ASIC (Expiry Date). No securities may be issued on the basis of this Prospectus after the Expiry Date. The distribution of this Prospectus in jurisdictions outside Australia may be restricted by law and persons who come into possession of these restrictions. Failure to comply with these restrictions may violate securities laws. Applicants who are resident in countries other than Australia should consult their professional advisers as to whether any governmental or other consents are required or whether any other formalities need to be considered and followed. This Prospectus does not constitute an offer in any place in which, or to any person to whom, it would not be lawful to make such an offer.

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

#### Web site—Electronic Prospectus

A copy of this Prospectus can be downloaded from the website of the Company at www.medicaltherapies.com.au. Any person accessing the electronic version of this Prospectus for the purpose of making an investment in the Company must be an Australian resident and must only access the Prospectus from within Australia. The Corporations Act prohibits any person passing onto another person an application form unless it is attached to a hard copy of this Prospectus or it accompanies the complete and unaltered version of this Prospectus. Any person may obtain a hard copy of this Prospectus free of charge by contacting the Company.

#### Exposure Period

This Prospectus will be circulated during the Exposure Period. The purpose of the Exposure Period is to enable this Prospectus to be examined by market participants prior to the raising of funds. Potential investors should be aware that this examination may result in the identification of deficiencies in the Prospectus and, in those circumstances, any application that has been received may need to be dealt with in accordance with Section 724 of the Corporations Act.

Applications for securities under this Prospectus will not be accepted by the Company until after the expiry of the Exposure Period. No preference will be conferred on persons who lodge applications prior to the expiry of the Exposure Period.

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### **INVESTMENT HIGHLIGHTS**

# Potentially benefiting sufferers of major diseases

O The Company is seeking to raise between A\$5 million and A\$10 million to assist the development of treatments for cancer and painful inflammatory diseases such as arthritis.

#### Large worldwide markets

- The market for cancer therapies was US\$42.4 billion in 2004, of which US\$9 billion came from chemotherapy products.
- The prescription market for non-steroidal anti-inflammatory drugs (NSAIDs) was US\$12.4 billion in 2003.

#### Novel technologies with well protected IP

- In animal studies, Technology One drug candidates have demonstrated reduced gastrointestinal and renal toxicity compared to conventional NSAIDs. The Technology may offer alternatives to the controversial COX-2 inhibitors such as Vioxx and Celebrex.
- In cell-line and recent animal studies, Technology Two drug candidates have, compared to existing treatments, demonstrated greater activity, substantially less toxicity, activity against a broader range of cancers, and less tendency to trigger drug resistance.
- Technology Three may provide the ability to target drugs and other compounds to specific DNA sequences for both therapeutic and diagnostic applications.
- The three Technologies are discrete but offer similar clinical development paths, potentially reducing costs and lowering development hurdles.
- The three Technologies are covered by a series of patents and international (PCT) patent applications.



#### Spread of technical and commercial risks

 Several technologies combined offer a pipeline of potential products and a spread of technical and commercial risks.

#### World leading research team

 The Technologies are being developed by world-leading researchers from the Universities of Sydney and Western Sydney.

#### University partners committed to success

- The Universities are providing the IP for each Technology in a cashless exchange for shares.
- Research agreements between the Company and the Universities ensure regular reporting of discoveries, milestones and product releases.
- Options will be issued to the Universities upon their achieving defined milestones.

#### Experienced Board and management team

 The Board and management team offer a depth of experience and understanding in the important areas of technology innovation and commercialisation, pharmaceutical markets and corporate governance.

#### Clear strategies to commercialise IP

- O The Company is ready to begin preparing for human clinical trials of topical and oral formulations of new NSAID compounds.
- The Company intends to fully commercialise the Technologies using a combination of in-house development, partnerships and licensing arrangements.
- Ongoing research is being used to strengthen the Company's existing patent position.



# 1 CHAIRMAN'S LETTER

#### Dear Investor,

Medical Therapies Limited (Medical Therapies or Company) is a pharmaceutical company formed to develop products to treat various cancers and chronic inflammatory diseases such as arthritis. These diseases are likely to affect all of us at some time in our lives, either directly, or indirectly via those we love. By bringing these products to market, our wish is to make a significant difference to the lives of those affected and their families—to relieve pain, improve quality of life and ultimately help save the many millions of people who currently die each year from these diseases or from the side effects of treatment.

The Intellectual Property (IP) acquired by Medical Therapies is derived from several significant discoveries made by researchers at the Universities of Sydney and Western Sydney. Together, these discoveries have the potential to generate a portfolio of chemotherapeutic and anti-inflammatory products to treat a range of diseases, and thus represent a major new business opportunity in the pharmaceutical field with a spread of technical and commercial risk. If successfully commercialised, the anti-inflammatory products are expected to be significantly less toxic than established treatments, and are a potential alternative to the formerly widely-prescribed but controversial COX-2 inhibitors, such as Vioxx and Celebrex. Furthermore, if successfully commercialised, the chemotherapeutic products are expected to substantially reduce the toxicity and resulting side effects of existing treatments, such as bone marrow depression, hair loss and nausea, with greater activity against a range of cancers, and less tendency to trigger drug resistance. Many pharmaceutical companies have recognised the limited commercial potential of single drug compounds, which are subject to competition from generic manufacturers once patents expire. A solution is to develop products based on platform technologies covering a broad class of drug candidates, to provide ongoing discovery and patent protection. The Company's IP covers three such platform technologies, which the Universities have agreed to assign in a cashless exchange for shares in the Company, demonstrating their commitment to the development of the IP and their belief in its commercial potential.

Our team of researchers includes Professor Trevor Hambley, Professor Peter Lay and Associate Professor Janice Aldrich-Wright. All are world-renowned experts in their field, leading their peers in areas of research relevant to the Company.

I am joined on the Board of Directors by the Company's CEO, Llewellyn Casbolt, and non-executive directors Professor Michael Vitale and Dr Michael Taverner. This highly qualified Board and management team offers an enormous depth of experience and understanding in the important areas of technology innovation and commercialisation, pharmaceutical markets and corporate governance, to guide the Company during its early growth.

We have established clear strategies for commercialising the Company's Technologies using the funds raised by this Issue, including immediately commencing commercial manufacture of human pharmaceutical grade formulations and documentation required to enter Phase I and Ila clinical trials of new antiinflammatory drugs, with a focus on regular reporting of discoveries, milestones and product releases.

Details of the Issue, including information on the Company's products, markets, management, risk factors and finances, are set out in this Prospectus, which I encourage you to read before making a decision to invest. On behalf of the Board, I am pleased to present this Prospectus to you and invite you to become a shareholder in the Company.

James T Dominguez CHAIRMAN 3 June 2005

### 2 INVESTMENT OVERVIEW

#### 2.1 Important notice

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

#### 2.2 Summary of the Offer

By this Prospectus, the Company invites investors to apply for 25,000,000 Shares at an issue price of A\$0.20 per Share to raise A\$5,000,000.

The Company may also accept oversubscriptions of up to A\$5,000,000 through the issue of a further 25,000,000 Shares (for a maximum raising of A\$10,000,000).

#### 2.3 Indicative timetable

Lodgement of Prospectus with ASIC	3 June 2005
Opening Date	11 June 2005
Closing Date	26 July 2005
Expected date of dispatch of Holding Statements	3 August 2005
Expected date of listing on ASX	12 August 2005

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

#### 2.4 Objective

The purpose of this raising is to raise sufficient funds to enable the Company to seek to develop and commercialise the intellectual property encompassed by the Technologies. Following completion of the Offer, the Directors believe the Company will have enough working capital to pursue these objectives successfully.

### 2.5 Use of proceeds

If the minimum subscription of A\$5,000,000 is raised from the Offer, the funds are intended to be applied as follows:

Description	year 1	year 2	year 3	total
	A\$	A\$	A\$	A\$
Technology development				
Technology One	415,469	318,778	-	734,247
Technology Two	-	-	-	-
Technology Three	380,145	330,470	-	710,615
Total technology development	795,614	649,248	-	1,444,862
Preclinical and clinical trials				
Technology One	879,995	-	-	879,995
Technology Two	180,000	-	-	180,000
Technology Three	-	33,000	-	33,000
Total preclinical and clinical trials	1,059,995	33,000		1,092,995
Protection of IP portfolio	30,000	30,000	_	60,000
Expenses of Offer	400,000	-	-	400,000
Broker handling fees	250,000	-	-	250,000
Total other costs	680,000	30,000		710,000
General working capital				
Salaries	307,380	340,080	-	647,460
Rent and other overheads	75,000	75,000	-	150,000
Other working capital	797,856	156,827	-	954,683
Total general working capital	1,180,236	571,907	-	1,752,143
Total	3,715,845	1,284,155	-	5,000,000

If the maximum subscription of A\$10,000,000 is raised from the Offer, the funds are intended to be applied as follows:

Description	year 1	year 2	year 3	total
	A\$	A\$	Α\$	A\$
Technology development				
Technology One	415,469	318,778	1,250,000	1,984,247
Technology Two	-	-	-	-
Technology Three	380,145	330,470	1,000,000	1,710,615
Total technology development	795,614	649,248	2,250,000	3,694,862
Preclinical and clinical trials				
Technology One	879,996	-	-	879,996
Technology Two	180,000	-	-	180,000
Technology Three	-	33,000	-	33,000
Total preclinical and clinical trials	1,059,996	33,000		1,092,996
Commercialisation of Technologies 2 & 3	-	400,000	900,000	1,300,000
Protection of IP portfolio	30,000	30,000	30,000	90,000
Expenses of Offer	400,000	-	-	400,000
Broker handling fees	500,000	-	-	500,000
Total other costs	930,000	430,000	930,000	2,290,000
General working capital				
Salaries	307,380	340,080	340,080	987,540
Rent and other overheads	75,000	75,000	75,000	225,000
Other working capital	547,855	489,160	672,587	1,709,602
Total general working capital	930,235	904,240	1,087,667	2,922,142
Total	3,715,845	2,016,488	4,267,667	10,000,000

If the amount raised from the Offer is intermediate between the minimum subscription of A\$5,000,000 and the maximum subscription of A\$10,000,000, the funds raised from the Offer are intended to be applied as per the table on page 8 with additional funds applied to broker handling fees (5%) and thereafter in priority to development and commercialisation of Technology Two and Technology Three in years two and three (up to a maximum of A\$3,550,000), with the balance applied to protection of the intellectual property portfolio and general working capital.

The Directors intend to seek additional funding from AusIndustry Commercial Ready and other government grants to assist development, commercialisation and clinical trialling of the Company's technologies. The Directors believe the funds raised from the Offer will give the Company sufficient working capital to achieve its objectives as stated in the above tables. However, funds raised under this Prospectus are unlikely to be sufficient to enable the Company to fully commercialise its technologies. As stated in Section 4.5 of this Prospectus, the Company's strategy is to licence its technologies in the early clinical phases of their development to licensees that are able to complete commercialisation of the technologies. The Company may seek to raise additional capital in the future if suitable licensees cannot be identified and the Company seeks to commercialise the technologies without licensees. The Directors currently anticipate that the Company will complete its Phase I clinical trials for formulations of copper-indomethacin by mid 2006 and, depending on the results of such trials, will complete Phase IIa by mid 2007.

The Directors anticipate that the Company will complete preclinical trials of its lead metal intercalating compound by December 2005. Depending on the results of these trials, further commercialisation of Technology Two may require additional research of the base compounds and/or additional preclinical trials. The funds raised under this Prospectus are unlikely to be sufficient to enable the Company to complete these development stages. The Company may seek to raise additional capital in the future if it seeks to further commercialise this technology.

Depending on the success or otherwise of the Company's research, commercialisation and preclinical trials of its sequence-selective compounds, and the timing and nature of any licensing arrangement relating to its sequence-selective compounds, the Company may seek to raise additional capital in the future to further develop this technology in a manner to be determined by the Directors.

On completion of the Offer, approximately 24,016,665 Options to acquire Shares in the Company will be on issue. If these Options are exercised, the Company may receive up to an additional A\$4,803,333 prior to the expiry date of the Options. Any such funds will be used for general corporate purposes and ongoing development of the Company's technologies. The exercise of Options is only likely to occur if the price of the Shares on ASX is higher than the exercise price of the Options, which is A\$0.20 for all classes of Options.

### 2.6 Capital structure

The capital structure of the Company following completion of the Offer is summarised below:

Shares	Number
Shares on issue at date of this Prospectus	13,779,916
Shares offered pursuant to this Prospectus	25,000,000
Shares to be issued to Universities	30,000,000
Total Shares on issue at completion of the Offer <sup>1</sup>	68,779,916
Options <sup>2</sup>	Number
Options on issue at date of this Prospectus	5,516,665
Milestone Options that may be issued to Universities <sup>3</sup>	10,000,000
Director Options to be issued to Directors	3,500,000
Executive Options to be issued to the CEO	5,000,000
Total options on issue at completion of the Offer	24,016,665

#### Notes

1 Assumes that the Offer is fully subscribed and that no oversubscriptions are accepted by the Company.

2 Please refer to Sections 11.5.2, 11.5.3 and 11.5.4 of this Prospectus for details of the terms and conditions attaching to the various classes of Options.

3 These Milestone Options will only be issued to the Universities in the event certain milestones are achieved. Please refer to Section 10.4 for further details. The Universities have separately agreed to issue a portion of these Milestone Options to the principal researchers.

# 3 DETAILS OF THE OFFER

### 3.1 The Offer

By this Prospectus, the Company offers for subscription 25,000,000 Shares at an issue price of A\$0.20 per Share to raise A\$5,000,000. The Company may also accept oversubscriptions of up to a further A\$5,000,000 through the issue of a further 25,000,000 Shares (for a maximum raising of A\$10,000,000). The Shares offered under this Prospectus will rank equally with the existing Shares on issue.

#### 3.2 Application for Shares

An application for Shares by an investor must be made using the Application Form.

Payment for the Shares must be made in full at the issue price of A\$0.20 per Share. An application for Shares must be for a minimum of 10,000 Shares and thereafter in multiples of 2,000 Shares. Completed application forms and accompanying cheques must be mailed or delivered to:

Computershare Investor Services Pty Limited GPO Box D182 Perth WA 6840 or

Computershare Investor Services Pty Limited Level 2, 45 St Georges Terrace Perth WA 6000

Cheques must be drawn in Australian dollars, be made payable to 'Medical Therapies Limited—Share Offer Account' and crossed 'Not Negotiable'. Completed Application Forms must reach the Share Registry by no later than the Closing Date.

#### 3.3 Allotment

Subject to ASX granting approval for the Company to be admitted to the Official List, allotment of Shares offered by this Prospectus will take place as soon as practicable after the Closing Date. Prior to allotment, all application monies shall be held by the Company in trust. The Company, irrespective of whether the allotment of Shares takes place, will retain any interest earned on the application monies.

The Directors reserve the right to allot Shares in full for any application or to allot any lesser number or to decline any application. Where the number of Shares allotted is less than the number applied for, or where no allotment is made, the surplus application monies will be returned by cheque to the applicant within seven days of the allotment date.

#### 3.4 Minimum subscription

The minimum amount to be raised pursuant to this Prospectus is A\$5,000,000.

If the minimum amount has not been raised within four months after the date of this Prospectus, all applications will be dealt with in accordance with the Corporations Act.

#### 3.5 ASX listing

The Company will apply to ASX within seven days after the date of this Prospectus for admission to the Official List and for Official Quotation of the Shares offered under this Prospectus. If ASX does not grant permission for Official Quotation of the Shares within three months after the date of this Prospectus, or such longer period as is permitted by the Corporations Act, none of the Shares offered under this Prospectus will be allotted or issued. In these circumstances, all applications will be dealt with in accordance with the Corporations Act.

#### 3.6 Applicants outside Australia

This Prospectus does not, and is not intended to, constitute an offer in any place or jurisdiction, nor to any person to whom it would not be lawful to make such an offer or to issue this Prospectus. The distribution of this Prospectus in jurisdictions outside Australia may be restricted by law and persons who come into possession of this Prospectus should seek advice on and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities law. No action has been taken to register or qualify these Shares or otherwise permit a public offering of the securities that are the subject of this Prospectus in any jurisdiction outside Australia. It is the responsibility of applicants outside Australia to obtain all necessary approvals for the allotment and issue of the Shares pursuant to this Prospectus. The return of a completed Application Form will be taken by the Company to constitute a representation and warranty by the applicant that all relevant approvals have been obtained.

#### 3.7 Underwriter

The Offer is not underwritten. However, the Company reserves the right to pay a commission of 5% (exclusive of GST) on amounts subscribed in respect of valid applications lodged and accepted by the Company bearing the stamp of the holder of an Australian Financial Services licensee. Payments will be subject to the receipt of a proper tax invoice from the Australian Financial Services licensee.

#### 3.8 CHESS

The Company will apply to participate in the Clearing House Electronic Subregister System (CHESS). CHESS is operated by ASX Settlement and Transfer Corporation Pty Limited (ASTC), a wholly owned subsidiary of ASX, in accordance with the Listing Rules and the ASTC Settlement Rules.

Under CHESS, the Company will not issue certificates to investors. Instead, Share and Option holders will receive a statement of their holdings in the Company. If an investor is broker-sponsored, ASTC will send a CHESS statement.

#### 3.9 Risk factors

Prospective investors in the Company should be aware that subscribing for securities that are the subject of this Prospectus involves a number of risks. These risks are set out in Section 9 of this Prospectus and investors are urged to consider those risks carefully (and if necessary, consult their professional adviser) before deciding whether to invest in the Company.

The risk factors set out in Section 9, and other general risks applicable to all investments in listed securities not specifically referred to, may in the future affect the value of the Shares. Accordingly, an investment in the Company should be considered speculative.

#### 3.10 Privacy Act

If you complete an Application Form, you will be providing personal information to the Company (directly or via the Share Registry). The Company collects, holds and will use that information to assess your application, service your needs, facilitate distribution payments and corporate communications to you as a Shareholder, and carry out administration. The information may also be used from time to time and disclosed to persons inspecting the register, bidders for your securities in the context of takeovers, regulatory bodies, including the Australian Taxation Office, authorised securities brokers, print service providers, mail houses and the Share Registry.

You can access, correct and update the personal information that we hold about you. Please contact the Company or the Share Registry if you wish to do so at the relevant contact numbers set out in this Prospectus.

Collection, maintenance and disclosure of certain personal information is governed by legislation including the Privacy Act 1988 (as amended), the Corporations Act and certain rules such as the ASTC Settlement Rules.

If you do not provide the information required on the Application Form, the Company may not be able to accept or process your application.

### 3.11 Financial forecasts

The Directors have considered the matters set out in ASIC Policy Statement 170 and believe that they do not have a reasonable basis to forecast future earnings because the operations of the Company are inherently uncertain. Accordingly, any forecast or projection information would contain such a broad range of potential outcomes and possibilities that it is not possible to prepare a reliable best estimate forecast or projection. "The mind has exactly the same power as the hands: not merely to grasp the world, but to change it."

Colin Wilson (1931–), English writer, essayist

### 4 COMPANY AND TECHNOLOGY OVERVIEW

Worldwide, 22 million people are living with cancer and 6 million die annually. Sales of cancer therapies reached an estimated US\$42.4 billion in 2004, over US\$9 billion of which came from sales of chemotherapy products. The incidence of arthritis and other chronic inflammatory diseases is increasing in the aging populations of the developed world. These diseases are commonly treated with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), which are taken daily by over 30 million people worldwide. The 2003 worldwide prescription market for NSAIDs was US\$12.4 billion.

#### 4.1 Overview

Since the Company was incorporated on 8 October 2004, the Directors have been assessing opportunities to acquire technologies capable of generating wealth for shareholders.

Following two seed raisings totalling A\$1,343,120 that were completed in late November 2004 and early March 2005, the Company entered into the Intellectual Property Assignment Deed with the University of Sydney (USYD) and the University of Western Sydney (UWS) (Universities), under which the Company agreed to acquire the Intellectual Property (IP) relating to the Technologies in return for issuing securities to the Universities.

The Company has also entered into a number of other material contracts, summaries of which are set out in Section 10 of this Prospectus.

At a general meeting of seed Shareholders held on 29 April 2005, approval was obtained to proceed with the acquisition of the IP.

# 4.2 Background to the Company's Technologies

4.2.1 Cancer in the modern world

Cancer continues to present a major and largely unmet medical challenge in the Western world. In many Western nations such as Australia and the United States, cancer is responsible for about one in four of all deaths. Worldwide, 22 million people are living with cancer and 6 million die annually. More than 10 million new cases are diagnosed each year. A US male has, on average, a 45% chance of developing some form of cancer over his lifetime, while for a US female the chance is 38%.

Cancer also touches the lives of many Australians. Each year over 88,000 new cases of cancer and 36,000 deaths are reported. The prevalence of cancer, and its cost both in human and financial terms, drive the search for new therapeutic drugs.

The estimated size of the market for cancer therapies in 2004 was US\$42.4 billion, over US\$9 billion of which came from sales of chemotherapy products. Two-thirds of the chemotherapy market is controlled by two companies: Sanofi-Aventis and Bristol-Myers Oncology. Two anti-cancer drugs—Taxotere (for breast cancer) and the platinum drug Eloxatin (for colorectal cancer)—generated over US\$3.3 billion in revenue in 2004 from the treatment of cancer. The unmet demand for more effective cancer treatments is a key driver of growth in the pharmaceutical industry generally, with large pharmaceutical companies keen to identify the next generation of anti-cancer drugs.

#### 4.2.2 Inflammatory diseases

Inflammation is the body's basic response to a variety of diseases and conditions such as infection, injury and hypoxia, and is characterised by the four symptoms of redness, heat, pain and swelling. Chronic inflammatory diseases include rheumatoid arthritis, osteoarthritis, inflammatory bowel disease, systemic lupus erythematosus, multiple sclerosis, and Type 1 diabetes. In the USA alone, these debilitating diseases affect 50 million people, and many are becoming increasingly common in an aging society. The total financial cost of inflammatory diseases in the developed world, as a result of lost productivity and health care costs, is estimated at 1.4-2.5% of GDP. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are a commonly-used class of drug that includes aspirin, ibuprofen and naproxen, as well as the newer COX-2 inhibitors such as Celebrex. They have widespread human and veterinary applications for the treatment of chronic inflammatory diseases, and are effective in reducing

pain and fever. The 2003 worldwide prescription market for NSAIDs was US\$12.4 billion, with more than 30 million people using NSAIDs daily. Despite their effectiveness, NSAIDs have significant and well-documented side effects. Long term use of conventional (non-selective) NSAIDs can cause life-threatening gastrointestinal irritation and bleeding. Every year in the USA alone, an estimated 107,000 people are hospitalised for NSAID-related gastrointestinal complications and at least 16,500 NSAID-related deaths occur among arthritis patients. In recent years, a new generation of more specific NSAIDs has been developed and released; the socalled COX-2 inhibitors. Until recently, these drugs, such as Celebrex, Vioxx and Bextra, have been widely prescribed to treat various inflammatory conditions. NSAIDs reduce inflammation by inhibiting the cyclooxygenase (COX) enzyme. Two forms of this enzyme have been identified: COX-1 and COX-2. Medical research has suggested that inhibition of COX-2 is the main pathway for reducing inflammation, while inhibition of COX-1 results in the side effects of conventional NSAIDs such as gastric irritation. By targeting primarily the COX-2 form of the enzyme, COX-2 inhibitors were expected to offer all the benefits of conventional NSAIDs without the gastrointestinal side effects.

In recent years, concern about the safety of COX-2 inhibitors has prompted further study of their side effects. In September 2004, early results from a study of Vioxx found in some cases the drug significantly increased the risk of heart attack and stroke, resulting in the drug being withdrawn from sale worldwide by its manufacturer Merck. In April this year, the FDA asked Pfizer to withdraw from sale its COX-2 inhibitor, Bextra, with the drug subsequently being withdrawn from US and European markets. It also asked Pfizer to include a boxed warning about the increased risk of cardiovascular events in the label of the world's most widely prescribed NSAID, Celebrex.

The safety concerns associated with long term use of both conventional NSAIDs and COX-2 inhibitors emphasise the need for potent but safer NSAIDs with reduced side effects.

#### 4.3 The Company's Technologies

#### 4.3.1 Overview of Technologies

Researchers at the Universities of Sydney and Western Sydney have recently made several significant discoveries in the areas of anti-cancer and anti-inflammatory drugs. Although these discoveries were made in three separate research areas, the resulting Technologies possess a number of important synergies:

- (a) the chief inventors are all senior researchers from the Universities of Sydney and Western Sydney;
- (b) the Technologies are covered by a series of patents and patent applications and, with one exception for veterinary applications, have not yet been licensed to any commercial party;

- (c) each of the Technologies shows evidence of reducing or eliminating some of the major side effects or limitations associated with existing treatments; and
- (d) the clinical development path is similar for each technology, which should lead to further synergies and economies of scale over time.

Notwithstanding these synergies, the Company, as owner of the IP, may also benefit materially from the discrete character of each of the Technologies. The scope of the protected IP covered by the three Technologies is detailed in the Patent Attorney's Report presented in Section 6. The three Technologies provide a rich pipeline of potential products, regular achievement of milestones, and hence a spread of risk, and combined, create a new business opportunity in the global markets for cancer and inflammation therapeutics.

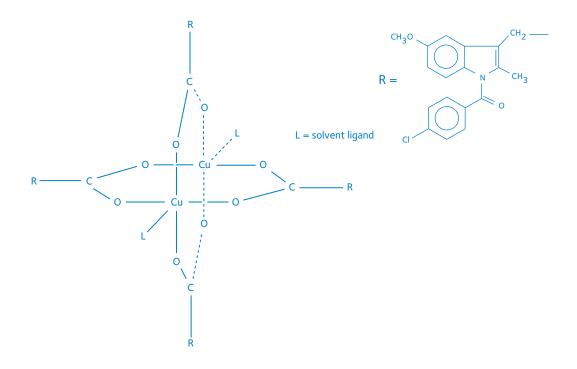
Technology One is currently being used in veterinary products and is ready for the commencement of commercial manufacture of human pharmaceutical grade formulations and documentation required to enter human clinical trials. Technology Two has undergone some preclinical testing and is intended to be ready for human clinical trials within one year subject to further standard toxicology testing. Technology Three is still being developed through fundamental research, but could have significant commercial potential in several applications. Technology One covers a range of anti-inflammatory compounds and their formulations, including topical, oral, ophthalmic and injectable formulations of copper-indomethacin. Metal complexes such as copperindomethacin are more potent and less toxic than their parent NSAIDs, which can cause gastrointestinal pain, bleeding and ulceration, and liver or kidney damage. The technology extends to new drugs that are a potential alternative in the treatment of arthritis and other chronic inflammatory diseases to the formerly widely-prescribed but now controversial COX-2 inhibitors such as Celebrex, Vioxx and Bextra. The technology also extends to the potential use of certain anti-inflammatory compounds in the prevention and treatment of cancer.

4.3.2 Technology One—Anti-inflammatory drugs There have been many reports over the years that metal complexes of NSAIDs are more effective and/or less toxic than the NSAIDs themselves. However, trials with such metal complexes have usually shown little improvement over the parent NSAID, perhaps because of insufficient stability of the complex in the formulation leading to release of the free NSAID either prior to being administered or while in the gut. Technology One relates to a range of antiinflammatory compounds and therapeutic formulations containing them. It encompasses the results of many years of work by researchers in the University of Sydney's School of Chemistry, in collaboration with a leading Australian veterinary pharmaceutical company, Nature Vet. One aspect of this technology is a set of new formulations of the copper complex of the NSAID indomethacin (Indo), known as copper-indomethacin (Cu-Indo). The chemical structure of Cu-Indo is illustrated on page 19. The new Cu-Indo formulations encompassed by Technology One exhibit greater stability than previous commercially available Cu-Indo formulations and appear to substantially reduce the gastrointestinal and renal toxicity problems associated with conventional NSAIDs by reducing the interaction of Indo with COX enzymes in the stomach wall.

The copper in these formulations also appears to contribute to the anti-inflammatory effect while reducing gastrointestinal irritation. As illustrated in the figures on page 20, the new Cu-Indo technology exhibits less gastrointestinal toxicity compared to free indomethacin and less renal toxicity than either indomethacin or celecoxib (Celebrex).

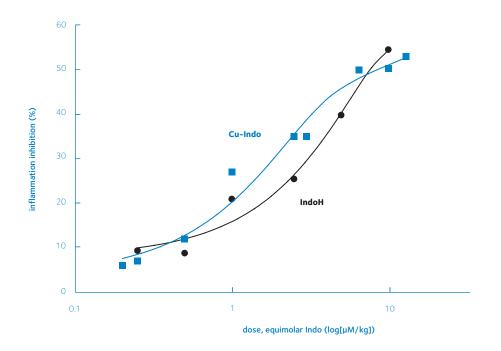
Several factors suggest that approval of formulations comprising metal-NSAID complexes for treating inflammation in humans is unlikely to be problematic. Specifically, indomethacin and other parent NSAIDs are already in widespread use and one metal-NSAID complex (i.e. Cu-Indo) has already been approved for animal use. Products containing Cu-Indo have been sold by Nature Vet in the form of tablets for dogs and paste for horses under the name Cu-Algesic® and have been used in veterinary practice in Australia, New Zealand, South Africa and other countries. Use of this product in dogs is particularly significant, given that oral administration of indomethacin and other NSAIDs in dogs can cause fatal gastrointestinal bleeding.

Indomethacin and other NSAIDs have previously been studied for the treatment of cancer; however, their utility is limited by the side effects associated with their long-term use. Technology One also extends to the potential use of certain anti-inflammatory compounds in the prevention and treatment of cancer.

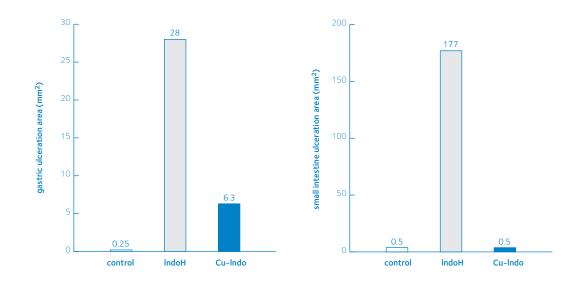


The chemical structure of Cu-Indo (above).

In standard animal tests, therapeutic doses of one of the Company's Cu-Indo formulations exhibit similar or greater effectiveness in reducing inflammation compared to the parent NSAID indomethacin (IndoH) (below).

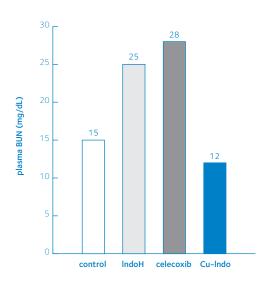


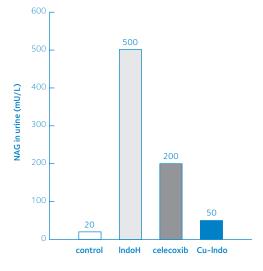
19



In animal studies, Cu-Indo produces significantly less gastric and intestinal ulceration than an equivalent dose of indomethacin, even when administered at 10 mg/kg of indomethacin (delivered as IndoH or Cu-Indo), 5–10 times the therapeutic dose (above).

Animal studies indicate that Cu-Indo at 15× the therapeutic dose exhibits lower renal toxicity than either IndoH at 10× or celecoxib (Celebrex) at 3×, as measured by the levels of BUN (blood urea nitrogen) in plasma and NAG (N-acetyl-beta-D-glucosaminidase) in urine (below).





### Technology Two covers a new class of platinum and other metal-based intercalating compounds with significant potential advantages over existing platinum cancer drugs such as cisplatin. Current experimental work indicates that, compared to cisplatin, these compounds have substantially greater potency, lower toxicity, activity against a broader range of cancer cell types, and less tendency to trigger drug resistance.

#### 4.3.3 Technology Two—Intercalating anticancer drugs

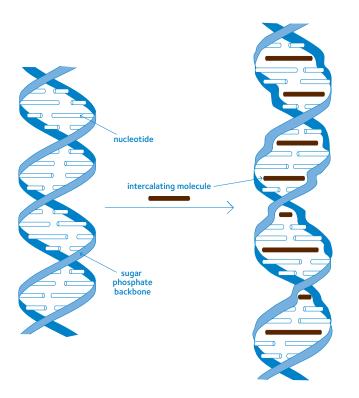
While studying the effects of electric fields on the growth of bacteria in the late 1960s, Barnett Rosenberg discovered that an electrolysis product of his platinum electrodes was inhibiting bacterial division. Further studies revealed that several platinum compounds exhibit significant anti-cancer activity; in particular the compound known as cisplatin. Cisplatin is an established anti-cancer drug. It is successfully used in the treatment of testicular and ovarian cancer and is effective against certain cancers of the cervix, bladder, head and neck. Use of cisplatin is limited by both its toxicity and its tendency to trigger resistance in the recipient, minimising its effectiveness. Cisplatin works by binding to cellular DNA, the information store of every living cell. By doing so it distorts the DNA molecule, thus interfering with transcription and preventing the cancer cells from replicating. However, cisplatin also binds to the DNA of healthy cells and to many other molecules in the body, making it a highly toxic drug with severe side effects ranging from hair loss, nausea and numbness to kidney and liver damage.

Several analogues of cisplatin have been developed with similar structures—carboplatin and oxaliplatin being the most prominent. These drugs have lower toxicities than cisplatin, allowing higher doses to be administered with less severe side effects. Unfortunately they also exhibit cross-resistance with cisplatin and are similarly limited in their effectiveness. Despite many years of research on platinum compounds, an effective alternative for cisplatin has yet to be developed.

Technology Two arose from a collaboration between researchers at the Universities of Sydney and Western Sydney. The product of this research is a potential new class of platinum and other metal-based cancer drugs offering significant advantages over existing treatments. Current experimental work indicates that, compared to cisplatin and its analogues, these compounds have substantially greater potency, lower toxicity, activity against a broader range of cancer cell types, and less tendency to trigger drug resistance. Importantly, these new platinum compounds exhibit a different mode of action to cisplatin. Cisplatin and its analogues disrupt DNA replication by formally binding to and thus bending the DNA molecule. The new platinum compounds instead intercalate with DNA. Intercalating compounds are flat molecules that, as illustrated on page 23, can slip between adjacent pairs of nucleotides, thus lengthening and disrupting the structure of the DNA molecule. This structural change may be sufficient to block the action of enzymes involved in DNA replication and transcription, causing the cell to die prematurely. Such compounds are most effective against cells with a high rate of division, such as cancer cells.

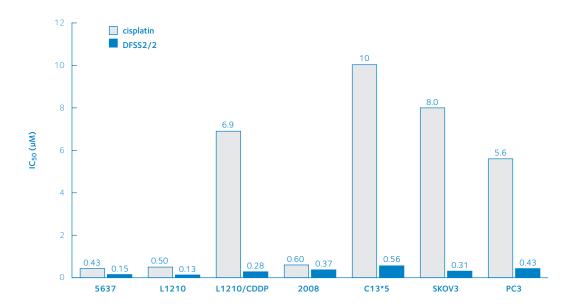
Several intercalating compounds are already wellestablished treatments for cancer. Drugs such as daunorubicin and doxorubicin are based on intercalating compounds and are currently used for the treatment of ovarian and breast cancers and acute leukaemias. The researchers have yet to synthesise and test all of the dozens of compounds encompassed by Technology Two. However, testing has demonstrated that several of the compounds encompassed by this technology are significantly more active against some cancer cell lines than cisplatin, particularly against cancer cell lines with intrinsic or acquired cisplatin resistance.

The compound DFSS2/2, for example, is at least 20 times more active than cisplatin against cell lines for cisplatin-resistant mouse leukaemia (L1210/ CDDP) and intrinsic cisplatin-resistant human ovarian carcinoma (SKOV3). More recent results show that an even more promising compound DF2192 is at least six times more active than DFSS2/2 (and at least 12 times more active than cisplatin) against cell lines for mouse leukaemia (L1210).



Intercalating compounds are flat molecules that can target DNA by slipping between adjacent pairs of nucleotides, thus lengthening and disrupting the structure of the DNA molecule. This structural change may be sufficient to block the action of enzymes involved in DNA replication and transcription, causing the cell to die prematurely (above).

Drug concentrations required to inhibit growth of various cancer cell lines for one of the most promising platinum compounds (DFSS2/2) compared to the common anti-cancer drug, cisplatin (below). Lower values represent greater potency.



Note: IC<sub>50</sub> value is defined as the concentration of compound required to inhibit 50% of cell growth after 48 hours of exposure.

5637	bladder carcinoma
L1210	mouse leukaemia
L1210/CDDP	mouse leukaemia (with cisplatin resistance)
2008	ovarian carcinoma
C13*5	ovarian carcinoma (with acquired cisplatin resistance)
SKOV3	ovarian carcinoma (with intrinsic cisplatin resistance)
PC3	human prostate cancer

Technology Three covers a class of compounds in which a metallocomplex, such as a platinum drug, is attached to one or more sequenceselective polyamides as a means of selectively targeting the drug to a particular genetic sequence. The technology offers the potential to develop sequence-selective drugs for treating various cancers or for use as antimicrobial and antiviral agents to treat diseases such as HIV/AIDS. It also has potential diagnostic and DNA-sequencing applications.

4.3.4 Technology Three—Sequence-selective compounds

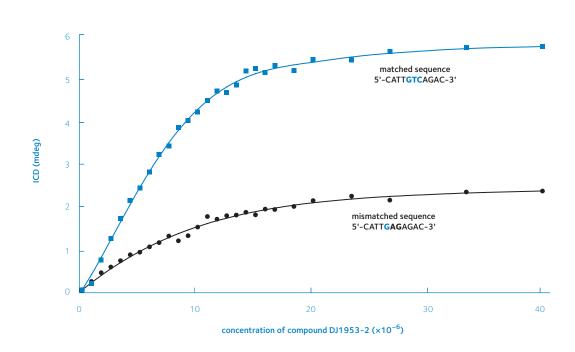
Most chemotherapeutic cancer agents are cytotoxic; that is, they indiscriminately attack both healthy cells and cancer cells. Their effectiveness stems from the uncontrolled rate of division exhibited by cancer cells compared to healthy cells. Nevertheless, the toxicity of these drugs is what causes their severe side effects, thus limiting dosage and reducing their effectiveness in treating cancer.

An ideal anti-cancer drug would be able to minimise toxic side effects by discriminating cancer cells from healthy cells, effectively disrupting the replication of cancer cells while leaving healthy cells unharmed. One approach to developing such selective drugs is to combine a chemotherapeutic agent with a compound that selectively binds to a particular genetic sequence. Genes are encoded in DNA, a long double-stranded molecule comprising various sequences of four nucleotides—adenine (A), guanine (G), thymine (T) and cytosine (C). One candidate at which sequenceselective compounds may be targeted is the repeating telomeric sequence d(TTAGGG)<sub>2</sub>. In most cancers, this sequence is more prevalent in the cancer cells than in healthy adult cells. Hence, a drug that selectively binds to this sequence or a portion of this sequence is likely to be more selective and hence more effective in targeting certain cancers.

Technology Three is based on research from the University of Western Sydney and relates to a class of sequence-selective compounds that target double-stranded polynucleotides such as DNA. If successfully commercialised, these sequenceselective compounds have the potential to revolutionise the treatment of cancer and numerous other diseases. Many diseases are known to be causally linked to the presence of specific genes. Compounds that specifically target such genes may therefore be used to change their expression to treat the disease or prevent it from developing in the first place. Sequence selectivity also offers the potential for developing drugs customised to match an individual's genome.

Sequence-selective compounds could be used as antimicrobial and antiviral agents to treat diseases such as HIV/AIDS. By creating a compound that binds to a specific sequence, a small amount of drug can be precisely delivered to, for example, block replication of a virus. Sequence-selective compounds also have potential application as effective DNA probes and DNA-sequencing agents.

Although this technology is currently at an early stage of development, early results from UWS researchers are promising. For example, a compound labelled DJ1953-2, which is designed to bind to DNA containing the sequence GTC, has been successfully synthesised. As illustrated on page 25, induced circular dichroism (ICD) studies have shown the compound binds more readily to DNA containing the matched sequence than to otherwise identical DNA containing the mismatched sequence GAG. This graph shows how well varying concentrations of the compound DJ1953-2 bind to DNA. The compound selectively binds to the matched DNA sequence for which it was designed (GTC) more readily than to a mismatched DNA sequence (GAG).



#### 4.4 Principal researchers

The principal researchers, who have played a major role in the original discoveries and will contribute to the development and commercialisation of the resulting three Technologies, are Professor Trevor Hambley and Professor Peter Lay, from the University of Sydney, and Associate-Professor Janice Aldrich-Wright, from the University of Western Sydney. Professors Hambley and Lay will be the principal researchers on Technology One and will be available to contribute to Technology Two and Technology Three. Associate Professor Aldrich-Wright will be the principal researcher on Technology Two and Technology Three.

#### Professor Trevor Hambley

Trevor Hambley has studied and worked at the University of Western Australia, the University of Adelaide, the Australian National University, the University of Sydney, Emory University (Atlanta) and Birkbeck College, University of London. He has received the Edgeworth David Medal of the Royal Society of NSW, the 'Supervisor of the Year' award in 1997 from the University of Sydney and an Excellence in Teaching Award for Postgraduate Supervision in 1998, also from the University of Sydney. Professor Hambley has made significant contributions in a number of research areas including molecular modelling, crystallography and medicinal inorganic chemistry. His most recent contributions have been in the area of medicinal inorganic chemistry and in particular platinum anti-cancer drugs.

Professor Hambley has published three books, nine reviews and more than 410 refereed journal papers, including four recent reviews of the relationship between the structure of platinum anti-cancer agents and their toxicity and anti-cancer activity, and on the modelling of platinum/DNA interactions. He has also recently received four separate invitations to produce book chapters and is in the top 0.1% of cited chemistry authors worldwide. He is Editor of the *Journal of Biological Inorganic Chemistry*, is a member of the Editorial Board of the *Journal of Inorganic Biochemistry*, and is a council member of the Society of Biological Inorganic Chemistry.

#### Professor Peter Lay

Peter Lay is Professor of Inorganic Chemistry and Associate Director (Bio-Metals) of the Centre for Heavy Metals Research, University of Sydney. In 2002 he was one of only 23 recipients of an inaugural five-year Australian Professorial Fellowship, awarded by the Australian Research Council. Professor Lay has previously studied and worked at the University of Melbourne, the Australian National University, Stanford University (California), the CSIRO Division of Applied Organic Chemistry and Deakin University, and has been a visiting professor at the University of Berne (Switzerland) and the University of Argentina. He has been awarded the Rennie Medal, the Burrows Medal, Fellowship of the Royal Australian Chemical Institute and the Edgeworth David Medal of the Royal Society of NSW.

Professor Lay has made many important contributions to Inorganic and Bioinorganic Chemistry. Together with Professor Hambley, he heads the collaborative project between the University of Sydney and Nature Vet on the development of copper antiinflammatories. Much of his other research has been on the chemistry, biochemistry and cell biology of metals, particularly their toxicology and role in occupational cancers, cardiovascular disease and diabetes. He is a world expert on chromium-induced cancers and the mechanism of action of chromium dietary supplements and anti-diabetic agents.

Professor Lay has extensive expertise in using a wide variety of spectroscopic, structural, biochemical and cell biology techniques to better understand molecular details. He has helped pioneer various applications of microprobe techniques for designing drugs and understanding the action of carcinogens and metals in disease processes within cells and tissues. He has collaborated on applications to develop new microprobes that will be used, in part, for medical science applications, at the Advanced Photon Source at Argonne National Laboratories (USA), the Stanford Synchrotron Research Laboratory (California), the Canadian Light Source, the Singapore Synchrotron and the Australian Synchrotron. He is also involved in commissioning of new medical microprobes at the Taiwan Synchrotron, and has given lectures on behalf of the Australian Synchrotron Research Program to medical researchers around Australia to highlight its applications to medicine. In the area of infrared and Raman microprobes, he is involved in developing faster and more reliable methods for breast cancer diagnosis in collaboration with the Institute of Magnetic Resonance Research at Royal North Shore Hospital.

Professor Lay has twice been an invited member on the Editorial Board of the American Chemical Society journal, *Chemical Research in Toxicology*, and is on the editorial board of the major international reference series, *Advances in Inorganic Chemistry*. He has published close to 200 book chapters, invited reviews and research articles. Associate Professor Janice Aldrich-Wright

Janice Aldrich-Wright has a PhD from Macquarie University and is an Associate Professor in the College of Science, Technology and Environment in the School of Science, Food and Horticulture at the University of Western Sydney.

Associate Professor Aldrich-Wright has been appointed a Visiting Scientist to the University of Wales and the University of British Columbia (Canada). She received the 1994 Cornforth Medal of the Royal Australian Chemical Institute (RACI) for the best chemistry PhD in Australia, a British Council Postgraduate Travelling Scholarship, and was awarded a Best Poster Award at the RACI National Convention in Adelaide, 1995. She has received invitations to speak at national and international conferences and institutions, and maintains active collaborations with research groups in Warwick (UK), San Diego (California), Sydney, Canberra and Townsville. She has served as the New South Wales representative for the Inorganic Division of the RACI from 1996 onwards.

Associate Professor Aldrich–Wright has made several significant contributions to the understanding of metal–DNA interactions. One of her major achievements has been the systematic design and synthesis of numerous metallo–intercalator complexes, with the aim of delineating the relative contributions of different types of non–covalent interactions with DNA. She has also contributed to the development of chiral stationary phases for chromatography, which have allowed simultaneous comparison of the DNA binding affinity of several metal complexes, and can also be used to separate chiral dinuclear metal complexes. More recently, she has co-discovered the system of synthesising sequence-selective compounds that forms Technology Three and the novel group of platinum compounds that forms Technology Two. The Company plans to develop its first product using Technology One a topical cream for the treatment of arthritis. Current formulations are sufficiently well advanced to immediately begin preparing to conduct FDA-approved clinical trials. The Company will also further assess its most promising compounds under Technology Two with the aim of developing a formulation suitable for commencing a Phase I clinical trial within one year. For Technology Three, the Company will aim to synthesise at least one proof-of-concept compound that can target and bind to a specific DNA sequence, within two years.

#### 4.5 Product development roadmap

#### 4.5.1 Overview

The three Technologies, although capable of independent development, nevertheless possess strong synergies both in the areas of technical expertise required for their further development and in their target markets, which should help to minimise the time and cost of product development. The three Technologies also represent a diversity of approaches to treating cancer and inflammatory diseases, giving rise to a significant portfolio of potential products that are expected to be delivered at regular intervals over the next few years. This diversity also reduces the overall commercial and technical risks associated with development of the Intellectual Property. To assist with commercialisation of the Technologies, the Company's management and researchers have entered into preliminary discussions with:

- (a) the Clinical Trials Centre at St Vincent's Hospital, Sydney, which has extensive experience in designing and conducting large clinical trials to test advances in treatments for various diseases, and has established close ties to other leading medical research centres around the world;
- (b) the Heart Research Institute at Royal Prince Alfred Hospital, Sydney, an internationallyrecognised research centre dedicated to preventing, diagnosing and curing heart disease; and

(c) the Sydney Cancer Centre at Royal Prince Alfred Hospital, Sydney, which hosts a wide range of clinical research and trials.

The researchers have established links with various research centres, medical institutions and industry bodies, including the Advanced Photon Source at Argonne National Laboratories (USA), the Stanford Synchrotron Research Laboratory (California), the Australian Synchrotron, the Taiwan Synchrotron, the Institute of Magnetic Resonance Research at Royal North Shore Hospital, Nature Vet Pty Limited, the Institute of Drug Technology Australia Limited, the University of Warwick (UK), the Department of Chemistry and Biochemistry at the University of California, San Diego, the School of Pharmacy and Molecular Sciences at James Cook University, and the School of Chemistry at the Australian Defence Force Academy (University of New South Wales).

The table on page 30 lists potential drug formulations that may be developed from the three Technologies, their applications and the established drug treatments for which the new drugs may offer an alternative treatment with a potential reduction in the severity of side effects compared to these existing treatments.

	formulations	possible applications	established drugs			
tech			drugs class	examples (Brand names)	main side effects	
One	topical, oral, parenteral, ophthalmic	pain and inflammation (e.g. rheumatoid arthritis, osteo- arthritis, psoriasis, gout)	OTC & prescription NSAIDs	aspirin (Aspro, Disprin), diclofenac (Fenac, Voltaren), diflunisal (Dolobid), ibuprofen (Act 3, Brufen, Nurofen), indomethacin (Arthrexin, Indocid), ketoprofen (Orudis, Oruvail), mefenamic acid (Mefic, Ponstan), naproxen (Naprosyn, Naprogesic), piroxicam (Feldene), sulindac (Clinoril), tenoxicam (Tilcotil), tiaprofenic acid (Surgam)	gastrointestinal pain, ulceration and bleeding, liver or kidney damage	
			COX-2 inhibitors	celecoxib (Celebrex), rofecoxib (Vioxx), valdecoxib (Bextra)	increased risk of heart attack and stroke, elevated blood pressure	
Two & Three	parenteral	various carcinomas and other cancers	chemo- therapeutics	cisplatin (Platinol), carboplatin (Paraplatin), busulfan (Myleran), thiotepa (Thioplex), vincristine (Oncovin), paclitaxel (Taxol), docetaxel (Taxotere)	various, including bone marrow depression (leading to anaemia, bleeding and infection), hair loss, nausea, vomiting and infertility	
Three	parenteral, oral	viral infections	antivirals	acyclovir (Zovirax), famciclovir (Famvir), idoxuridine (Stoxil, Virasolve+), valaciclovir (Valtrex), zanamvir (Relenza), zidovudine/ AZT (Retrovir)	various, including bone marrow depression (AZT), headache, nausea and vomiting (acyclovir)	
	N/A	DNA probes diagnostics	N/A			

# 4.5.2 Technology One—Anti-inflammatory drugs

The scope of Technology One covers the design and development of new topical, oral, injectable and ophthalmic formulations of non-steroidal anti-inflammatory drugs, based on a number of international (PCT) patent applications and provisional patent applications. Over the next 24 months, new product formulations will be developed, studied and trialled for the treatment of various inflammatory diseases, such as arthritis.

The Company plans to develop its first product using this technology—a topical cream for the treatment of arthritis. Current formulations are sufficiently well advanced to immediately begin preparing to conduct FDA-approved clinical trials. A combined Phase I and IIa trial of a topical formulation and a Phase I trial of an oral formulation are expected to begin within nine months of the date of this Prospectus. The topical formulation offers a quicker route to market than the oral formulation, given its more modest regulatory requirements. A product based on the topical formulation is expected to be available within 18 months of the Completion Date, as defined in the Intellectual Property Assignment Deed. Major research programmes will also immediately commence to strengthen the current patent position through:

 (a) synthesising and characterising several antiinflammatory compounds (within 12 months of the Completion Date, as defined in the Intellectual Property Assignment Deed);

- (b) conducting further animal studies on the efficacy and safety of topical, oral, ophthalmic and injectable formulations of several new antiinflammatory compounds for the treatment of inflammation (12–18 months);
- (c) conducting cell line and animal studies to assess the efficacy of certain anti-inflammatory compounds against various other diseases (24 months); and
- (d) filing national phase applications from the existing PCT patent applications, filing new PCT applications claiming priority from the existing provisional patents, and filing new provisional patents in respect of new disease indications (24 months).

Beyond the initial clinical trials, the Company has two strategies for fully commercialising Technology One. The first strategy is to develop and formulate one or more products in-house, with manufacturing, marketing and distribution outsourced. Under this strategy, revenues would be generated by sales through established and leading distribution channels under either an emerging or existing brand name. This strategy offers higher returns than the second strategy, but with specific financial risks relating to the uncertainty of market acceptance. This is the preferred strategy for the topical formulations.

A second strategy is to enter into partnering or licensing arrangements with one or more leading pharmaceutical companies to fund further clinical trials and to develop, manufacture, market and distribute the formulations. This is the traditional commercialisation route for new pharmaceutical drugs, but offers lower returns than the first strategy. This is the preferred strategy for the oral, ophthalmic and injectable formulations, which will require more extensive testing. Discussions with leading pharmaceutical companies will begin immediately. Several strategies have been identified to mitigate the technical risks associated with development of this technology. NSAIDs, for example, are already well-established drugs with demonstrated efficacy against inflammatory diseases, while oral and topical formulations of Cu-Indo have already been developed and approved for veterinary applications. Furthermore, efficacy can potentially be improved by changing the mode of application or modifying the formulation chemistry to, for example, increase absorption. Potential applications in treating a diversity of diseases are also being investigated, mitigating the risks of ineffectiveness against any one disease.

The technical risks associated with toxicity are also relatively low. For instance, current NSAIDs have known toxicity and are already FDA-approved for treating inflammatory diseases. Cu-Indo also has demonstrated substantially lower levels of toxicity compared to indomethacin. Even a modest reduction in toxicity of NSAIDs offers medical and commercial benefits for the treatment of inflammation. Toxicity can also potentially be reduced by increasing the stability of the complex, encapsulating the complex or otherwise modifying the formulation to affect absorption, changing the mode of administration, improving efficacy to thus reduce the amount of drug required, and co-administering the drug with a metal chelator to avoid metal toxicity. Finally, the technology covers a diverse portfolio of complexes and formulations, mitigating the risks of toxicity in any one formulation.

To mitigate the risk of the animal or clinical studies failing to produce conclusive results, the studies will be conducted using reputable and FDA-approved testing facilities. Should a study fail, the reasons for failure will be investigated and, if appropriate, the study will be promptly repeated, taking into account the reasons for previous failure.

#### 4.5.3 Technology Two—Intercalating anticancer drugs

The intercalating platinum compounds encompassed by Technology Two offer commercial potential as chemotherapeutic anti-cancer agents. Several candidate compounds have been identified, the most promising of which will immediately undergo detailed animal testing for efficacy and toxicity to assess their suitability for undergoing human clinical trials. Should these animal trials prove successful, the drug formulation will be optimised and preparations will begin to conduct the human trials. If the animal trials are encouraging but unsuccessful, the Company may consider designing, synthesising and testing additional Technology Two compounds and conducting further in vitro and in vivo testing of the most promising of these to select a new candidate to undergo human clinical trials.

To complete the clinical trials, the Company intends to enter into a partnership with one or more leading pharmaceutical companies. Large pharmaceutical companies, such as Sanofi-Aventis, Bristol-Myers Squibb and GlaxoSmithKline, are actively searching for proven chemotherapeutic compounds to replace existing drugs such as cisplatin. The Company's objective is to generate revenue from the technology via licensing, royalties and contracted research. Several strategies have been identified to mitigate the technical risks associated with development of this technology. A candidate compound has already been synthesised and demonstrated to have greater potency, greater solubility and less toxicity than cisplatin, as evidenced through initial cell-line and animal studies. The nature of the technology also offers significant potential to modify candidate compounds to alter their efficacy, toxicity, solubility or stability without losing the other required properties. Finally, the diverse portfolios of parent compounds and synthesis techniques mitigate the risks associated with any one compound proving unsuitable for therapeutic use.

4.5.4 Technology Three—Sequence-selective compounds

The sequence-selective compounds that form Technology Three offer the potential foundation for an array of new drugs to treat a diversity of cancers and viral diseases such as HIV/AIDS. The technology also has potential diagnostic applications. The initial development milestones are to complete compound characterisation and specific binding studies, and to synthesise at least one proof-ofconcept compound that can target and bind to a specific DNA sequence, within 24 months of the Completion Date, as defined in the Intellectual Property Assignment Deed.

Once proof-of-concept for the technology has been achieved through meeting these milestones, the preferred commercialisation strategy is to enter into partnership with one or more leading pharmaceutical companies to further develop the technology into a range of products. The Company plans ultimately to generate revenue from development of the technology via licensing and royalties.

Several strategies have been identified to mitigate the technical risks associated with developing this technology. A method for synthesising the sequenceselective section of the compounds has already been established and several alternative routes for synthesis are being explored. The technology also covers a diversity of compounds to mitigate this risk.

To mitigate the risk that a compound cannot be synthesised to cross the cell membrane, that is active against target cells, and also that is not excessively toxic, the activity and toxicity of a variety of compounds of different sizes and structures will be tested. Non-chemotherapeutic applications of the technology, such as DNA probes, will also be investigated and pursued.

The suitability of the compounds as chemotherapeutic agents also depends on their solubility and stability. Various means of modifying the compounds have been identified that mitigate the risks that they will be relatively unstable or insoluble. "One day in perfect health is a lot. " Arabian Proverb

and a

### 5 DIRECTORS AND COMPANY SECRETARY



### James Dominguez BA BCOM CBE AM Chairman

Jim Dominguez is a non-executive director of several companies including E\*Trade Australia Limited, Nestle Australia and WESBEAM Holdings Limited. He is also a director of Singapore-based Tat Hong Holdings Limited, a construction and infrastructure company operating throughout Southeast Asia and Australia. Jim holds advisory roles for a number of technology companies, including Cisco Systems Australia, EMC Australia Global Holding Company, Fuji Xerox Co Limited of Japan and TeleTech International Australia. He has been an advisor to Liberal and Labor Federal Governments, and to the NSW Government. He is currently Chairman of BioMed North Limited, which is actively protecting and commercialising the intellectual property generated by medical research of Royal North Shore and Westmead Hospitals.

In 1976, Jim founded Stock Exchange Member firm, Dominguez and Barry, which is now owned by UBS AG Australia. Prior to retirement from the investment banking world, he spent eight years as a nonexecutive director of Samuel Montagu & Co of London.

Jim was for some years Chairman of St Vincent's Hospital, Sydney, a major public teaching institution, and a member of the Committee of Management of the Garvan Institute of Medical Research. He has also been a Fellow of the Senate of the University of Sydney and is an Honorary Life trustee of the Committee for Economic Development of Australia (CEDA).



## Llewellyn Casbolt BAPPSC Managing Director And Chief Executive Officer

Llewellyn Casbolt has a professional background that includes over 30 years' experience as a senior executive and consultant. He has extensive experience in strategic management, marketing, and product research and development across a diverse range of industries including finance and investment, software, pharmaceuticals, cosmetics, toiletries and confectionery.

Llewellyn was formerly CEO of Australia's only privately-funded biotechnology business incubator, Xcelerator Limited, an unlisted public company, where he provided on-the-ground business and operational advice to 'new economy' biotechnology and bio-informatics businesses. He was founder and Managing Director of QuickSmart OnLine Pty Limited, a successful financial planning software development firm, which licensed its technology to large financial institutions in Australia and New Zealand, and recently founded a private company exploiting IP in the area of haemophilia, in which he has a significant interest. Llewellyn has been responsible for the development and implementation of corporate and product marketing strategies for retail and wholesale banks, securities and stockbroking companies, fund managers, insurance companies, friendly societies, building societies, finance houses, trustee companies and credit cooperatives. His clients have included AMP, ANZ Bank Limited, Bankers Trust Australia Limited, Commonwealth Bank of Australia, Commonwealth Securities Limited, News Limited Suburban Network, Paladin Australia Limited, Perpetual Funds Management Limited, Perpetual Trustees Australia Limited, PricewaterhouseCoopers, Price Waterhouse Konsultan (Indonesia), Rothschild Australia Asset Management Limited, Royal & Sun Alliance Life Assurance Limited and Xcelerator Limited. Llewellyn has held senior executive positions in Australia and overseas for several multi-national corporations including Chase AMP Bank (General Manager Marketing), Elders Finance Group (Marketing Director), IOOF of Victoria (Marketing Manager), HJ Heinz, Cheseborough Ponds, Nicholas International, Cussons and Wynn Winegrowers. He has also worked as a senior R&D chemist, specialising in pharmaceutical, cosmetic and toiletry product research, development and commercialisation.



## Professor Michael Vitale BA PHD MBA Non-Executive Director

Michael Vitale currently researches, teaches and consults on start-up and early stage companies (particularly in biotechnology), innovation and commercialisation, and IT governance. He currently sits on the advisory boards for bizCapital, Cleanskins.com, Elastagen Pty Limited and iSelect. Michael's Australian Consulting and Executive Education Clients Include ASIC, ASX, the Attorney-General's Department, Australia Post, Brambles Marine, the Department of Finance and Administration, Ernst & Young, Geelong Radiological Clinic, Hewlett Packard, Hospital Supplies Australia, Kolotex Australia, Macquarie Bank, Melbourne Water, National Australia Bank, PricewaterhouseCoopers, SA Water (member of IT Advisory Board) and Victorian Imaging Group.

Michael's previous positions include Dean and Director of the Australian Graduate School of Management, Professor at the Centre for Management of Information Technology, Melbourne Business School, Foundation Professor of Information Systems and Head of the Information Systems Department at the University of Melbourne, Fellow at the Ernst & Young Center for Business Innovation in Boston, Executive Vice-President, Information Technology and Corporate Services, for Prudential Insurance Company of America, and Associate Professor at the Harvard Business School. He was also a non-executive Director of Deloitte Touche Tohmatsu (Australia).

Michael is a member of the Professional Education Board of CPA Australia, a Fellow of the Association for Information Systems and Treasurer of the Harvard Club of Australia. He was previously President of the Association for Information Systems and a member of Council of the Australian Computer Society.



## Dr Michael Taverner BAGRICSCI MAGRICSCI PHD Non-Executive Director

Michael Taverner is a scientific consultant and company director. He currently serves on boards and consults to a variety of companies and organisations involved in biotechnology, research and development, innovation, and training.

Mike is a non-executive director of Biosignal Limited, a company recently listed on ASX to commercialise novel antibacterial technology. He is a non-executive director of the Rural Industries R&D Corporation, the Australian Poultry CRC and the Australian Rural Leadership Foundation Limited.

Mike has worked as a technical consultant to the Grains R&D Corporation since 1996. He served as Chairman of national R&D advisory groups for the chicken meat and egg industries, and for six years before that was Executive Director of the Pig R&D Corporation. His career started as a research scientist in the animal industries where over 17 years he developed a considerable international reputation. Mike now also runs his own consulting business in Canberra working with national and international clients on research, innovation and commercialisation. He is an internationally-accredited trainer in human resources and operates widely in public sector organisations around Australia.



## lan Gilmour FCIS CA FAICD JP(NSW) Company Secretary (Part-Time)

Ian Gilmour is also currently part-time company secretary of Biosignal Limited, a company recently listed on ASX to commercialise novel antibacterial technology. He is a consultant on corporate governance, a consultant to Nova Legal & Advisory, and company secretary of a proprietary company operating in the telecommunications area. Ian is a member of and active in Chartered Secretaries Australia (CSA). He is Chairman of the Corporate and Legal Issues Committee, a member of the Subject Advisory Committee, and a guest presenter for the Graduate Diploma course and other training and development courses. For the last two years he has been an adjudicator on corporate governance for the CSA-sponsored Australasian Reporting Awards. From 1979 until April 2003, Ian held the position of company secretary of Goodman Fielder, Australasia's largest food company, having been employed with the group since 1979 in positions that included assistant company secretary and group accountant of one of the merged groups. During this time, the group saw significant growth, mergers, acquisitions and rationalisations. He was previously employed for approximately 10 years with Coopers & Lybrand (now PricewaterhouseCoopers). During this time he was called up for approximately two years' National Service in the Australian Army, including a period of service in Singapore.

Ian is a Fellow of the Institute of Chartered Secretaries and Administrators and a Chartered Accountant. He recently completed the Graduate Diploma course of the Australian Institute of Company Directors and is a Justice of the Peace in New South Wales.

## 6 PATENT ATTORNEY'S REPORT

Level 37, Grosvenor Place 225 George Street Sydney NSW 2000 www.bdw.com Tel + 61 2 9258 6000 Fax + 61 2 9258 6999

DX 355 Sydney, Locked Bag N6 PO Grosvenor Place, Sydney NSW 2000 Australia

## BLAKE DAWSON WALDRON PATENT SERVICES

## 6.1 Introduction

Blake Dawson Waldron Patent Services was engaged to prepare this report by Medical Therapies Limited (ACN 111 304 119) (Medical Therapies). Specifically, we have been asked by Medical Therapies to list the details and status of patent matters in the patent portfolio referred to in this report for inclusion in a prospectus to be dated on or about 3 June 2005 and issued by that company. The patent portfolio consists of seven patent families divided into three broad technology categories. The Technologies are in the life sciences area and, more particularly, pertain to cancer treatments and anti-inflammatory pharmaceutical compositions and drugs.

#### 6.1.1 Executive summary

The patent matters comprising the patent families are in various stages of progress. Some are granted patents, whereas others are patent applications that are currently being examined by the applicable Patent Offices, provisional patent applications or International (PCT) patent applications. This summary should be read subject to the rest of this report.

#### 6.1.2 Blake Dawson Waldron Patent Services

We are a patent attorney firm associated with, but separate from, Blake Dawson Waldron Lawyers. We did not prepare or file the various patent matters comprising the patent portfolio, nor do we currently have any responsibility for the management of any of the patent families in the patent portfolio.

#### 6.1.3 Report scope

This report outlines the Technologies of the patent portfolio and sets out details of the various patent matters as well as their status.

For the purposes of this report, we have not undertaken any independent patentability searches nor provided any opinion on the patentability of any of the Technologies to which the patent families relate.

This report is subject to the limitations and qualifications set out in Section 6.5 and, in particular, the limited sources of information described in Section 6.5.1.

#### 6.2 Patents generally

A patent is a statutory monopoly granted in respect of an invention that, in Australia at least, provides the patentee with the exclusive right to 'exploit' the invention, including the exclusive right to make, use or sell the patented invention, and to import or export products covered by the patent. As mentioned in Sections 6.4.5 and 6.4.6, this does not mean that exploitation of the invention will not infringe a third party patent. Nor does it mean that a third party does not have any rights in, or in relation to, any patent or patent application. We have not in this report advised on inventorship, or on the existence of, or any possible infringement of, others' patent rights. The granting of a patent does not provide any rights outside of the jurisdiction in which the patent is granted. In most jurisdictions, a patent has a term of 20 years from the filing date of the patent application on which the patent is granted. The patent laws of at least some jurisdictions including those of Australia have provisions that allow for the term of a patent granted in respect of a pharmaceutical substance to be extended, usually by up to five years.

If it is desired to pursue patent protection in a significant number of foreign jurisdictions, a single international patent application can be filed under the Patent Cooperation Treaty (PCT) designating foreign jurisdictions of interest that are party to the PCT. To pursue patent coverage in jurisdictions that are not party to the PCT, it is necessary to file separate patent applications in those jurisdictions.

There is no such thing as a world patent, and an international (PCT) application must ultimately be entered into each jurisdiction originally designated in the international (PCT) application and that remains of interest. This is known as entry into the 'national phase' or, in the case of Europe, the 'regional phase'. Entry of the international (PCT) application into the jurisdictions of interest effectively converts the application into a bundle of national and/or regional patent applications. Each such application is then pursued before the national/regional patent office of the relevant jurisdiction.

Most national/regional patent offices around the world including the European Patent Office, IP Australia and the United States Patent & Trademark Office (USPTO), conduct substantive examination on a complete patent application. All issues that may be raised by the applicable patent office during this examination process must be overcome before a patent in the corresponding jurisdiction will be granted. The scope of the patent protection sought in a complete application is defined in the claims of the patent application. During substantive examination, it may be necessary to amend the claims to address issues raised by the patent examiner. This may result in the scope of patent protection sought being restricted. Therefore, the scope of protection for an invention that is provided by a granted patent may be less than that originally sought in the patent application on which the patent was granted.

The scope of a patent or patent application can only be evaluated by reference to the specification for the patent or patent application.

#### Table 1: Details and status of patent matters in patent family 1.

International (PCT) application no.	Applicant/ patentee	Priority application(s)	Country/ region	Application no.	Status	Patent no.
PCT/AU90/00209 filed 21 May 1990	Biochemcal Veterinary Research Pty Limited	PJ4328 filed 22 May 1989	Australia	-	-	-
			Australia	56663/90	granted	629943
			Canada	2,058,754	granted	2,058,754
			Europe	90908178.8	granted	0473655
			Ireland	-	granted	81142
			New Zealand	233776	granted	233776
			Norway	19910004565	granted	175148
			South Korea	19910071536	granted	156231
			United States	773,601	granted	5,310,936
			United States	217,520	granted	5,466,824

#### 6.3 The patent portfolio

This overview of the patent portfolio is not to be taken as a definition of the scope of the patent families, and merely serves to provide a general explanation of the Technologies to which the patent families relate.

We have been asked to provide our report on patent families 1–5 under the heading 'Technology One', patent family 6 under the heading 'Technology Two' and patent family 7 under the heading 'Technology Three'. The specification for the international (PCT) application in patent family 6 has been published, as have the specifications for the granted patents in patent family 1. Copies of the specifications for those matters can be obtained from the applicable patent offices. The Australian. European and United States patents in patent family 1 are described in Section 6.3.1(a)(ii) to provide an indication of the technology encompassed by that patent family that has been found to be patentable by the patent offices of those jurisdictions. As at the date of this report, none of the specifications for any of the provisional or non-provisional patent applications in patent families 2–5 or 7 have been officially published (see Sections 6.5.5 and 6.5.6), with the possible exception of the international (PCT) application in patent family 7 (see Section 6.3.3(a)(ii)).

#### 6.3.1 Technology One

## (a) Patent family 1—Divalent metal salts of indomethacin

(i) Overview

This patent family relates to metal complexes of the non-steroidal anti-inflammatory drug (NSAID) indomethacin. The patent family further relates to a method for the preparation of an indomethacin salt of a divalent metal, comprising dissolving indomethacin and a salt of the divalent metal in a tertiary amide or cyclic tertiary amide, and adding a C1-4 alkanol or C3-6 ketone to the solution to precipitate the indomethacin metal salt. The technology also extends to a method for treating inflammation and pain, comprising administering an "antiinflammatory and analgesically effective" amount of an indomethacin salt of a divalent metal, and to pharmaceutical compositions comprising an indomethacin salt of a divalent metal produced as described immediately above.

The European patent application in this patent family designated all countries that were party to the European Patent Convention (EPC) at the time the International (PCT) application for this patent family was entered into the European regional phase, including the United Kingdom, Germany, France, Spain, Italy and The Netherlands. For a European patent to have effect in a jurisdiction designated in the application on which the patent was granted, it is necessary to 'validate' the patent in the jurisdiction within a limited time period following the granting of the patent. We have not undertaken any searches to determine in which countries the European patent in this patent family was validated.

- (ii) Granted patents
  - (A) Australian patent no. 629943—This patent has been granted with claims relating to a method for the treatment of inflammation and pain in a mammal. The method comprises administering an anti-inflammatory and analgesically effective amount of "a salt of indomethacin and a divalent metal capable of forming a stable complex therewith". This patent has also been granted with claims relating to a method for the preparation of "an indomethacin salt of a divalent metal capable of forming a stable complex with indomethacin". The method comprises forming a solution by dissolving indomethacin and a salt of the divalent metal in a tertiary amide or cyclic tertiary amide. The method further comprises adding a C1-4 alkanol or C3-6 ketone to the solution. In addition, the patent has been granted with a claim relating to "a salt of indomethacin

with a divalent metal capable of forming a stable complex therewith" produced by the method described immediately above.

- (B) European patent no. 0473655—This patent has been granted with claims relating to a method for the preparation of an indomethacin salt of a divalent metal selected from copper and zinc. The method comprises forming a solution by dissolving indomethacin and a salt of the divalent metal in a solvent, precipitating the indomethacin metal salt and separating the indomethacin metal salt precipitate from the solution. The method is stated in the claims to be characterised in that the indomethacin and the salt of the divalent metal are dissolved in dimethylformamide, N-methyl-pyrrolidine and/or dimethyl acetamide, and the indomethacin salt is prepared by adding a C1-4 alkanol or C3-6 ketone to the solution.
- (C) United States patent no. 5,310,936—This patent has been granted with claims relating to a method for the preparation of "an indomethacin salt of a divalent metal capable of forming a stable complex with indomethacin". The method comprises forming a solution of indomethacin and a salt of the divalent metal in a tertiary amide or in an N-substituted lactam of the formulae specified in the claims(s). A C1-4 alkanol

Table 2: Details and status of patent matters in the patent family 2.

International (PCT) application no.	Priority application(s)
PCT/AU2005/000442 filed 30 March 2005	Australian provisional application no. 2004901694 filed 30 March 2004
	Australian provisional application no. 2005901464 filed 24 March 2005
	United States provisional application no. (TBA) filed 24 March 2005

or C3-6 ketone is added to the solution to precipitate the indomethacin metal salt, and the precipitated indomethacin metal salt is separated from the solution.

(D) United States patent no. 5,466,824 —This patent has been granted with claims relating to a method for the treatment of inflammation or pain. The method comprises administering an effective amount of a complex of indomethacin and a divalent transition metal of the formula [M]2[indomethacin]4[Xn] wherein M is the divalent transition metal and X is a tertiary amide or N-substituted lactam of the formulae specified in the claim(s).

The patent has also been granted with claims relating to the complex of indomethacin and a divalent transition metal, and to a pharmaceutical composition containing the complex of indomethacin and divalent transition metal together with a pharmaceutically acceptable carrier, diluent, excipient or combination thereof.

## (b) Patent family 2—Anti-inflammatory compositions

#### (i) Overview

This patent family relates to pharmaceutical compositions comprising a metal complex of a carboxylate (metal carboxylate complex) having anti-inflammatory activity.

The carboxylate is described as typically comprising a non-steroidal anti-inflammatory drug (NSAID). NSAIDs are referred to as being used to treat inflammatory conditions such as rheumatoid arthritis, osteoarthritis, acute musculoskeletal disorders (e.g. tendonitis), lower back pain, inflammation, and pain and oedema following surgical or non-surgical procedures. The specification for the international (PCT) application in this patent family states that free NSAIDs when administered orally can cause adverse gastrointestinal effects and describes formulation of the pharmaceutical compositions to enhance the stability of the metal carboxylate complexes. Metal carboxylate complexes that may be used in the pharmaceutical compositions are stated to include copper carboxylate complexes such as copper indomethacin. The technology further extends to methods

for treating an inflammatory condition in humans and animals comprising administering the pharmaceutical composition.

(ii) Applicant(s)

The international (PCT) application and the Australian provisional applications identified in Table 2 naming the University of Sydney as the sole applicant. The United States provisional application identified in Table 2 was filed listing inventor(s) as the applicant(s) for that application as required in the United States. Table 3: Details and status of patent matters in patent family 3.

#### Priority application(s)

Australian provisional application no. 2005901464 filed 24 March 2005 United States application no. (TBA) filed 24 March 2005 International (PCT) application no. PCT/AU2005/000442 filed 30 March 2005

Table 4: Details and status of patent matters in patent family 4.

Applicant	Priority application(s)
USYD 2005	Australian provisional application no. 2005901462 filed 24 March

Table 5: Details and status of patent matters in patent family 5.

Applicant	Priority application(s)
USYD	Australian provisional application no. 2005901463 filed 24 March 2005

(iii) Publication

The specification for the international (PCT) application in this patent family is not due to be officially published (see Section 6.5.5) until on or about 30 September 2005.

#### (c) Patent family 3—Copper complexes

(i) Overview

This patent family relates to certain copper complexes (**Cu complexes**), and the use of the Cu complexes in the treatment of inflammatory conditions in humans and animals. It also relates to the treatment of inflammation using the Cu complexes.

(ii) Applicant(s)

The international (PCT) application and the Australian provisional application identified in Table 3 name the University of Sydney as the sole applicant. The United States provisional application identified in Table 3 was filed listing certain inventor(s) as the applicant(s) for that application as required in the United States.

(iii) Publication

No international (PCT) application claiming priority from the priority applications identified in Table 3 has yet been filed. An international (PCT) application claiming priority from those priority applications is not due to be filed until 24 March 2006. If filed, the international (PCT) application would not be officially published (see Section 6.5.5) until on or about 24 September 2006.

#### (d) Patent family 4—Methods for treating inflammatory conditions in humans and animals

(i) Overview

This patent family relates to certain compounds having anti-inflammatory, analgesic and antipyretic activity. It also relates to pharmaceutical compositions containing the compounds.

(ii) Publication

No international (PCT) application claiming priority from the priority application identified in Table 4 has yet been filed. An international (PCT) application claiming priority from that priority application is not due to be filed until 24 March 2006. If filed, the international (PCT) application would not be officially published (see Section 6.5.5) until on or about 24 September 2006.

- (e) Patent family 5—Method of treatment of carcinomas
- (i) Overview

This patent family relates to the treatment of carcinomas in humans and animals using a specific class of compounds found to have anti-cancer activity. It also relates to systemic or topical administration of the compounds, and pharmaceutical compositions containing the compounds.

#### Table 6: Details and status of patent matters in patent family 6.

International (PCT) application no.	Applicant	Priority application(s)	Country/ region	Application no.	Status	Patent no.
PCT/AU02/00167 filed 22 Feb 2002	USYD	PR3302 filed 23 February 2001	Australia	-	-	-
			Australia	2002231463	pending	-
			Canada	2448251	pending	-
			Europe	02711648.2	pending	-
			Japan	2002-565952	pending	-
			New Zealand	528415	pending	-
			United States	10/468,935	pending	-

The European patent application in this patent family designated all countries that were party to the European Patent Convention (EPC) at the time the International (PCT) application for this patent family was entered into the European regional phase.

Table 7: Details and status of patent matters in patent family 7.

International (PCT) application no.	Applicant	Priority application(s)
PCT/AU2004/001368 filed 7 October 2004	UWS	Australian provisional application no. 2003905512 filed 7 October 2003

(ii) Publication

No international (PCT) application claiming priority from the priority application identified in Table 5 has yet been filed. An international (PCT) application claiming priority from that priority application is not due to be filed until 24 March 2006. If filed, the international (PCT) application would not be officially published (see Section 6.5.5) until on or about 24 September 2006.

- 6.3.2 Technology Two
- (a) Patent family 6—Metal complexes and therapeutic uses thereof

#### (i) Overview

This patent family relates to particular metallo-intercalator compounds, pharmaceutical compositions containing them, and their use as anti-microbial agents and in the treatment of proliferative diseases such as cancer. The metallo-intercalator compounds comprise a metal selected from the group consisting of platinum (II), palladium (II) and copper (II), together with an intercalator moiety and a bidentate ligand.

The specification for the international (PCT) application for this patent family states that the metallo-intercalator compounds are thought to intercalate (or insert) into DNA, changing the shape and/or structure of the DNA, thereby potentially impacting on cell growth and/or viability.

Examples of cancers that the metallo-intercalator compounds may be used to treat are stated in the specification to include breast, ovary, lung and bladder cancers as well as cervical cancer and leukaemia, among others.

- 6.3.3 Technology Three
- Patent family 7—Sequence-selective compounds
- (i) Overview

This patent family relates to compounds comprising pyrrole-imidazole polyamide(s), which bind to polynucleotides (e.g. DNA). The choice of the pyrrole and imidazole moieties in the polyamide(s) determines the sequence-selectivity of the compounds. The specification for the international (PCT) application in this patent family states that the compounds may be used as sequence-specific drugs or as diagnostic agents. The patent family also relates to pharmaceutical compositions comprising the compounds, methods of targeting therapeutic and/or diagnostic agents to a specific nucleic acid sequence of a polynucleotide, and methods of treating cancers using the compounds.

(ii) Publication

The specification for the international (PCT) application in this patent family was due to be officially published (see Section 6.5.5) on or about 7 April 2005.

## 6.4 Further issues

6.4.1 Method of treatment claims

Although claims to methods for the treatment or prophylaxis of diseases or conditions in animals and human beings are generally allowable in Australia and the United States, such subject matter is excluded from patentability in most other major jurisdictions around the world. However, patent protection may be able to be obtained in at least some such jurisdictions by recasting the claims into a format allowed in those jurisdictions, provided of course that the requirements for patentability have been met (see Section 6.5.2).

#### 6.4.2 Patent opposition proceedings

Some jurisdictions provide for third party opposition once an application has been examined and found to be allowable. Australia, for instance, provides for pre-grant opposition to the granting of a patent. Europe in contrast provides for post-grant opposition. Opposition proceedings may result in the claims of the application or patent being held invalid, or claims of the application or patent being cancelled or amended in a way that may restrict the scope of the claims.

#### 6.4.3 Enforceability

Once a patent has been granted, the patentee may initiate infringement proceedings against an alleged infringer of the patent. Patent infringement proceedings cannot be initiated on the basis of a pending non-provisional patent application. However, in many jurisdictions, once a patent is granted, damages may be awarded for any infringements occurring from the date on which the patent specification for the application was initially published (see Sections 6.5.5 and 6.5.6) provided certain criteria are met. We have not checked any public records nor advised on whether or not any of the patent matters in the patent portfolio are the subject of patent litigation.

#### 6.4.4 Validity of a patent

The validity of the claims of a patent cannot be guaranteed and can be challenged in court during revocation proceedings brought by a third party, or during infringement proceedings initiated against an alleged infringer by the patentee.

#### 6.4.5 Rights of third parties

We have not undertaken any steps to confirm inventorship in respect of any of the patent families comprising the patent portfolio. Furthermore, we have not been asked to determine whether any third party may have any rights, title or interest in or to any of the patent families.

#### 6.4.6 Infringement of third-party rights

A patent may be granted even though the technology in respect of which the patent has been granted falls within the scope of, and may thus infringe, a patent of a third party. We have not conducted any searches to identify any patents that may be infringed by the exploitation of any product or method referred to in the patent portfolio that is the subject of this report. Nor have we provided any patent infringement advice in respect of any of the Technologies to which the patent portfolio relates.

## 6.5 Limitations and qualifications

#### 6.5.1 Information source(s)

In preparing this report we obtained a copy of the specifications for the international (PCT) applications in patent families 1 and 6 from a commercial database. We were provided with a copy of the specifications for the international (PCT) patent applications in patent families 2 and 7 and the

specifications for the provisional patent applications listed in patent families 3–5 by the Australian patent attorney firms currently responsible for the management of those patent families. The details set out in Tables 1–7 were derived from searches conducted by us or on our behalf using publicly available database(s), with the exception of the application details for the international (PCT) applications in patent families 2, 3 and 7. Those details have been confirmed to us orally by IP Australia. The information contained in Tables 1–7 in Section 6.3 was correct as at 5 April 2005.

#### 6.5.2 Jurisdictional requirements

To obtain valid patent protection, an invention must be novel and constitute an inventive step (that is, be non-obvious). An invention must also have utility and be industrially applicable. More specifically, each jurisdiction has its own patent laws and particular requirements that need to be met for the grant of a patent. Accordingly, the assessment of novelty and non-obviousness varies from jurisdiction to jurisdiction, and subject matter that may be patentable in one jurisdiction may be excluded from patentability in another. Moreover, the different jurisdictional requirements may result in variation in the scope of patent protection obtained for the same invention in different jurisdictions.

#### 6.5.3 Timing considerations

The outcome of substantive examination of a patent application by the patent office of one jurisdiction is not binding on the patent office of any other jurisdiction. Examinations of the patent applications of a patent family also occur at different times in different jurisdictions. As such, there is always a risk that a patent may be granted on a patent application in one jurisdiction, and that prior art relevant to the validity of the patent may be subsequently cited during substantive examination of another patent application in the patent family that has been filed elsewhere.

#### 6.5.4 Patentability search limitations

A patentability search conducted by a patent office during the patent application procedure cannot be guaranteed to locate all prior art that may exist that is potentially relevant to the assessment of novelty and inventive step of a claimed invention. Such searches are generally computer-based searches and, as such, depend on the databases searched and their coverage. Databases may, for instance, not include older documents and may only include information sourced from particular organisations or geographical areas. All patentability searches are subject to the accuracy of records as well as the indexing and classification of the subject matter comprising the records. The scope of each search also depends on the search strategy used and, for example, the key words selected for the search.

## 6.5.5 Further limitations of patentability searches

Non-provisional patent applications are not normally published until at least 18 months from the earliest applicable priority date. Accordingly, a patentability search would not normally identify any third party patent applications potentially relevant to the assessment of patentability that have a priority date that is less than 18 months prior to the date of the patentability search.

#### 6.5.6 Publication in the United States

Prior to 29 November 2000, publication in the United States did not occur until the time of grant of the patent in that jurisdiction. Non-provisional United States patent applications having a filing date on or after 29 November 2000 are now published 18 months after the priority date of the application. However, the applicant of a non-provisional United States patent application can request that the application not be published if the invention to which the application relates has not, and will not, be the subject of a patent application filed in another jurisdiction in which patent applications are published 18 months from the priority date.

#### 6.5.7 Other forms of prior art disclosures

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

#### 6.5.8 Commercialisation/secret use

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

#### 6.5.9 Entitlement to claimed priority date(s)

For subject matter contained in a non-provisional patent application to be entitled to the priority date established by a corresponding priority patent application, in Australia at least, there must be a real and reasonably clear disclosure of the subject matter in the priority application. Subject matter disclosed in a non-provisional patent application that is not contained in a corresponding priority application is generally only entitled to the filing date of the nonprovisional application as a priority date.

#### 6.5.10 Renewal fees

The patent offices of most, if not all, jurisdictions around the world levy official renewal fees on non-provisional patent applications and/or granted patents. Typically, an initial renewal fee is payable a number of years after the filing date of a nonprovisional patent application, and subsequent renewal fees fall due on each following anniversary of the filing date for the life of the application and/or patent. If a renewal fee is not timely paid, the application or patent becomes abandoned with loss of rights. We have not undertaken any steps to confirm that all renewal fees have been paid in respect of any complete patent applications in the patent portfolio.

Blake Dawson Waldron Patent Services

Blake Dawson Waldron Patent Services Dated: 26 May 2005

# "Hold tenderly that which you cherish."

Bob Alberti, American jazz pianist, composer & conductor

## 7 HISTORICAL FINANCIAL INFORMATION

The financial information presented below should be read in conjunction with the summary of significant accounting policies in this section, the risk factors in Section 9 and other information contained in this Prospectus.

## 7.1 Overview of financial performance

Set out below is a summary of the historical results for Medical Therapies Group (as defined below) for the period ended 30 June 2004 and the eight month period ended 28 February 2005.

	Reviewed period from incorporation on 24 September 2003 to 30 June 2004	Reviewed eight months to 28 February 2005
	A\$,000	A\$,000
Revenue from ordinary activities		
Other	1	4
Total revenue from ordinary activities	1	4
Expenses from ordinary activities		
Consulting expenses	140	320
Other	107	264
Total expenses from ordinary activities	247	584
Loss before income tax	246	580
Income tax credit	-	-
Net loss	246	580

## 7.2 Review of historical results

Medical Therapies was a new entity registered as a public company on 8 October 2004 to issue equity instruments to effect a business combination with Biotech Pty Limited.

On 13 October 2004, Medical Therapies acquired the share capital of Biotech Pty Limited in an equity exchange (Medical Therapies Group).

Biotech Pty Limited was incorporated on 24 September 2003 with seed capital from founding shareholders. In accordance with AASB 3, Biotech Pty Limited has been identified as the acquirer and the results above reflect the consolidated position of Medical Therapies Group accordingly.

Consulting expenses relate to company establishment costs and preliminary research and activity in connection with an initial public offering. Other expenses include salary and wages, rental and other sundry expenses.

## 7.3 Reconciliation of loss to net cash outflow from operating activities The loss for the period above can be reconciled to net cash outflow from operating activities as follows:

ltem	Period to 30 June 2004	Eight months to 28 February 2005	
	A\$,000	A\$,000	
Loss for the period	(246)	(580)	
Change in operating assets	-	(83)	
Change in operating liabilities	-	96	
Net cash outflow from operations	(246)	(567)	

## 7.4 Pro-forma statement of financial position

The balance sheet below has been extracted from the unaudited accounts of Medical Therapies at 28 February 2005 that were reviewed by PricewaterhouseCoopers Securities Limited. The pro-forma Statement of Financial Position below has been adjusted for the gross proceeds from the issue of Shares and Options under this offer and other movements in share capital less estimated issue expenses, and acquisition of Intellectual Property (IP) under the agreements with USYD and UWS as if these transactions had occurred at 28 February 2005.

Consolidated	Ref	Reviewed 28 Feb 2005	Pre-IPO capital raising <sup>1</sup>	Effect of IPO: minimum raising of A\$5m <sup>2</sup>	Pro-forma 28 Feb 2005: minimum raising of A\$5m	Effect of IPO: including over- subscription up to A\$10m <sup>2</sup>	Pro-forma 28 Feb 2005: over-subs- cription up to A\$10m
		A\$,000	A\$,000	A\$,000	A\$,000	A\$,000	A\$,000
Current assets							
Cash assets	Note 20	a 415	500	3,869	4,784	8,869	9,784
Other	Note 20	a 83	-	831	914	831	914
Total current assets		498	500	4,700	5,698	9,700	10,698
Non-current assets		25			25		25
Plant and equipment		25	-	-	25	-	25
Intellectual Property	Note 2 <i>t</i>		-	4,280	4,280	4,280	4,280
Total non-current assets		25	-	4,280	4,305	4,280	4,305
Total assets		523	500	8,980	10,003	13,980	15,003
Current liabilities				(400)	(100)	(100)	(100)
Payables	Note 20	c (96)	-	(400)	(496)	(400)	(496)
Provisions Total current liabilities		(96)	_	(400)	(496)	(400)	(496)
Net assets		427	500	8,580	9,507	13,580	14,507
Equity							
Contributed equity	7.6	1,253	500	8,905	10,658	13,905	15,658
Accumulated losses	7.6.2	(826)	-	(325)	(1,151)	(325)	(1,151)
Total equity		427	500	8,580	9,507	13,580	14,507

Notes

1 The Company raised A\$500,000 between 28 February and 29 April 2005 via a private placement totalling 3,125,000 shares to existing and new shareholders.

2a The minimum subscription for the Offer is A\$5,000,000 and the Company may accept oversubscriptions of up to A\$5,000,000. The proforma balance sheet shows the minimum subscription of A\$5,000,000 alongside the potential maximum capital raising of A\$10,000,000. The cash assets raised are net of:

 (i) A\$831,042 project research costs payable in advance on commencement of the projects, to USYD and UWS on the IPO listing date, comprising A\$508,020 for Technology One A\$40,000 for Technology Two and A\$283,022 for Technology Three; and

(ii) A\$300,000 cash payment for the acquisition of the Nature Vet IP (Regtop / Biffin Patents).

2b IP consists of fair market value of A\$3,980,000 as determined in the Independent Experts Report issued by WHK Greenwoods dated 23 March 2005 and the A\$300,000 cash payment for the acquisition of the Nature Vet IP.

2c A\$400,000 represents direct costs associated with the IPO of A\$69,000 for legal fees, accounting fees of A\$100,000 and costs associated with the issue of the prospectus of A\$231,000. These costs associated with the IPO have been netted against equity raised (see Section 7.5.7).

# 7.5 Summary of significant accounting policies

#### 7.5.1 Basis of preparation

The financial information in this section has been prepared in accordance with Australian equivalents to International Financial Reporting Standards (AIFRS), other authoritative pronouncements of the Australian Accounting Standards Board, Urgent Issues Group Interpretations and the Corporations Act 2001. Some of the disclosure requirements under these accounting standards have not been included where the information that would be disclosed is not considered material or relevant to potential investors. The financial information has been prepared under the historical cost convention.

#### 7.5.2 Principles of consolidation

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of Medical Therapies as at 28 February 2005 and the results of all the subsidiaries for the period then ended. Medical Therapies and its subsidiaries together are referred to in this Prospectus as Medical Therapies Group or the Group.

Subsidiaries are entities over which the Group has the power to govern the financial and operating policies, generally accompanying a shareholding of more than one-half of the voting rights. Subsidiaries are fully consolidated from the date on which control is transferred to the Group.

#### 7.5.3 Research and development costs

Expenditure on research activities, undertaken with the prospect of obtaining new scientific or technical knowledge and understanding, is recognised in the income statement as an expense when it is incurred. Expenditure on development activities, being the application of research findings or other knowledge to a plan or design or the production of new or substantially improved products or services before the start of commercial production or use, is capitalised if the product or service is technically and commercially feasible and adequate resources are available to complete developments. Other development expenditure is recognised in the income statement as an expense as incurred. Capitalised development expenditure is stated at cost less accumulated amortisation. Amortisation is calculated using the straight-line method to allocate the cost over the period of the expected benefit, which varies from three to five years.

#### 7.5.4 Income tax

The income tax expense or revenue for the period is the tax payable on the taxable income for the current period based on the national income tax rate adjusted for changes in deferred tax assets and liabilities attributable to temporary differences between the tax bases of assets and liabilities and their carrying amounts in the financial statements and to unused tax losses. Deferred tax assets are recognised for deductible temporary differences and unused tax losses only if future taxable amounts will probably be available to utilise those temporary differences and losses.

#### 7.5.5 Intangible assets

Intellectual property acquired has a finite useful life and is carried at cost less accumulated amortisation and impairment losses. Amortisation is calculated using the straight-line method to allocate the cost of the intellectual property over its estimated useful life of five years.

#### 7.5.6 Impairment of assets

Assets that are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount.

#### 7.5.7 Acquisition of assets

The purchase method of accounting is used for all acquisitions of assets regardless of whether equity instruments or other assets are acquired. Cost is measured as the fair value of the assets given, shares issued or liabilities undertaken at the date of exchange plus costs directly attributable to the acquisition. Transaction costs arising on the issue of equity instruments are recognised directly in equity.

#### 7.5.8 Share-based payments

Share options granted after 7 November 2002 and vested after 1 January 2005 are recognised as an expense with a corresponding increase in equity based on the fair value of the options granted. The fair value is measured at grant date and recognised over the period during which the option-holder becomes unconditionally entitled to the options.

The fair value at grant date is independently determined using a Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the vesting and performance criteria, the impact of dilution, the non-tradable nature of the option, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield, and the risk-free interest rate for the term of the option.

The fair value of the options granted excludes the impact of any non-market vesting conditions (for example milestone targets). Non-market vesting conditions are included in assumptions about the number of options that are expected to become exercisable. Upon the exercise of options, the balance of the share-based payments reserve relating to those options is transferred to share capital.

#### 7.5.9 Contributed equity

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

## 7.6 Contributed equity

The note below details the components that make up the contributed equity figure under the minimum subscription amount of A\$5,000,000.

Medical Therapies Group	Date of issue/grant	Price	No. Shares	Cost of Shares	No. Options	Value of Options
		A\$		A\$,000		A\$,000
On issue at 28 February 2005	As at 28 February		10,654,916	1,253	5,516,665	-
Pre-IPO capital raising through private placement	March 2005	0.16	3,125,000	500	-	-
Issued as part of IPO to:						
- Universities	30 May 2005	0.133	30,000,000	3,980	10,000,000	-
- Directors	30 May 2005		-	-	3,500,000	253
-CEO	30 May 2005		-	-	1,000,000	72
	on FDA approval		-	-	1,500,000	-
	on FDA approval		-	-	2,500,000	-
	and market-based hurdles					
- Public	30 May 2005	0.20	25,000,000	5,000	-	-
Less: issue costs (see Section 7.4, note 2 <i>c</i> )				(400)		
Total pro-forma no. equity ir	nstruments on issue/gra	nt	68,779,916	10,333	24,016,665	325

### 7.6.1 Ordinary Shares

Ordinary Shares entitle the holder to participate in dividends and the proceeds on the winding up of the Company in proportion to the number of Shares held. Each Shareholder has, on a show of hands, one vote and, on a poll, one vote for every ordinary Share held. As at 28 February 2005, 10,654,916 Shares were on issue.

#### 7.6.2 Share Options

- (a) The 5,516,665 Options on issue as at 28 February 2005 were granted to all Shareholders on 13 October 2004 as part of the equity issue to acquire the share capital of Biotech Pty Limited.
- (b) Up to 10 million Options can be granted and issued to USYD and UWS, 31 to 40 months after the Completion Date, subject to the Universities meeting certain milestones relating to development of each of the three Technologies. Further details are given in Section 10.4.
- (c) The Chairman and non-executive Directors will be issued 3,500,000 Options on IPO as follows:

Director	Position	No. Director Options	Fair value of Director Options on IPO
			A\$,000
James Dominguez	Chairman	2,500,000	181
Dr Michael Taverner	non-executive Director	500,000	36
Professor Michael Vitale	non-executive Director	500,000	36
Total		3,500,000	253

The Director Options entitle the holders to Shares in the Company and will only be issued in the event of a successful IPO. The options are exercisable at any time prior to 31 December 2008 at an exercise price of A\$0.20.

The fair value of these options of A\$253,000 granted and vested on IPO have been accounted for in accordance with AIFRS and the accounting policy adopted for share-based payments as described in Section 7.5.8 above. This amount, together with A\$72,000 of options granted and vested on the date of IPO to the CEO as detailed below, have been credited to contributed equity in the pro-forma balance sheet and treated as a cost of the business, thus increasing accumulated losses.

#### (d) The Executive Options granted will vest in three tranches as follows:

Tranche	Milestone	No. Executive Options	Fair value of Executive Options
			A\$,000
Tranche 1	On successful IPO	1,000,000	72
Tranche 2	On successful completion of FDA-approved Phase I clinical trials for any of the Technologies	1,500,000	108
Tranche 3	On the volume-weighted average price of the Company's shares exceeding A\$0.50 for five consecutive Business Days and the first Key Mileston being achieved for any of the Technologies, as define in the Research Agreements		145
Total		5,000,000	325

The Executive Options are exercisable at any time on or prior to 5.00pm (AEDT) on 31 December 2008. The fair value of Tranche 1 of the Executive Options of A\$72,000 granted and vested on IPO have been accounted for in accordance with AIFRS and the accounting policy adopted for share based payments as described in Section 7.5.8 above.

Tranche 2 of the Executive Options will only vest and may only be exercised in the event the Company completes FDA-approved Phase I clinical trials in respect of any of the Technologies or the associated IP. Tranche 3 of the Executive Options will only vest and may only be exercised in the event the volume-weighted average price of the Company's Shares as traded on ASX exceeds A\$0.50 for five consecutive Business Days and the first Key Milestone is achieved for any of the Technologies, as defined in the Research Agreements. The fair value of Tranches 2 and 3 of the Executive Options granted is A\$108,000 and A\$145,000 respectively and will be expensed over the periods to 31 December 2008.

### 7.7 International Financial Reporting Standards

This historical financial information section of the prospectus has been prepared and presented in accordance with Australian International Financial Reporting Standards (AIFRS). Medical Therapies will be required to prepare financial statements that comply with Australian equivalents to International Financial Reporting Standards (AIFRS), as issued by the Australian Accounting Standards Board, from 1 July 2005. The financial report for the half year ending 31 December 2005 will be the first financial report prepared in compliance with AIFRS.

In preparing the pro-forma balance sheet and adjustments contained therein, the impacts of adoption of AIFRS have been considered and have been fully reflected. No further impacts are anticipated by the company as a result of the transition to AIFRS.

"The voyage of discovery lies not in finding new landscapes, but in having new eyes."

Marcel Proust (1871–1922), French writer

# PriceWaTerhouseCoopers 🛛

PricewaterhouseCoopers Securities Ltd ACN 003 311 617 ABN 54 003 311 617 Holder of Australian Financial Services Licence No 244572

Darling Park Tower 2 201 Sussex Street GPO BOX 2650 SYDNEY NSW 1171 DX 77 Sydney Australia www.pwc.com/au Telephone +61 2 8266 0000 Facsimile +61 2 8266 9999

3 June 2005 The Board Of Directors Medical Therapies Limited Level 11, 91 York Street SYDNEY NSW 2000

Subject: Investigating Accountant's Report on Historical Financial Information

#### Dear Sirs

We have prepared this report on the historical financial information of Medical Therapies Limited and controlled entities (the Company) for inclusion in a Prospectus dated on or about 3 June 2005 (the Prospectus) relating to the issue of ordinary Shares in the Company.

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

The nature of this Report is such that it should be given by an entity that holds a dealer's licence under the Financial Services Reform Act 2001. PricewaterhouseCoopers Securities Limited is wholly owned by PricewaterhouseCoopers and holds the appropriate Australian Financial Services Licence.

#### 8.1 Background

Medical Therapies Limited (Company) is a pharmaceutical company formed to develop products to treat various cancers and chronic inflammatory diseases such as arthritis.

Following two seed capital raisings completed in late November 2004 and early March 2005, the Company entered into the Intellectual Property Assignment Deed with the University of Sydney and the University of Western Sydney, under which the Company agreed to acquire the Intellectual Property (IP) relating to the Technologies in return for issuing securities to the Universities. The IPO is a condition precedent for the contract to acquire the IP and associated research agreements to proceed.

The Company has established strategies for commercialising the IP using the funds raised from the IPO, including immediately commencing commercial manufacture of human pharmaceutical grade formulations and documentation required to enter Phase I and IIa clinical trials of new antiinflammatory drugs, with a focus on regular reporting of discoveries, milestones and product releases.

#### 8.2 Scope

You have requested PricewaterhouseCoopers Securities Limited to prepare an Independent Accountant's Report (the **Report**) covering the following information:

Historical financial information

- (a) the historical financial performance of the Company for the periods ended 30 June 2004 and 28 February 2005;
- (b) the historical statement of financial position as at 28 February 2005 and the pro-forma statement of financial position as at 28 February 2005 that assumes completion of the contemplated transactions disclosed in Section 7 of the Prospectus (the pro-forma transactions),

#### (collectively, the **Historical Financial Information**). This Report has been prepared for inclusion in the Prospectus. We disclaim any assumption of responsibility for any reliance on this Report or on the Historical Financial Information to which it relates for any purposes other than for which it was prepared.

# 8.3 Scope of review of Historical Financial Information

The Historical Financial Information set out in Section 7 of the Prospectus for the period ended 28 February 2005 and the Historical Financial Information for the period ended 30 June 2004 has been based on the unaudited financial statements of the Company that have been reviewed by PricewaterhouseCoopers

Securities Limited. The Directors are responsible for the preparation of the Historical Financial Information We have conducted our review of the Historical Financial Information in accordance with Australian Auditing Standard AUS 902 Review of Financial Reports. We made such inquiries and performed such procedures as we, in our professional judgement, considered reasonable in the circumstances including:

- (a) an analytical review of the unaudited financial performance of the Company for the relevant historical periods;
- (b) a review of work papers, accounting records and other documents;
- (c) a review of the assumptions used to compile the pro-forma statement of financial position as at 28 February 2005 (the pro-forma transactions);
- (d) a comparison of consistency in application of the recognition and measurement principles in Accounting Standards and other mandatory professional reporting requirements in Australia, including under Australian International Financial Reporting Standards (AIFRS), and the accounting policies adopted by the Company disclosed in Section 7 of the Prospectus, and
- (e) enquiry of directors, management and others. These procedures do not provide all the evidence that would be required in an audit; thus the level of assurance provided is less than given in an audit. We have not performed an audit and, accordingly, we do not express an audit opinion.

# 8.4 Review statement on Historical Financial Information

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

- (a) the pro-forma statement of financial position has not been properly prepared on the basis of the pro-forma transactions;
- (b) the pro-forma transactions do not form a reasonable basis for the pro-forma statement of financial position; or
- (c) the Historical Financial Information, as set out in Section 7 of the Prospectus, does not present fairly:
  - the historical financial performance of the Company for the period ended 30 June 2004 and the period ended 28 February 2005; nor
  - (ii) the historical and pro-forma statement of financial position as at 28 February 2005,

in accordance with the recognition and measurement principles prescribed in Accounting Standards and other mandatory professional reporting requirements in Australia, including under Australian International Financial Reporting Standards (AIFRS) and accounting policies adopted by the Company disclosed in Section 7 of the Prospectus.

#### 8.5 Subsequent events

Apart from the matters dealt with in this Report, and having regard to the scope of our Report, to the best of our knowledge and belief no material transactions or events outside of the ordinary business of the Company have come to our attention that would require comment on, or adjustment to, the information referred to in our Report or that would cause such information to be misleading or deceptive.

# 8.6 Independence or disclosure of interest

PricewaterhouseCoopers Securities Limited does not have any interest in the outcome of this issue other than the preparation of this Report and participation in due diligence procedures for which normal professional fees will be received.

Yours faithfully

hoben Sneddon.

AJ Sneddon Authorised Representative of PricewaterhouseCoopers Securities Limited

## 9 RISK FACTORS

### 9.1 Introduction

An investment in the Company is not risk free and prospective new investors should consider the risk factors described below, together with information contained elsewhere in this Prospectus, before deciding whether to apply for Shares.

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

# 9.2 Development and commercialisation of intellectual property

Medical Therapies is relying on its ability to develop and commercialise the IP. A failure to successfully develop and commercialise the IP could lead to a loss of opportunities and adversely impact on the Company's operating results and financial position.

## 9.3 Intellectual property rights

Securing rights to intellectual property, and in particular patents, is an integral part of securing potential product value from the outcomes of pharmaceutical research and development. Competition in retaining and sustaining protection of intellectual property and the complex nature of intellectual property can lead to expensive and lengthy patents disputes for which there can be no guaranteed outcome. The granting of a patent does not guarantee that the rights of others are not infringed nor that competitors will not develop competing intellectual property that circumvents such patents. The Company's success depends, in part, on its ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties. Because the patent position of pharmaceutical companies can be highly uncertain and frequently involves complex legal and scientific evaluation, neither the breadth of claims allowed in pharmaceutical patents nor their enforceability can be predicted. There can be no assurance that any patents the Company or Universities may own or control or licence now and in the future will afford the Company commercially significant protection of the IP, nor that any of the projects that may arise from the IP will have commercial applications.

Although the Company is not aware of any third party interests in relation to the intellectual property rights of the IP, and has taken steps to protect and confirm its interest in these rights, there is always a risk of third parties claiming involvement in technological and medical discoveries, and if any disputes arise, they could adversely affect the Company. Although the Company will implement all reasonable endeavours to protect its IP, there can be no assurance that these measures have been, or will be sufficient.

#### 9.4 Research and development

The Company can make no representation that any of its research into or development of the IP will be successful, that the development milestones will be achieved, or that the IP will be developed into products that are commercially exploitable.

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

## 9.5 Economic risks

General economic conditions, movements in interest and inflation rates and currency exchange rates may have an adverse effect on the Company's activities, as well as on its ability to fund those activities.

## 9.6 Additional requirements for capital

The Company's capital requirements depend on numerous factors. Depending on the Company's ability to generate income from its operations, the Company may require further financing in addition to amounts raised under the Capital Raising. Any additional equity financing will dilute shareholdings, and debt financing, if available, may involve restrictions on financing and operating activities.

If the Company is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations and scale back its expansion and development programmes.

### 9.7 Reliance on key management

The responsibility of overseeing the day-to-day operations and the strategic management of the Company depends substantially on its senior management and its key personnel. There can be no assurance given that there will be no detrimental impact on the Company if one or more of these employees ceases their employment.

#### 9.8 Competition

There is a risk that the Company will not be able to continue to compete profitably in the competitive pharmaceutical industry in the long term. The potential exists for the nature and extent of the competition to change rapidly, which may cause loss to the Company.

### 9.9 Management of growth

There is a risk that the Company's managers will not be able to implement the Company's growth strategy. The capacity of the new managers to properly implement and manage the strategic direction of the Company may affect the Company's financial performance.

## 9.10 Loss of key clients

The Company has yet to establish important client relationships. Although the Company is expected to establish these relationships through development of the IP, the loss of one or more key clients is likely to adversely affect the operating results of the Company.

#### 9.11 Share market

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

- (a) general economic outlook;
- (b) interest rates and inflation rates;
- (c) currency fluctuations;
- (d) changes in investor sentiment toward particular market sectors;
- (e) demand for, and supply of, capital; and
- (f) terrorism or other hostilities.

## 9.12 Product liability and uninsured risks

Through its intended business, the Company is exposed to potential product liability risks that are inherent in the research and development, manufacturing, marketing and use of its products or products developed with future co-development alliance partners. It will be necessary to secure insurance to help manage such risks. The Company may not be able to maintain insurance for product or service liability on reasonable terms in the future and, in addition, the Company's insurance may not be sufficient to cover large claims, or the insurer could disclaim coverage on claims.

Although the Company endeavours to work to rigorous standards, there is still the potential for the products to contain defects that may result in system failures. These defects or problems could result in the loss of or delay in generating revenue, loss of market share, failure to achieve market acceptance, diversion of development resources, injury to the Company's reputation or increased insurance costs.

If the Company fails to meet its clients' expectations, the Company's reputation could suffer and it could be liable for damages.

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

## 9.13 Additional financing requirements

The Directors expect that the proceeds of the public capital raising will provide sufficient capital resources to enable the Company to achieve its initial business objectives. However, the Directors can give no assurances that such objectives will in fact be met without future borrowings or further capital raisings, and if such borrowings or capital raisings are required, that they can be obtained on terms favourable to the Company.

## 9.14 Regulatory risk

The introduction of new legislation or amendments to existing legislation by governments, developments in existing common law, or the respective interpretation of the legal requirements in any of the legal jurisdictions that govern the Company's operations or contractual obligations, could impact adversely on the assets, operations and, ultimately, the financial performance of the Company and its shares. In addition, there is a commercial risk that legal action may be taken against the Company in relation to commercial matters.

## 9.15 Unforeseen expenditure risk

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

#### 9.16 Licensing and marketing risks

The Directors believe the funds raised from the Offer will give the Company sufficient working capital to achieve its objectives as stated in Sections 2.4 and 2.5 of this Prospectus. However, funds raised under this Prospectus are unlikely to be sufficient to enable the Company to fully commercialise its technologies. The Company may seek to raise additional capital in the future if suitable licensees cannot be identified and the Company seeks to commercialise the therapies without licensees.

The Company intends to review the potential of the Technologies in the markets of Australia and overseas. There can be no assurance that these markets will be established successfull y and the failure to do so could have a material adverse effect on the Company's business, financial condition and results of operations. Furthermore, there is no guarantee that the targeted markets will accept the new technologies and use the products developed by the Company.

## 9.17 Investment is speculative

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

Therefore, the securities to be issued pursuant to this Prospectus carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those securities.

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

## 10 SUMMARY OF MATERIAL CONTRACTS

## 10.1 Intellectual Property Assignment Deed

The Company has entered into an Intellectual Property Assignment Deed with the Universities pursuant to which the Company has agreed to acquire all of the Universities' right, title and interest in the Intellectual Property in consideration for allotting and issuing Shares to the Universities as follows:

- (a) Technology One: 17,142,856 Shares to USYD;
- (b) Technology Two: 4,285,715 Shares to USYD and 4,285,715 Shares to UWS; and
- (c) Technology Three: 4,285,714 Shares to UWS. The material terms of the Intellectual Property Assignment Deed are set out below:
- (a) (Conditions precedent): Completion of the acquisition of the Intellectual Property is subject to a number of conditions precedent. As at the date of this Prospectus, the only outstanding conditions precedent are:
  - the Company successfully raising a minimum of A\$5 million pursuant to this Prospectus through the issue of Shares at an issue price of A\$0.20 each;
  - (ii) the Company delivering to each University confirmation that it has successfully raised a minimum of A\$5 million pursuant to this Prospectus;

- (iii) the Company receiving conditional approval to list on ASX; and
- (iv) the Company delivering to each University a certified copy of the conditional approval of the ASX for listing of the Shares on ASX.
- (b) (Arrangements regarding Nature Vet): The right, title and interest in Technology One assigned under the deed is subject to the rights granted to Nature Vet under various agreements with Nature Vet.
- (c) (Licence of background intellectual property): On the Completion Date, the Universities grant the Company a perpetual, irrevocable, royalty– free and non-exclusive licence under their background intellectual property relating to the Technologies to the extent necessary to allow the Company to exploit any invention claimed in the Intellectual Property anywhere in the world and to use, reproduce and adapt the core materials anywhere in the world.
- (d) (Ownership of background intellectual property): The Universities shall retain ownership of all background intellectual property and the Company has no right, title or interest in or in relation to background intellectual property other than the licence granted to it and outlined in the deed.

- (e) (Warranties): The Universities each give warranties regarding ownership and status of the Intellectual Property that are customary in deeds of this type.
- (f) (Indemnity by the Company): The Company must indemnify and keep indemnified the Universities from and against:
  - (i) any liability incurred by the Universities;
  - (ii) any loss or damage to property of the Universities; and
  - (iii) any loss or expense incurred by the Universities in dealing with any claim against it (including legal costs and expenses on a solicitor and own-client basis and the cost of time spent, resources used and disbursements paid by the Universities), arising from any breach by the Company of the warranty relating to the Shares being free from encumbrances when issued, except to the extent that the liability, loss, damage or expense was caused by the negligence (including breach of statutory duty) of the Universities or any breach by the Universities of their obligations under the deeds.

- (g) (Cap on liability and indemnity of the Company): To the extent permitted by law, the liability of the Company:
  - (i) for any claim by the Universities under or in relation to the deed, whether in contract, tort (including negligence and breach of statutory duty) or otherwise; or
  - to indemnify the Universities under each of the deeds, is limited to A\$20 million to USYD and A\$8 million to UWS.
- (h) (Indemnity by the Universities): The Universities must indemnify and keep indemnified the Company from and against:
  - (i) any liability incurred by the Company;
  - (ii) any loss or damage to property of the Company; and
  - (iii) any loss or expense incurred by the Company in dealing with any claim against it (including legal costs and expenses on a solicitor and own-client basis and the cost of time spent, resources used and disbursements paid by the Company),

arising from any breach by the Universities of certain warranties in the deed, except to the extent that the liability, loss, damage or expense was caused by the negligence (including breach of statutory duty) of the Company or any breach by the Company of its obligations under the deeds.

- (i) (Cap on liability and indemnity of the Universities): To the extent permitted by law, the liability of the Universities:
  - (i) for any claim by the Company under or in relation to each of the deeds, whether in contract, tort (including negligence and breach of statutory duty) or otherwise; or

(ii) to indemnify the Company under the deed, is limited to A\$20 million in the case of USYD and A\$8 million in the case of UWS.

In relation to Technology Two, if:

- (a) the Company receives a final report from UWS
   (or a third party contractor) in relation to the in vivo animal studies to be undertaken on the lead compound in Phase I (including all reasonable amendments, changes and clarifications that the Company has sought) (Final Report);
- (b) either of the Universities have written to the Company requesting whether the Company intends to either:
  - proceed with Phase 2 (pursuant to and in accordance with the procedures specified in Schedule 1 of the Research Agreement relating to Technology Two); or
  - begin using its best endeavours to proceed towards conducting clinical trials in humans based on results in relation to the lead compound tested in Phase 1, (the, Query); and
- (c) the Company has not, on or before the later of three months after receiving the Final Report or

10 days after receiving the Query, notified the Universities in writing that it intends to:

- proceed with Phase 2 (pursuant to and in accordance with the procedures specified in Schedule 1 of the Research Agreement relating to Technology Two); or
- begin using its best endeavours to proceed towards conducting clinical trials in humans based on results in relation to the lead compound tested in Phase 1,

then the Company:

- (iii) must assign to the Universities as tenants in common, absolutely and as beneficial owners, the entire right, title and interest in and in relation to the core IP, core materials, project IP and research results relating to Technology Two; including but not limited to the right to apply for any patent rights anywhere in the world claiming priority from the Technology Two core IP or project IP, and the right to sue for and recover damages and other relief in relation to any infringement of the Technology Two core IP; and
- (iv) must promptly do all such things reasonably required by the Universities (including execute any document) to give effect to the assignment described in sub-clause (iii) above.

The Intellectual Property Assignment Deed otherwise contains terms and conditions that are customary in deeds of this type.

### 10.2 Research Agreements

The Company has entered into research agreements with the Universities in relation to each of Technology One, Technology Two and Technology Three (Research Agreements). Each of the terms and conditions of these agreements are substantially the same.

Under the Research Agreements the Universities will carry out a programme of research and development to further develop the core intellectual property in relation to each of Technology One, Technology Two and Technology Three.

The material terms of the Research Agreements are set out below:

- (a) (Appointment): The Company appoints each University as its independent contractor to carry out the research project in relation to each of the Technologies (Research Project).
- (b) (Research obligations of Universities): Under the Research Agreements, the Universities must:
  - carry out the Research Project diligently, to a high scientific standard and using professional care and skill;
  - (ii) conduct the Research Project with a view to achieving the Key Milestones and the other milestones efficiently and expeditiously;
  - (iii) appoint researchers and principal researchers with the necessary skills, qualifications and experience to undertake and perform the Research Project;

- (iv) apply appropriate equipment, facilities and University background intellectual property to carry out each Research Project;
- (v) effectively supervise the activities of the researchers and the principal researchers in the performance of each Research Project;
- (vi) report verbally to the board of directors of the Company on the status of each Research Project from time to time on the Company's reasonable request;
- (vii) spend or otherwise apply all research funds paid by the Company towards the conduct of the Research Projects and substantially in accordance with the budget; and
- (viii) apply their capital items and their laboratories and equipment to the performance of each Research Project.
- (c) (Funding obligations of the Company): The Company must fund the Research Projects by paying the research funds to the Universities.
- (d) (Key Milestones): means:
  - (i) in relation to Technology One:
    - (A) completed synthesis and characterisation of new copper and zinc NSAID complexes as anti-inflammatory drugs; and
    - (B) completed studies on the efficacy and safety of topical, oral and ophthalmic formulations of new copper and zinc NSAID complexes, for the treatment of inflammation;

- (ii) in relation to Technology Two:
  - (A) an identified lead compound with less toxicity and no less efficacy than cisplatin, as evidenced through both in vitro and in vivo studies; and
  - (B) an optimised formulation of the identified compound that is suitable for commencing a Phase I clinical trial; and
- (iii) in relation to Technology Three:
  - (A) successful completion of compound characterisation and specific binding studies; and
  - (B) at least one proof-of-concept compound that can target and bind to a specific DNA sequence of at least three base pairs in length.
- (e) (Timing for completing Key Milestones): The agreements provide for the following expected times for completion of the Key Milestones:
  - (i) in relation to Technology One—within 12 months from the agreed commencement date of the project;
  - (ii) in relation to Technology Two—within 15 and 21 months of the commencement date of Phase 2; and
  - (iii) in relation to Technology Three—within 12 and 24 months from the agreed commencement date of the project.

- (f) (Reporting by Universities): The Universities must provide the Company with quarterly research and expenditure reports. Each research report must include:
  - (i) in relation to the previous quarter:
    - (A) the progress of and activities undertaken in the performance of the Research Projects;
    - (B) details of any milestones achieved;
    - (C) a summary of the research results so far;
    - (D) any material technical developments in the Research Projects;
    - (E) the appointment of all new employees or permitted contractors to conduct the Research Projects; and
  - (ii) any recommendations to the Universities on the future conduct of the Research Project including:
    - (A) any amendment to the Research
       Projects proposed by any key researcher
       or researchers;
    - (B) any recommendations for registration or protection of any intellectual property; and
    - (C) any other proposed alterations to the content of the research projects.

- (g) (Licence to the Universities of Intellectual Property): The Company grants to the Universities a non-exclusive royalty-free license to use the core Intellectual Property to conduct the Research Projects in Australia for the term of the Research Agreements.
- (h) (Licence to the Company under the University background intellectual property): The Universities grant to the Company a perpetual, irrevocable, royalty-free and non-exclusive licence to use the Universities' background intellectual property solely to the extent necessary or desirable:
  - to exploit any invention claimed in the Intellectual Property or the Technologies anywhere in the world; and
  - (ii) to exploit, reproduce and adapt the research results anywhere in the world.
- (Ownership of background IP): The Company acknowledges that the Universities shall retain ownership of all background intellectual property.
- (j) (Ownership of technology IP and research results): All intellectual property created under the Research Agreements and all research results shall be owned by Company and shall vest in the Company immediately upon creation.

- (k) (Filing, prosecution and maintenance): The Company is solely responsible for all decisions and costs regarding registration or protection of any intellectual property and for filing, prosecution, registration and maintenance of any intellectual property.
- (I) (Principal researcher inventions): All intellectual property rights in inventions made by the principal researchers outside the scope of the research work are owned by the Universities. However, the Company will have a first right of refusal in relation to any dealing with this intellectual property by the Universities during the term of the research agreements, subject to any prior third party rights.
- (m) (Publications): The Universities will be allowed to publish results of their research work in certain circumstances and with the prior consent of the Company.
- (n) (Limitation of liability): The liability of the Universities to the Company is limited to the aggregate of the research funds paid by the Company. The liability of the Company to the University is limited to the aggregate of the balance of the research funds not paid by the Company in accordance with the agreement and A\$1,000,000.

- (o) (Insurance): The Universities are responsible for taking out and maintaining in force in Australia adequate insurance in relation to the Research Projects.
- (p) (Term): The Research Agreements shall commence on the date of settlement under the Intellectual Property Assignment Deed and, unless terminated earlier, shall continue until the earlier of the completion of the Research Project or the second anniversary of the commencement date (or such longer term as the parties agree in writing).
- (q) (Termination for breach): If any party commits a material breach of the Research Agreements then the other party may request in writing that the breach be remedied. If the party committing the breach does not remedy the breach within 30 days then the other party may terminate the agreement immediately by notice in writing.
- (r) (Termination for insolvency events): Any party may immediately terminate a Research Agreement by notice in writing to the other party if the other party is involved in an insolvency event.
- (s) (Resignation etc. of principal researchers): If any principal researcher resigns from the Universities or for any reason ceases or suspends for 30 consecutive days his or her participation in the Research Project (whether by death, incapacity or otherwise) and the Universities do not replace the principal researcher with a person of equivalent skills and experience who is reasonably acceptable to the Company within

30 days of the resignation or cessation of participation, then the Company may terminate the Research Agreements immediately by notice in writing.

- (t) (Termination for failure to meet Key Milestone): If the Universities give the Company a notice advising that a Key Milestone is unlikely to be achieved within the term, then the Company may terminate the relevant Research Agreement by giving 30 days' notice in writing.
  - (i) If the Universities fail to meet the Key Milestone by the date agreed, then the time for achievement of the Key Milestone shall be automatically extended by two months.
  - (ii) If the Universities fail to meet the Key Milestone by the date as extended, then the Company may terminate the relevant Research Agreement immediately by notice in writing.
- (u) (Termination for failure to meet milestones in the second year):
  - (i) If at any time after the first anniversary of the commencement date, the Universities fail to meet any milestone by the date agreed, then the time for achievement of the milestone shall be automatically extended by two months and such additional time as the Universities' failures to meet the milestone was caused by the Company's breach of the Company's obligations under the agreement.

 (ii) If the Universities fail to meet a milestone by the date as extended, then the Company may terminate the relevant Research Agreement immediately by notice in writing.

The Research Agreements otherwise contain terms and conditions that are customary in agreements of this type.

### 10.3 Nature Vet Licence Agreement

Medical Therapies has entered into a licence agreement with Nature Vet, whereby the Company has granted to Nature Vet an exclusive royalty-free set of licences to exploit certain of the Company's intellectual property in the 'veterinary field'.

The material terms of the agreement are as follows:

- (a) (Reservation of rights): Nature Vet acknowledges that all patent rights and intellectual property granted to Nature Vet under the agreement remains the property of the Company. Nature Vet does not have the right to use any of the licensed intellectual property in relation to the diagnosis, prevention or treatment of human diseases.
- (b) (Improvements): Nature Vet assigns to the Company its entire right, title and interest in all intellectual property in any improvements effective on their creation.
- (c) (Exploitation of licensed products): Nature Vet must use diligent efforts to pursue the maximum exploitation of the licensed products as well as opportunities in major markets for the exploitation of the licensed products and to promote, market and exploit the licensed products in the veterinary field.

- (d) (Royalties): Nature Vet must pay to the Company a royalty of 2% of all net sales of 'Category 2 Products and Category 2 Methods' and a royalty of 3.5% of all net sales of 'Category 3 Products and Category 3 Methods' (as those terms are defined in the agreement). Royalty payments are to be made within 30 days after the end of each Quarter.
- (e) (Technical information and assistance): The Company shall provide Nature Vet with training, technical assistance and consultancy services reasonably requested by Nature Vet to enable it to exploit the licensed products. Nature Vet is to pay the Company for any training, technical assistance and consultancy services at such reasonable commercial rates as the parties agree to in writing.
- (f) (Joint review committee): The parties have established a joint review committee in order to distinguish any proposed new licence product from other existing or proposed products of the Company, and thereby to support the effective commercialisation of licensed products.
- (g) (Maintenance of patent rights): The Company is solely responsible for the filing, prosecution and maintenance of any patent rights in the licensed intellectual property and for meeting the costs of filing, prosecution and maintenance. The agreement provides for a procedure whereby Nature Vet can assume this obligation if the Company declines to pursue any such filing, prosecution or maintenance of any patent rights.

- (h) (Indemnity by Nature Vet): Nature Vet indemnifies the Company from, and must hold the Company harmless against all actions, claims, proceedings or demands brought by any third party against the Company, in respect of any loss, death, injury, illness or damage arising out of:
  - the exploitation by Nature Vet of licensed products or licensed methods (including death of or personal injury to persons or property damage);
  - (ii) a breach of the warranties provided by Nature Vet under the agreement; or
  - (iii) the failure of any officer, employee, consultant or agent of Nature Vet to use reasonable care in carrying out Nature Vet's obligations under the agreement;

and from and against all damages, costs and expenses incurred in defending or settling any such claim, proceeding or demand, except to the extent that the loss, claim, proceeding or demand was caused by the negligence (including breach of statutory duty) of the Company, any unlawful conduct of the Company or any breach by the Company of its obligations or warranties in the agreement.

 (i) (Insurance): Nature Vet must take out, maintain and keep current product liability insurance in an amount of not less than A\$5,000,000 in relation to the exploitation of the licensed product.

- (j) (Term and termination): Unless terminated earlier by the parties, the rights and obligations under the agreement continue until the expiry, withdrawal, revocation or lapsing of the last patent right forming part of the licensed intellectual property. The licenses granted expire in relation to a country once all patent rights forming part of the licensed intellectual property in that country expire, lapse, or are withdrawn or revoked.
- (k) (Early termination): Either party may terminate the agreement by giving 30 days' written notice to the other party if the other party is in material breach of any material provision of the agreement and (where the breach is capable of remedy) the party in breach has failed to rectify the breach within 30 days of receipt of written notice from the other party describing the breach and calling for it to be remedied.

Further, the Company may terminate the agreement immediately by a written notice to Nature Vet if an insolvency event occurs in relation to Nature Vet or there is a change of control in Nature Vet which occurs without the prior written consent of the Company.

### 10.4 Option Deed

The Company has agreed to issue to each of the Universities options to acquire Shares (Milestone Options) on the occurrence of certain milestone events in the development of the Intellectual Property.

The number of Milestone Options and the circumstances in which they will be issued is set out below:

- (a) If on the End Date the Technology One Milestone (USYD), the Technology Two Milestone (USYD and UWS) and the Technology Three Milestone (UWS) have all been met, then the Company must allot and issue:
  - (i) 7,142,857 Milestone Options to USYD; and(ii) 2,857,143 Milestone Options to UWS.
- (b) If on the End Date the Technology One Milestone and the Technology Two Milestone have been met but the Technology Three Milestone has not been met, then the Company must allot and issue:
  - (i) 8,333,333 Milestone Options to USYD; and
  - (ii) 1,666,667 Milestone Options to UWS.
- (c) If on the End Date the Technology One Milestone and the Technology Three Milestone have been met but the Technology Two Milestone has not been met, then the Company must allot and issue:
  - (i) 7,142,857 Milestone Options to USYD; and
  - (ii) 2,000,000 Milestone Options to UWS,

and the Company in its reasonable discretion may (but is not obliged to) allot and issue as a performance reward a further 857,143 Milestone Options in total to USYD and/or UWS in such portions as the Company reasonably determines.

- (d) If on the End Date the Technology Two Milestone and the Technology Three Milestone have been met but the Technology One Milestone has not been met, then the Company must allot and issue:
  - (i) 3,333,333 Milestone Options to USYD; and
  - (ii) 6,666,667 Milestone Options to UWS.
- (e) If on the End Date the Technology One Milestone has been met but the Technology Two Milestone and the Technology Three Milestone have not been met, then the Company must allot and issue:
  - (i) 8,333,333 Milestone Options to USYD; and

(ii) nil Milestone Options to UWS,

and the Company in its reasonable discretion may (but is not obliged to) allot and issue as a performance reward a further 1,666,667 Milestone Options in total to USYD and/or UWS in such portions as the Company reasonably determines.

- (f) If on the End Date the Technology Two Milestone has been met but the Technology One Milestone and the Technology Three Milestone have not been met, then the Company must allot and issue:
  - (i) 5,000,000 Milestone Options to USYD; and
  - (ii) 5,000,000 Milestone Options to UWS.

- (g) If on the End Date the Technology Three Milestone has been met but the Technology One Milestone and the Technology Two Milestone have not been met, then the Company must allot and issue:
  - (i) nil Milestone Options to USYD; and

(ii) 6,666,667 Milestone Options to UWS,
and the Company in its reasonable discretion
may (but is not obliged to) allot and issue as
a performance reward a further 3,333,333
Milestone Options in total to USYD and/or UWS
in such portions as the Company reasonably
determines.

(h) If on the End Date neither the Technology One Milestone, the Technology Two Milestone nor the Technology Three Milestone has been met then the Company shall not allot nor issue any Milestone Options.

However, for the purposes of the allocations set out above, if, on or before the End Date, the Technology Two core IP has been assigned back to the Universities in accordance with the provisions of the IP Assignment Deed, then the Milestone Options will be allocated and issued as follows:

- (a) If on the End Date the Technology One Milestone
   (USYD) and the Technology Three Milestone
   (UWS) have been met, then the Company must allot and issue:
  - (i) 8,000,000 Milestone Options to USYD; and
  - (ii) 2,000,000 Milestone Options to UWS.
- (b) If on the End Date the Technology One Milestone has been met but the Technology Three Milestone has not been met, then the Company must allot and issue:
  - (i) 10,000,000 Milestone Options to USYD; and
  - (ii) nil Milestone Options to UWS.
- (c) If on the End Date the Technology Three Milestone has been met but the Technology One Milestone has not been met, then the Company must allot and issue:
  - (i) nil Milestone Options to USYD; and
  - (ii) 10,000,000 Milestone Options to UWS,
- (d) If on the End Date neither the Technology One Milestone nor the Technology Three Milestone has been met, then the Company shall not allot nor issue any Milestone Options.

The Milestone Options will be issued on substantially the same terms as the Options set out in Section 11.5.4, except that the expiry date will be two years from the date of issue of the Milestone Options. The Regtop/Biffin Patents are the patents listed in the table below, which relate to Cu-Indo as an anti-inflammatory drug and which arose from the SPIRT Grants C00107786 and C29804819.

Country	Patent no.	Application no.
Australia	629943	56663/90
Canada	2,058,754	2,058,754
Europe	0473655	90908178.8
Ireland	81142	-
New Zealand	233776	233776
Norway	175148	19910004565
South Korea	156231	19910071536
United States	5,310,936	773,601
United States	5,466,824	217,520
(CIP of US 773,601)		

Regtop/Biffin Patents: The European countries designated in EP 90908178.8 are Austria, France, Belgium, United Kingdom, Switzerland, Italy, Lichtenstein, Luxembourg, Germany, The Netherlands, Denmark, Sweden and Spain.

### 10.5 Deed of Assignment of Regtop/ Biffin Patents

The Company has entered into an agreement with Nature Vet pursuant to which the Company will be irrevocably assigned the Regtop/Biffin Patents. The consideration payable by the Company for the assignment is A\$300,000 in cash and the assignment is conditional on the Company successfully completing its initial public offer of securities. As part of the agreement, the Company has agreed to provide Nature Vet with a worldwide, perpetual license to exploit the intellectual property in the veterinary field.

# 10.6 Deed of Termination, Assignment and Acknowledgement

Previously, USYD, Biochemical Veterinary Research Pty Limited (BVR), Nature Vet and UCOM Seven Pty Limited (UCOM7) had entered into certain agreements with respect to the development, licensing and commercialisation of the intellectual property developed by USYD, BVR and Nature Vet by UCOM7 and Nature Vet.

Under the deed, the Company has agreed to meet some of the obligations of the parties in the earlier agreements and the parties have agreed to terminate a number of existing agreements.

Under the deed, the following earlier agreements are terminated:

- (a) 1998 SPIRT Agreement;
- (b) 2001 SPIRT Agreement;

- (c) March 1996 Licence Agreement;
- (d) University-Nature Vet Licence;
- (e) Nature Vet-UCOM7 Licence; and
- (f) August 2004 Intellectual Property Agreement.

Set out below is a summary of the other material terms of the deed:

- (a) (BVR assignment of intellectual property): BVR has assigned to USYD all of BVR's right, title, and interest in and in relation to all 'Project Intellectual Property' (as that term is defined in the 1998 SPIRT Agreement and the 2001 SPIRT Agreement). This assignment includes the right to sue for and recover damages and other relief in relation to any infringement of any of the rights assigned, including any infringement that may have occurred before the date of the deed.
- (b) (The Linkage Projects Agreement): The Company, Nature Vet and USYD acknowledge and agree that the Company shall own all right, title and interest in the 'Project Intellectual Property' emerging from the research work referred to in the Linkage Projects Agreement.
- (c) (Nature Vet assignment of intellectual property): Nature Vet has agreed to assign to the Company its entire right, title, and interest in and in relation to the 'Project Intellectual Property' and USYD assigns to the Company its entire right, title, and interest in and in relation to the 'Project Intellectual Property'.

- (d) (Maintenance of patent rights): The Company must support and pay for all registration costs of registrable intellectual property emerging from the research work and reimburse USYD for all its unfunded costs reasonably incurred in performing the research work within 30 days of USYD rendering an invoice.
- (e) (Licence): The Company grants to USYD a non-exclusive royalty-free licence to conduct the research work in relation to the intellectual property in Australia for the term of the Linkage Projects Agreement as well as an exclusive royalty-free licence to use any invention claimed in the project intellectual property in Australia for internal, academic and non-commercial research and teaching at USYD.
- (f) (UCOM7 assignment of intellectual property): UCOM7 has assigned to the Company its entire right, title and interest in the 'Project Intellectual Property' or the 'Patents' (as those terms are defined in the August 2004 Intellectual Property Agreement) and further releases USYD and the Company from, and must hold the Company and USYD harmless against, any claim, demand, suit, cause of action or proceeding by UCOM7 (or any person claiming through UCOM7) against USYD or the Company that asserts or relies on any such right, title or interest.

### 10.7 Research Licence Agreement

The Company has entered into a research licence agreement with the Universities pursuant to which the Company has agreed to grant the Universities a non-exclusive royalty-free licence to:

- (a) use any invention claimed in the core Intellectual Property or the intellectual property created under the Research Agreements; and
- (b) use, reproduce and adapt the core materials and the research results under the Research Agreements,

in Australia for internal, academic, non-commercial research and teaching at the Universities.

The Universities have each executed their own agreement but they are on substantially identical terms.

The material terms of the research licence agreements are set out below:

- (a) (Sub-licensing): The Universities must not sub-license any of the rights granted to them under the agreements without the prior written consent of the Company.
- (b) (Notice of research programs): The Universities must:
  - (i) notify the Company in writing of any research or education program it proposes to conduct pursuant to the licence granted under the agreements; and
  - (ii) not conduct any research or education program pursuant to the licence without the prior written consent of the Company (which must not be unreasonably withheld).

- (c) (Fully-funded research): If at any time the Company gives the University notice in writing that it wishes to fund a program of research on a fully-funded basis, then the University must enter into a research agreement with the Company under which:
  - (i) the Company will fully fund the program of research and development; and
  - the Company will own all intellectual property rights created in the course of the program,

on substantially the same terms as the Research Agreements.

- (d) (Researchers and students): The Universities must ensure that before they commence any research or education under the agreements, each researcher and student has entered into an agreement with the relevant University under which they:
  - (i) assign to the University their entire right, title, and interest in and in relation to all improvements and new inventions (including intellectual property rights); and
  - (ii) undertake to the University to keep all confidential information, new improvements and inventions confidential.
- (e) (Ownership of improvements and new inventions): All intellectual property rights in improvements and new inventions created under the licences are owned by the relevant University; however, the Company will have an exclusive first right of refusal in relation to any

proposed dealing by the University with any intellectual property rights in or in relation to any improvement or new invention.

- (f) (Publications): Subject to the Company's right to protect the Company's confidential information, the Universities are entitled to publish the results of its research to obtain recognition within the scientific community and to advance the state of scientific knowledge.
- (g) (Term): Unless terminated earlier in accordance with its terms, each agreement shall continue until the expiry, lapsing, revocation or withdrawal of the last Australian intellectual property right in or in relation to the core materials, core intellectual property, research results, improvements or new inventions to expire, lapse, be revoked or withdrawn.
- (h) (Termination for breach): If either party commits a material breach of an agreement, then the other party may request in writing that the breach be remedied. If the party committing the breach does not remedy it within 30 days, then the other party may terminate the agreement immediately by notice in writing.
- (i) (Termination for insolvency events): Either party may immediately terminate an agreement by notice in writing to the other party if the other party is involved in an insolvency event.

The agreements otherwise contain terms and conditions that are customary in agreements of this type.

# 10.8 Consultancy Agreement with Llewellyn Casbolt

The Company has entered into a consultancy agreement with Llewellyn Casbolt and his service company (Consultant) on the following material terms and conditions:

- (a) the Company has agreed to appoint the Consultant to provide services to the Company for a term of two years commencing on 1 June 2005 and the Consultant has agreed to accept such appointment and covenants that Mr Casbolt will provide the services on its behalf for the duration of the engagement;
- (b) in return for the services provided by the Consultant, the Company will pay the Consultant a fee equal to A\$27,500 per month (exclusive of GST);
- (c) the Company agrees to appoint Mr Casbolt as Managing Director and Chief Executive Officer for the duration of the engagement;
- (d) in addition to the base fee, the Consultant will be entitled to be reimbursed for reasonable expenses incurred in the performance of the services; and
- (e) the engagement of the Consultant may be terminated by the Company in a number of circumstances, including:
  - by giving one month's written notice in the event the Consultant or Mr Casbolt is found guilty of any serious breach of the agreement or unreasonably neglects to perform their duties under the agreement;

- summarily without notice if Mr Casbolt is convicted of any major criminal offence that brings the Company into any lasting disrepute; and
- (iii) without reason by giving the Consultant 3 months' notice and then paying the equivalent of three months' fee or dispensing with the notice period and paying the Consultant the equivalent of six months' fee (subject to the requirements of the ASX Listing Rules and the Corporations Act).

### 10.9 Employee incentive option plan

The Scheme is designed to provide employees and consultants (Eligible Participants) with an ownership interest in the Company and to provide additional incentives for Eligible Participants to increase profitability and returns to Shareholders.

The summary of the Scheme is set out below for the information of potential investors in the Company. The detailed terms and conditions of the Scheme may be obtained free of charge by contacting the Company.

### 10.9.1 General

The Directors may, in their absolute discretion, offer to issue options to Eligible Participants under the Scheme.

The options will be issued for no consideration and will carry the right in favour of the option holder to subscribe for one fully paid ordinary share in the capital of the Company.

Subject to the ASX Listing Rules, the Directors may determine the exercise price of options issued pursuant to the Scheme.

### 10.9.2 Eligible Participants

Full-time or part-time employees and consultants of the Company and its subsidiaries are eligible to participate in the Scheme.

Directors, employees and consultants who join the Company or one of its subsidiaries after the date of commencement of the Scheme are also Eligible Participants.

#### 10.9.3 Lapse of Options

Unless the Directors in their absolute discretion determine otherwise, options shall lapse upon the earlier of:

- (a) the holder ceasing to be an employee, consultant or Director of the Company or one of its subsidiaries for any reason whatsoever and the conditions of exercise have not been met;
- (b) the conditions of exercise of any of the options are unable to be met;
- (c) the lapsing date of the options has past; or
- (d) where the holder of the options ceases to be an employee, consultant or Director of the Company or one of its subsidiaries prior to the lapsing date and the conditions of exercise have been met, the holder will be entitled to exercise the options for a period of up to 60 days after ceasing to be an employee, consultant or director.

### 10.9.4 Participation in future issues

There are no participating rights or entitlements inherent in the options and holders will not be entitled to participate in new issues of capital offered to Shareholders during the currency of the options. However, the Company will ensure that for the purposes of determining entitlements to any such issue, the record date will be at least seven business days after the issue is announced. This will give option holders the opportunity to exercise their options prior to the date for determining entitlements to participate in any such issue.

Subject to the Listing Rules, if during the exercise period in respect of an option, there is a pro-rata issue (except a bonus issue) to the holders of Shares, the exercise price of the options may be reduced according to the formula specified in the ASX Listing Rules.

In the event of a bonus issue of Shares being made pro rata to Shareholders (other than an issue in lieu of dividends), the number of Shares issued on exercise of each option will include the number of bonus Shares that would have been issued if the option had been exercised prior to the record date for the bonus issue. No adjustment will be made to the exercise price per Share of the option.

### 10.9.5 Quotation

Options will not be quoted on ASX. However, application will be made to ASX for official quotation of the Shares allotted pursuant to the exercise of options if the Company's Shares are listed on ASX at that time.

#### 10.9.6 Reorganisation

The terms upon which options will be granted will not prevent them being reorganised as required by the Listing Rules on the reorganisation of the capital of the Company.

#### 10.9.7 Performance-related factors

At the absolute discretion of the Directors, the terms upon which options will be granted may incorporate performance related factors. Such factors may reflect, inter alia, profitability levels, increases in production or decreases in production costs, and may be amended from time to time in a manner favourable to the option holder.

### 10.9.8 Trigger Events

Upon the occurrence of a Trigger Event, the Directors may determine:

- (a) that the options may be exercised at any time from the date of such determination, and in any number until the date determined by the Directors acting bona fide so as to permit the holder to participate in any change of control arising from a Trigger Event, provided that the Directors will forthwith advise in writing each holder of such determination. Thereafter, the options shall lapse to the extent they have not been exercised; or
- (b) to use their reasonable endeavours to procure that an offer is made to holders of options on like terms (having regard to the nature and value of the options) to the terms proposed under the Trigger Event, in which case the Directors shall determine an appropriate period during which the holder may elect to accept the offer and, if the holder has not so elected at the end of that period, the options shall immediately become exercisable and if not exercised within 10 days, shall lapse.

### 10.9.9 Restrictions

ASIC Class Order 03/184 provides that the Company is not required to issue a prospectus for the offer of options to employees under the Scheme provided a number of conditions are satisfied, including without limitation:

- (a) the options may not be exercised until the Shares have been quoted on ASX throughout the 12 month period immediately before the exercise of the option without suspension for more than a total of two trading days during that period; and
- (b) the total number of Shares that would be issued under the Scheme, were each option issued pursuant to the Scheme exercised, and the number of Shares issued by the Company pursuant to any employee share or option scheme implemented by the Company during the previous five years (which there are none) may not exceed 5% of the total number of Shares on issue as at the date any options are offered pursuant to the Scheme.

### 10.10 Directors' Deeds of Indemnity

The Company has entered into a Deed of Indemnity, Insurance and Access with each of the Directors and the Company Secretary (Deeds).

Pursuant to the Deeds, the Company agrees to indemnify each officer (to the maximum extent permitted by the Corporations Act) against any liability arising as a result of the officer acting as an officer of the Company. The Company is required under the Deeds to maintain insurance policies for the benefit of the relevant officer for the term of the appointment (and for at least seven years after the officer ceases to be an officer of the Company) and must also allow the officers to inspect board papers in certain circumstances. "When we do the best that we can, we never know what miracle is wrought in our life, or in the life of another."

> Helen Keller (1880–1968), American memoirist, lecturer

## **11 ADDITIONAL INFORMATION**

### 11.1 Disclosure of interests

Directors are not required under the Company's Constitution to hold any Shares. As at the date of this Prospectus, the Directors have relevant interests in Shares and Options as follows:

Director	No. of Shares	No. of Options
James Dominguez	-	2,500,000
Llewellyn Casbolt	-	5,000,000
Dr Michael Taverner	50,000	500,000
Professor Michael Vitale	-	500,000

The Options referred to above will only be issued in the event the Company successfully lists on ASX.

The Options to be issued to each of James Dominguez, Professor Michael Vitale and Dr Michael Taverner are 'Director Options'. The material terms and conditions of the Director Options are set out in Section 11.5.2 of this Prospectus.

The Options to be issued to Llewellyn Casbolt are 'Executive Options'. The material terms and conditions of the Executive Options are set out in Section 11.5.3 of this Prospectus.

### 11.2 Remuneration

The Company's Constitution provides that the remuneration of non-executive Directors will be not more than the aggregate fixed sum determined by shareholders in general meetings. The aggregate remuneration has been set at an amount of A\$300,000 per annum.

The remuneration paid to the Directors in the last two years and the fees that are currently proposed to be paid to the Directors in relation to holding the position of a director are set out below:

Director	Past fees	Future fees (per month)
	A\$	A\$
James Dominguez	17,500	3,500
Dr Michael Taverner	12,500	2,500
Professor Michael Vitale	12,500	2,500

### 11.3 Fees and benefits

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

- (a) director or proposed director of the Company;
- (b) 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;
- (c) promoter of the Company; or
- (d) underwriter,

has, or had within two years before lodgement of this Prospectus with ASIC, any interest in:

- (a) the formation or promotion of the Company;
- (b) any property acquired or proposed to be acquired by the Company in connection with its formation or promotion or in connection with the offer of Shares under this Prospectus; nor
- (c) the offer of Shares under this Prospectus, and

no amounts have been paid or agreed to be paid and no benefits have been given or agreed to be given to any of those persons as an inducement to become, or to qualify as, a director of the Company or for services rendered in connection with the formation or promotion of the Company or the offer of Shares under this Prospectus.

Steinepreis Paganin has acted as the solicitors to the Company in relation to the Offer and have been involved in due diligence enquiries on legal matters involving the Company. The Company estimates it will pay Steinepreis Paganin approximately A\$40,000 for these services. Subsequently, fees will be charged in accordance with normal charge-out rates. During the 24 months preceding lodgement of this Prospectus with ASIC, Steinepreis Paganin has received fees of approximately A\$30,000 for other legal services provided to the Company.

Blake Dawson Waldron Patent Services has acted as the patent attorneys to the Company in relation to the Offer, have been involved in due diligence enquiries in relation to the IP and have prepared the Intellectual Property Report set out in Section 6 of this Prospectus. The Company estimates it will pay Blake Dawson Waldron Patent Services approximately A\$57,000 for these services. Subsequently, fees will be charged in accordance with normal charge-out rates. During the 24 months preceding lodgement of this Prospectus with ASIC, Blake Dawson Waldron Patent Services has received no fees for other legal services provided to the Company. PricewaterhouseCoopers Securities Limited has acted as the investigating accountant in relation to the Offer, has been involved in due diligence enquiries in relation to the financial matters involving the Company and has prepared the Investigating Accountant's Report set out in Section 8 of this Prospectus. The Company estimates it will pay PricewaterhouseCoopers Securities Limited approximately A\$100,000 for these services. Subsequently, fees will be charged in accordance with normal charge-out rates. During the 24 months preceding lodgement of this Prospectus with ASIC, PricewaterhouseCoopers Securities Limited has received no fees for other legal services provided to the Company.

### 11.4 Consents

Each of the parties referred to in this section:

- (a) does not make, or purport to make, any statement in this Prospectus other than those referred to in this section; and
- (b) to the maximum extent permitted by law, expressly disclaims and takes no responsibility for any part of this Prospectus other than a reference to its name and a statement included in this Prospectus with the consent of that party as specified in this section.

Steinepreis Paganin has given its written consent to being named as the solicitors to the Company in this Prospectus and has not withdrawn its consent prior to the lodgement of this Prospectus with ASIC. Blake Dawson Waldron Patent Services has given its written consent to being named as the patent attorneys to the Company in this Prospectus and to the inclusion of the Patent Attorney's Report set out in Section 6 of this Prospectus. Blake Dawson Waldron Patent Services has not withdrawn its consent prior to the lodgement of this Prospectus with ASIC.

PricewaterhouseCoopers Securities Limited has given its written consent to being named as the investigating accountant in this Prospectus and to the inclusion of the Investigating Accountant's Report set out in Section 8 of this Prospectus. PricewaterhouseCoopers Securities Limited has not withdrawn its consent prior to the lodgement of this Prospectus with ASIC.

Computershare Investor Services Pty Limited has given its written consent to being named as the share registry for the Company in this Prospectus and has not withdrawn its consent prior to the lodgement of this Prospectus with ASIC.

WHK Greenwoods has given its written consent to being named as the auditor for the Company in this Prospectus and has not withdrawn its consent prior to the lodgement of this Prospectus with ASIC.

# 11.5 Rights and liabilities attaching to securities

#### 11.5.1 Ordinary Shares

The rights, liabilities, privileges and restrictions attaching to Shares can be summarised as follows:

#### General meetings

Shareholders are entitled to be present in person, or by proxy, attorney or representative to attend and vote at general meetings of the Company. Shareholders may requisition meetings in accordance with Section 249D of the Corporations Act and the Constitution of the Company.

### Voting rights

Subject to any rights or restrictions for the time being attached to any class or classes of Shares, at general meetings of Shareholders or classes of Shareholders:

- (a) each Shareholder entitled to vote may vote in person or by proxy, attorney or representative;
- (b) on a show of hands, every person present who is a Shareholder or a proxy, attorney or representative of a Shareholder has one vote; and
- (c) on a poll, every person present who is a Shareholder or a proxy, attorney or representative of a Shareholder shall, in respect of each fully paid Share held by them, or in respect of which they are appointed a proxy, attorney or representative, have one vote for the Share, but in respect of partly paid Shares shall

have such number of votes as bears the same proportion to the total of such Shares registered in the shareholder's name as the amount paid (not credited) bears to the total amounts paid and payable (excluding amounts credited).

#### **Dividend rights**

Subject to the rights of persons (if any) entitled to Shares with special rights as to dividend the Directors may declare a final dividend out of profits in accordance with the Corporations Act and may authorise the payment or crediting by the Company to the shareholders of such a dividend. The Directors may authorise the payment or crediting by the Company to the shareholders of such interim dividends as appear to the Directors to be justified by the profits of the Company. Subject to the rights of persons (if any) entitled to shares with special rights as to dividend all dividends are to be declared and paid according to the amounts paid or credited as paid on the shares in respect of which the dividend is paid. Interest may not be paid by the Company in respect of any dividend, whether final or interim.

#### Winding-up

If the Company is wound up, the liquidator may, with the authority of a special resolution of the Company, divide among the shareholders in kind the whole or any part of the property of the Company, and may for that purpose set such value as he considers fair upon any property to be so divided, and may determine how the division is to be carried out as between the shareholders or different classes of shareholders. The liquidator may, with the authority of a special resolution of the Company, vest the whole or any part of any such property in trustees upon such trusts for the benefit of the contributories as the liquidator thinks fit, but so that no shareholder is compelled to accept any shares or other securities in respect of which there is any liability.

### Transfer of Shares

Generally, shares in the Company are freely transferable, subject to formal requirements, the registration of the transfer not resulting in a contravention of or failure to observe the provisions of a law of Australia and the transfer not being in breach of the Corporations Act or the Listing Rules.

#### Variation of rights

Pursuant to Section 246B of the Corporations Act, the Company may, with the sanction of a special resolution passed at a meeting of shareholders vary or abrogate the rights attaching to shares.

If at any time the share capital is divided into different classes of shares, the rights attached to any class (unless otherwise provided by the terms of issue of the shares of that class), whether or not the Company is being wound up may be varied or abrogated with the consent in writing of the holders of three-quarters of the issued shares of that class, or if authorised by a special resolution passed at a separate meeting of the holders of the shares of that class.

### 11.5.2 Director Options

It is proposed that Director Options will be issued to each of James Dominguez, Professor Michael Vitale and Dr Michael Taverner. The material terms of the Director Options are as follows:

- (a) each Director Option entitles the holder to one Share in the Company;
- (b) the Director Options are exercisable at any time on or prior to 5.00pm (AEDT) on 31 December 2008 (Expiry Date) by completing a Director Option exercise form and delivering it together with the payment for the number of Shares in respect of which the Director Options are exercised to the registered office of the Company;
- (c) the Director Options will only be issued in the event the Company successfully completes the Capital Raising;
- (d) the Director Option exercise price is A\$0.20 (for each Share);
- (e) a Director Option does not confer the right to a change in exercise price nor a change in the number of underlying securities over which the Director Option can be exercised;
- (f) the Director Options are not transferable;
- (g) all Shares issued upon exercise of the Director Options will rank pari passu in all respects with the Company's then issued Shares;
- (h) there are no participating rights or entitlements inherent in the Director Options and holders

will not be entitled to participate in new issues of capital offered to Shareholders during the currency of the Director Options. However, the Company will ensure that, for the purposes of determining entitlements to any such issue, the record date will be at least seven Business Days after the issue is announced. This will give Director Option holders the opportunity to exercise their Director Options prior to the date for determining entitlements to participate in any such issue; and

 (i) if at any time the issued capital of the Company is reconstructed, all rights of a Director Option holder are to be changed in a manner consistent with the Corporations Act and the Listing Rules.

### 11.5.3 Executive Options

It is proposed that Executive Options will be issued to Llewellyn Casbolt. The material terms of the Executive Options are as follows:

- (a) each Executive Option entitles the holder to one Share in the Company;
- (b) the Executive Options are exercisable at any time on or prior to 5.00pm (AEDT) on 31 December 2008 (Expiry Date) by completing an Executive Option exercise form and delivering it together with the payment for the number of Shares in respect of which the Executive Options are exercised to the registered office of the Company;

- (c) the Executive Options will only be issued in the event the Company successfully completes the Capital Raising;
- (d) the Executive Options will vest in three tranches, two of which are subject to achievement of certain performance milestones, as follows:
  - (i) 1,000,000 of the Executive Options (First Tranche) will vest and may be exercised by the holder immediately after the date of issue;
  - (ii) 1,500,000 of the Executive Options
     (Second Tranche) will only vest and may only be exercised in the event the Company completes FDA-approved Phase I clinical trials in respect of any of the Technologies or the associated IP; and
  - (iii) 2,500,000 of the Executive Options (Third Tranche) will only vest and may only be exercised in the event the volume-weighted average price of the Company's Shares as traded on ASX exceeds A\$0.50 for five consecutive Business Days and the first Key Milestone is achieved for any of the Technologies, as defined in the Research Agreements;
- (e) the Executive Option exercise price is A\$0.20 (for each Share);
- (f) an Executive Option does not confer the right to a change in exercise price nor a change in the number of underlying securities over which the Executive Option can be exercised;
- (g) the Executive Options are not transferable;

- (h) all Shares issued upon exercise of the Executive Options will rank pari passu in all respects with the Company's then issued Shares;
- (i) there are no participating rights nor entitlements inherent in the Executive Options, and holders will not be entitled to participate in new issues of capital offered to Shareholders during the currency of the Executive Options. However, the Company will ensure that for the purposes of determining entitlements to any such issue, the record date will be at least seven Business Days after the issue is announced. This will give Executive Option holders the opportunity to exercise their Executive Options prior to the date for determining entitlements to participate in any such issue; and
- (j) if at any time the issued capital of the Company is reconstructed, all rights of an Executive Option holder are to be changed in a manner consistent with the Corporations Act and the Listing Rules.

### 11.5.4 Options

The material terms and conditions of the Options are as follows:

- (a) each Option entitles the holder to one Share in the Company;
- (b) the Options are exercisable at any time on or prior to 5.00pm (Western Standard Time) on 31 December 2007 by completing an Option exercise form and delivering it together with the payment for the number of Shares in respect of which the Options are exercised to the registered office of the Company;

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- (c) the Option exercise price is A\$0.20 per option;
- (d) an Option does not confer the right to a change in exercise price or a change in the number of underlying securities over which the option can be exercised;
- (e) subject to the Corporations Act and the Company's Constitution, the Options are freely transferable;
- (f) all Shares issued upon exercise of the Options will rank pari passu in all respects with the Company's then issued Shares;
- (g) there are no participating rights or entitlements inherent in the Options and holders will not be entitled to participate in new issues of capital offered to Shareholders during the currency of the Options. However, the Company will ensure that for the purposes of determining entitlements to any such issue, the record date will be at least seven Business Days after the issue is announced. This will give Option holders the opportunity to exercise their Options prior to the date for determining entitlements to participate in any such issue; and
- (h) if at any time the issued capital of the Company is reconstructed, all rights of an Option holder are to be changed in a manner consistent with the Corporations Act and the Listing Rules.

### 11.6 Corporate governance

The Directors monitor the business affairs of the Company on behalf of Shareholders and intend to formally adopt a corporate governance policy designed to encourage Directors to focus their attention on accountability, risk management and ethical conduct.

### 11.7 Expenses of the Offer

The total expenses of the Offer (assuming A\$5,000,000 is raised) are estimated to be approximately A\$400,000 and are expected to be applied towards the items set out in the table below:

Item of expenditure	Amount
	A\$
ASIC fees	2,010
ASX fees	37,000
Advisers' fees	197,000
Printing	25,000
Miscellaneous	138,990
Total	400,000

As set out in Section 3.7 of this Prospectus, the Company may pay broker handling fees of 5% (exclusive of GST) on any valid applications received bearing the stamp of an Australian Financial Services licensee. The table above does not provide for the payment of broker handling fees.

### 11.8 Litigation

As at the date of this Prospectus, the Company is not involved in any legal proceedings and the Directors are not aware of any legal proceedings pending or threatened against the Company.

## **12 DIRECTORS' AUTHORISATION**

This Prospectus is issued by the Company and its issue has been authorised by a resolution of the Directors. In accordance with Section 720 of the Corporations Act, each Director has consented in writing to the lodgement of this Prospectus with ASIC.

### Llewellyn Casbolt

Managing Director and Chief Executive Officer for and on behalf of Medical Therapies Limited

## 13 GLOSSARY

Where the following terms are used in this Prospectus they have the following meanings:

**A\$** means an Australian dollar.

**AEDT** mean Australian Eastern Daylight Time, Sydney, NSW.

**APPA** means Australian Provisional Patent Application.

**Application Form** means the application form attached to or accompanying this Prospectus.

**ASIC** means the Australian Securities and Investments Commission.

**ASX** means Australian Stock Exchange Limited.

**BIP** means Background Intellectual Property.

**Board** means the board of Directors of the Company as constituted from time to time.

**Business Day** means a week day when trading banks are ordinarily open for business in Perth, Western Australia. **Closing Date** means the closing date for receipt of Application Forms under this Prospectus, being 5.00pm (WST) on 26 July 2005 (unless the Offer is extended or closed early).

**Company** or **Medical Therapies** means Medical Therapies Limited (ACN 111 304 119).

**Completion Date** means the date on which Settlement occurs.

**Constitution** means the constitution of the Company.

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

Cu-Indo means copper-indomethacin

**Director Option** means an option to acquire a share on the terms set out in Section 11.5.2 of this Prospectus.

**Directors** means the directors of the Company at the date of this Prospectus.

**DNA** means Deoxyribonucleic Acid.

#### End Date means:

 (a) if the Company has elected (pursuant to and in accordance with Schedule 1 of the Research Agreement relating to Technology Two) not to proceed with Phase 2 of Technology Two, that date which is 31 months after the Completion Date; or

(b) if the Company has elected (pursuant to and in accordance with Schedule 1 of the Research Agreement relating Technology Two) to proceed with Phase 2 of Technology Two, that date which is 40 months after the Completion Date.

**Executive Option** means an option to acquire a Share on the terms set out in Section 11.5.3 of this Prospectus.

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

**FDA** means the Food and Drug Administration, a body that, among other things, regulates the licensing and sale of drugs throughout the USA.

**GAAP** means Generally Accepted Accounting Principles, a common set of accounting principles, standards and procedures. **General Meeting** means the general meeting of Shareholders held on 29 April 2005.

**GDP** means Gross Domestic Product, the total market value of all the goods and services produced within the borders of a nation during a specified period.

Indo means indomethacin.

**IndoH** means the (uncharged) carboxylic acid form of indomethacin.

**Intellectual Property** or **IP** means the patents and patent applications relating to the Technologies.

Intellectual Property Assignment Deed means the intellectual property assignment deed entered into between the Company and the Universities pursuant to which the Company has agreed to acquire the Intellectual Property, a summary of which is set out in Section 10.1 of this Prospectus.

**Listing Rules** means the official Listing Rules of ASX.

**Milestone Option** means an option to acquire a share which may be issued to the Universities in accordance with the terms of the Option Deed. Nature Vet means Nature Vet Pty Limited (ACN 002 692 426).

**Nature Vet/UCOM7 Licence** means the agreement executed on 2 August 2004 between Nature Vet and UCOM Seven, whereby Nature Vet granted an exclusive royalty-free licence to UCOM Seven for exploitation of the IP and BIP available to be licensed by Nature Vet for the prevention and treatment of human diseases.

**NSAID** means Non-Steroidal Anti-Inflammatory Drug.

**Offer** means the invitation to investors to apply for Shares pursuant to this Prospectus.

**Official List** means the Official List of ASX.

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

**Option** means an option to subscribe for a Share subject to the terms and conditions set out in Section 11.5.4 of this Prospectus.

**Option Deed** means the option deed entered into between the Company and the Universities, the material terms of which are summarised in Section 10.4 of this Prospectus. **PCT** means the Patent Cooperation Treaty.

Prospectus means this prospectus.

Regtop/Biffin Patents means

the patents referred to in Section 10.5 relating to Cu-Indo as an antiinflammatory drug.

Research Agreements means

the research agreements entered into between the Universities and the Company pursuant to which the Company will agree to fund the development and commercialisation of the Technologies for a period of two years, subject to the Universities achieving defined research milestones, the material terms of which are set out in Section 10.2 of this Prospectus.

**Settlement** means settlement of the acquisition of the IP by the Company pursuant to the terms of the Intellectual Property Assignment Deed.

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

**Shareholder** means a holder of Shares.

#### Technology One means the further development of compounds and metal complexes of indomethacin and related NSAID ligands, topical, oral, injectable and ophthalmic formulations thereof, methods of treatment using the compounds and metal complexes, and methods for the preparation thereof, that are encompassed by International (PCT) Patent Application no. PCT/AU2005/000442, APPA 2005901462, APPA 2005901463 and APPA 2005901464 and United States provisional application filed 24 March 2005 with an identical specification to APPA 2005901464, all listing the University of Sydney as the applicant and owned by USYD, and by the Regtop/Biffin Patents.

**Technology Two** means the further development of new platinum and other metal-complex-based anticancer compounds encompassed by the national phase patent applications derived from International (PCT) Patent Application no. PCT/ AU02/00167 filed in the name of the University of Sydney and owned jointly in equal share by USYD and UWS.

#### **Technology Three** means the further development of sequenceselective compounds encompassed by International (PCT) Patent Application no. PCT/AU2004/001368 filed in the name of the University of Western Sydney and owned by UWS.

#### **Technology One Option Milestone** means both of:

- (a) Commence Phase I of FDA approved human trials for both oral and topical applications of Cu-Indo, within 12 months of the Completion Date; and
- (b) Complete mouse studies for at least one lead compound such that it is ready for clinical trials, within 21 months of the Completion Date.

#### Technology Two Option Milestone

means complete biological studies on at least one lead compound such that it is ready for clinical trials, within 21 months of the agreed commencement date.

### **Technology Three Option**

**Milestone** means at least one proofof-concept compound constructed that can target and bind to a specific DNA sequence, within 24 months of the Completion Date.

**Technologies** means each of Technology One, Technology Two and Technology Three.

**TGA** means the Therapeutic Goods Administration, a body that, among other things, regulates the licensing and sale of drugs throughout Australia.

**UCOM7** means UCOM Seven Pty Limited (ACN 102 498 546).

### **Universities** means USYD and UWS.

US\$ means a United States dollar.

**USYD** means the University of Sydney.

**UWS** means the University of Western Sydney.

**WST** means Western Standard Time, Perth, Western Australia.

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Joint Applicant 3 or Account Designation								_
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## How to complete this form

### A Shares Applied for

Enter the number of Shares you wish to apply for. The application must be for a minimum of 10,000 Shares. Applications for greater than 10,000 Shares must be in multiples of 2,000 Shares.

### Application Monies

В

Enter the amount of Application Monies. To calculate the amount, multiply the number of Shares by the price per Share.

### C Applicant Name(s)

Enter the full name you wish to appear on the statement of share holding. This must be either your own name or the name of a company. Up to 3 joint Applicants may register. You should refer to the table below for the correct forms of registrable title. Applications using the wrong form of names may be rejected. Clearing House Electronic Subregister System (CHESS) participants should complete their name identically to that presently registered in the CHESS system.

### D Postal Address

Enter your postal address for all correspondence. All communications to you from the Registry will be mailed to the person(s) and address as shown. For joint Applicants, only one address can be entered.

### E Contact Details

Enter your contact details. These are not compulsory but will assist us if we need to contact you.

### F CHESS

Medical Therapies Limited (the Company) will apply to the ASX to participate in CHESS, operated by ASX Settlement and Transfer Corporation Pty Ltd, a wholly owned subsidiary of Australian Stock Exchange Limited. In CHESS, the company will operate an electronic CHESS Subregister of security holdings and an electronic Issuer Sponsored Subregister of security holdings. Together the two Subregisters will make up the Company's principal register of securities. The Company will not be issuing certificates to applicants in respect of Shares allotted. 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 this section blank and on allotment, you will be sponsored by the Company and allocated a Securityholder Reference Number (SRN).

### G Payment

Make your cheque or bank draft payable to Medical Therapies Limited in Australian currency and cross it Not Negotiable. Your cheque or bank draft must be drawn on an Australian Bank.

Complete the cheque details in the boxes provided. The total amount must agree with the amount shown in box B.

Cheques will be processed on the day of receipt and as such, sufficient cleared funds must be held in your account as cheques returned unpaid may not be re-presented and may result in your Application being rejected. Pin (do not staple) your cheque(s) to the Application Form where indicated. Cash will not be accepted. Receipt for payment will not be forwarded.

Before completing the Application Form the applicant(s) should read this prospectus to which this application relates. By lodging the Application Form, the applicant agrees that this application for Shares in Medical Therapies Limited is upon and subject to the terms of the prospectus and the Constitution of Medical Therapies Limited, agrees to take any number of Shares that may be allotted to the Applicant(s) pursuant to the prospectus and declares that all details and statements made are complete and accurate. It is not necessary to sign the Application Form.

### Lodgement of Application

Application Forms must be received at the Perth office of Computershare Investor Services Pty Limited by no later than 5pm WST on 26 July 2005. Return the Application Form with cheque(s) attached to:

Computershare Investor Services Pty Limited	OR	Computersh
GPO Box D182		Level 2
PERTH WA 6840		45 St Georg

Computershare Investor Services Pty Limited Level 2 45 St Georges Terrace PERTH WA 6000

### Privacy Statement

Personal information is collected on this form by Computershare Investor Services Pty Limited ("CIS"), as registrar for securities issuers ("the issuer"), for the purpose of maintaining registers of securityholders, facilitating distribution payments and other corporate actions and communications. Your personal information may be disclosed to our related bodies corporate, 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 2001, you may be sent material (including marketing material) approved by the issuer 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 form or E-mail privac@computershare.com.au

If you have any enquiries concerning your application, please contact the Computershare Investor Services Pty Limited on 1300 557 010.

### Correct forms of registrable title(s)

Note that ONLY legal entities are allowed to hold Shares. 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 the 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 if completed exactly as described in the examples of 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) - Do not use the name of the trust	Ms Penny Smith <penny a="" c="" family="" smith=""></penny>	Penny Smith Family Trust
Deceased Estates - Use executor(s) personal name(s) - Do not use the name of the deceased	Mr Michael Smith <est a="" c="" john="" smith=""></est>	Estate of Late John Smith
Minor (a person under the age of 18) - Use the name of a responsible adult with an appropriate designation	Mr John Alfred Smith <peter a="" c="" smith=""></peter>	Peter Smith
Partnerships - Use partners personal name(s) - Do not use the name of the partnership	Mr John Smith & Mr Michael Smith <john &="" a="" c="" smith="" son=""></john>	John Smith & Son
Clubs/Unincorporated Bodies/Business Names - Use office bearer(s) personal name(s) - Do not use the name of the club etc	Mrs Janet Smith <abc a="" association="" c="" tennis=""></abc>	ABC Tennis Association
Superannuation Funds - Use the name of trustee of the fund - Do not use the name of the fund	John Smith Pty Ltd <super a="" c="" fund=""></super>	John Smith Pty Ltd Superannuation Fund

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## MEDICALTHERAPIES ()

#### Directors

James Dominguez (Chairman) Llewellyn Casbolt (Managing Director and Chief Executive Officer) Dr Michael Taverner (Non-Executive Director) Professor Michael Vitale (Non-Executive Director)

Company Secretary (part-time) Ian Gilmour

Australian Company Number 111 304 119

### Registered and Principal Office Level 11, 91 York Street SYDNEY NSW 2000 Telephone: (02) 9299 0050

Auditor

WHK Greenwoods Level 15, 309 Kent Street SYDNEY NSW 2000

#### Investigating Accountant

PricewaterhouseCoopers Darling Park Tower 2 201 Sussex Street SYDNEY NSW 2000

#### Solicitors to the Company

Steinepreis Paganin Lawyers & Consultants Level 4, Next Building 16 Milligan Street PERTH WA 6000

#### Patent Attorneys

Blake Dawson Waldron Patent Services Grosvenor Place 225 George Street SYDNEY NSW 2000

#### Share Registry

Computershare Investor Services Pty Limited Level 2, 45 St Georges Terrace PERTH WA 6000

