

Probiomics Limited ABN 97 084 464 193

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The Australian Stock Exchange Limited Companies Announcements Office SYDNEY

10 October 2011

#### PROPOSED MERGER OF PROBIOMICS WITH HUNTER IMMUNOLOGY

The board of Probiomics Limited (**Probiomics**) is pleased to announce a prospective merger proposal with Hunter Immunology Limited (**Acquisition**). In this regard, Probiomics has signed a non-binding Memorandum of Understanding to acquire all of the shares of Hunter Immunology Limited (**Hunter Immunology**).

Hunter Immunology operates as a clinical-stage biotechnology company to develop a range of orally-administered vaccines, the most advanced of which being evaluated seeks to reduce the number and severity of exacerbations in patients with Chronic Obstructive Pulmonary Disease.

Hunter Immunology is in advanced stages of its Phase IIb clinical trials (with 320 patients fully enrolled) for its compound HI-1640V, an enteric-coated tablet containing killed bacteria (Haemophilus influenzae) that has demonstrated in Phase IIa trials positive results particularly on patients with moderate to severe COPD.

### Key terms of the transaction include:

- Probiomics will make an off market takeover bid for all Hunter Immunology shares.
- The takeover bid will be subject to a number of conditions, including acceptances in respect of at least 90% (by number) of all Hunter Immunology shares, obtaining necessary Probiomics shareholder approvals, a successful Public Offer (referred to below) and re-admission of Probiomics to the official list after those shareholder approvals have been obtained and no superior offer having been made.
- The implied valuation of Probiomics shares for the purposes of this proposed takeover bid is 1.1 cents per Probiomics share.
- Bid consideration payable to Hunter Immunology shareholders will be 9 Probiomics shares for every 1 Hunter Immunology share, valuing each Hunter Immunology share at 9.9 cents, and Hunter Immunology's total issued capital at approximately \$29.74 million.
- Probiomics will seek to raise up to \$3 million from the issue of new fully paid ordinary shares by means of a prospectus offering.



- All post takeover bid issued shares in Probiomics will subsequently be consolidated on a one for twenty (1:20) basis and options restructured accordingly.
- Upon successful completion of the Acquisition, it is intended that Probiomics will change its name to "Bioxyne Limited".

A more detailed overview of the proposed merger and a description of Hunter Immunology is set out below.

Patrick Ford
Chairman,
Probiomics Limited

### **CONTACTS**

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Mr David Radford – Managing Director, Hunter Immunology Limited

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Probiomics has proprietary ownership of a unique probiotic strain – PCC®. PCC® has been clinically proved to have superior qualities – particularly in promoting systemic immune response.

Probiomics' commercial objective is to earn royalties from licensing PCC® to distribution companies selling products in global markets.

For further information, please go to www.probiomics.com.au



#### 1. MATERIAL TERMS OF ACQUISITION

It is intended that the proposed Acquisition will be effected as follows:

- Probiomics will make an off market takeover bid for all Hunter Immunology shares;
- The takeover bid will be subject to a number of conditions, including acceptances in respect of at least 90% (by number) of all Hunter Immunology shares, obtaining necessary Probiomics shareholder approvals, a successful Public Offer (referred to below) and re-admission of Probiomics to the official list after those shareholder approvals have been obtained and no superior offer having been made;
- The bid consideration payable to Hunter Immunology shareholders will be 9 Probiomics shares for every 1 Hunter Immunology share;
- The bid consideration values each Hunter Immunology share at 9.9 cents, and Hunter Immunology's total issued capital at approximately \$29.74 million;
- The implied valuation of Probiomics shares for the purposes of this proposed takeover bid is 1.1 cents per Probiomics share;
- All post takeover bid issued shares in Probiomics will subsequently be consolidated on a one for twenty (1:20) basis and options restructured accordingly (**Share Consolidation**).
- the Acquisition as contemplated will result in a change of control of the Board of Directors of Probiomics. That change will be subject to shareholder and regulatory approval;
- If Probiomics acquires 100% of the shares in Hunter Immunology under the merger proposal, Probiomics will issue approximately 2.703 billion pre consolidation Probiomics shares (on a pre Share Consolidation basis) which will in turn be reduced to 135,163,415 new Probiomics shares (on a post Share Consolidation basis) to Hunter Immunology shareholders and current note holders. Those Hunter Immunology shareholders and current note holders would then collectively own approximately 89% of the merged group, and the aggregate shareholding of existing Probiomics shareholders will be diluted to approximately 11% of the merged group.

#### 2. MATERIAL TERMS OF PUBLIC OFFER

It is intended that the proposed public offer by Probiomics (Public Offer) will be effected as follows:

- Probiomics will seek to raise up to \$3 million from the issue of new fully paid ordinary shares by means of a prospectus offering;
- the issue price will be 22 cents per Probiomics share (on a post Share Consolidation basis);
- it is intended that 272,727,273 shares on a pre Share Consolidation basis (or 13,363,364 shares on a post Share Consolidation basis) (Public Offer Shares) will be issued if the Public Offer is fully subscribed;
- the terms and conditions attaching to the Public offer Shares will be identical in all respect with the terms and conditions attaching to the currently issued Probiomics shares;
- the purpose of the Public Offer will be to fund planned research into and commercial exploitation of the merged group's intellectual property and also for working capital requirements;
- Probiomics shareholder approval will be required as a condition to the making of the Public Offer;
   and



the Public Offer will be primarily be to the public at large. However, Probiomics shareholders will be entitled, on a collective basis, to a priority entitlement of no less than 10% of the Public Offer Shares. Hunter shareholders will not be entitled to participate in that priority entitlement offer but will otherwise be entitled to participate in the Public Offer.

It is important to note that the completion of the Acquisition and the Public Offer are conditional upon **both** Probiomics shareholder approval of a number of resolutions and the grant by ASX of Re-admission (as that term is described below).

#### 3. DETAILS ABOUT HUNTER IMMUNOLOGY LIMITED

## **Background of Hunter Immunology**

Hunter Immunology Limited ACN 106 556 094 was incorporated on 3 October 2003 and is an unlisted public company with approximately 275 individual shareholders.

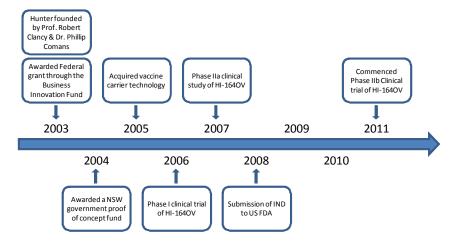
Hunter Immunology operates as a clinical-stage biotechnology company to develop a range of orally-administered vaccines. The first of these products is focused upon the reduction in both the number and severity of exacerbations in patients with Chronic Obstructive Pulmonary Disease (COPD).

COPD, which includes emphysema and chronic bronchitis, is largely caused by smoking although in some developing countries, pollution also plays a significant role. Some Australian studies indicate that 10-15% of patients presenting with COPD have never been smokers - 'passive' damage is increasingly recognised. COPD is an irreversible disease and there is no cure and is characterized by progressive and irreversible airflow obstruction and the underlying pathology of the disease, including narrowing of the small airways and destruction of the lung.

The origins of Hunter Immunology's technology stem from pioneering work conducted in the mid 1980s at the Newcastle Mucosal Immunology Group (**NMIG**) leg by Emeritus Professor Robert Clancy AM. Early work by Hunter Immunology's founders and NMIG led to the development of an enteric-coated tablet containing killed H.influenzae (NTHi) which was shown to be safe and effective in a number of published clinical trials in COPD.

This work led to the development of Hunter Immunology's main HI-1640V which is in the advanced stages of Phase IIb clinical trials with 320 patients enrolled and fully dosed, the results of which are expected in the 1<sup>st</sup> half of calendar 2012.

A time line of Hunter Immunology's activities and developments over the last 8 years are set out below:





### Hunter Immunology's HI-1640V

Hunter Immunology's approach has been to show that these obstructed airways in COPD patients usually harbour chronic infections with bacteria, in particular, *Haemophilus influenzae* (*H influenzae*), which create the conditions of continued damage to the airway walls. If this process could be slowed or halted then the result should be an improvement in the health of the COPD patient.

Research efforts by Hunter Immunology's clinical team and NMIG led to the development of HI-1640V and its subsequent clinical evaluation. HI-1640V, is an entericcoated tablet containing killed bacteria (Haemophilus influenzae) that has demonstrated positive Phase IIa data, particularly in patients with moderate to severe COPD. Recent study results have indicated that use of HI-1640V may enable a significant reduction in antibiotic usage.

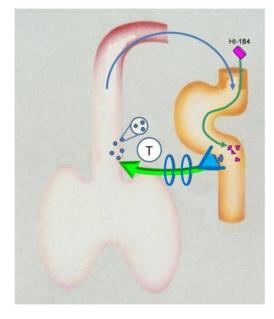


Fig 1: Mechanism of action of HI-1640V.

HI-164OV is not intended to replace standard-of-care treatments, but to enhance clinical outcomes via combined use. COPD therapeutics are a major target of pharmaceutical company research. The main companies focused on COPD product development are GSK, Nycomed, Bayer, Merck, Johnson and Johnson, Forest, Pfizer, Boehringer Ingelheim, AstraZeneca and Novartis. They also carry respiratory pharmaceutical sales forces.

#### **Development and Commercialisation Strategy**

The development strategy has been driven by 20 years of clinical experience, both defining mechanisms of action and demonstrated proof of concept that oral whole cell immunotherapy using inactivated H.influenzae could reduce colonisation in damaged airways. This included reductions in the frequency and severity of acute exacerbations and the amount of antibiotics required by the patient.

In a small Phase II clinical study (37 patients) in patients with severe COPD, HI-164OV resulted in a significant reduction in hospitalisation for exacerbations by 90%. There were also large reductions in the use of corticosteroids (63%) and antibiotics (72%) for treating exacerbations. Patients would benefit from a decrease in medication and improved quality of life (CHEST 2010: 137(4); 805-811).

In a second study, (102 patients) in a more heterogeneous group of patients with airways disease at the less severe end of the clinical spectrum, the drug failed to show benefit. This has guided the current much ongoing study larger study to examine the treatment in patients with moderate to severe COPD.

The recognition that orally-administered microbes can stimulate a cellular immune response at other mucosal surfaces means that Hunter Immunology has the opportunity to develop a pipeline of products based on this platform technology. Hunter Immunology has identified the following potential applications:



- (a) Haemophilus influenzae for severe allergic asthma and Otitis media (other applications for HI-164OV);
- (b) Pseudomonas aeruginosa for COPD and Cystic Fibrosis;
- (c) Staphylococcus aureus for hospital acquired infections; and
- (d) Candida albicans for Thrush.

Hunter Immunology has recognised that there are several key milestones that could add substantial value to HI-164OV:

- (a) Demonstrate proof of efficacy and safety in a much larger multi site Phase II trial in COPD
- (b) Demonstrate the utility of HI-164OV in severe allergic asthma and other applications.

A Phase IIb clinical trial of HI-164OV at 21 major centres of respiratory medicine in Australia has completed enrollment and dosing prior to the winter season. The trial is a multi-centre, randomised, placebo controlled, single-season double-blinded trial with an enrolment of 320 patients with moderate to severe COPD with the primary goal of reducing the number of exacerbations per patient requiring oral/parenteral corticosteroid treatment or hospitalisation.

There are a number of secondary endpoints aimed at determining if HI-164OV can reduce the severity of exacerbations. These include the time to use of corticosteroids, antibiotics or hospitalisation; the proportion of patients experiencing exacerbations requiring oral/ parenteral corticosteroid treatment or hospitalisation, the extent of use of antibiotics and/or corticosteroids, duration of exacerbations and extent of hospitalisation.

The final study report should be available in the 2nd quarter of calendar 2012.

Hunter Immunology's main objective is to demonstrate convincing evidence for HI-164OV in reducing the number and severity of exacerbations in patients with moderate to severe COPD. A secondary objective is to add value to this product by extending its use to other indications such as mild to moderate COPD and severe allergic asthma.

Success in commercialising HI-164OV will further validate Hunter Immunology's Mucosal Immunology Platform. This platform technology has the potential to yield other products for which mucosal immunity could have significant advantages.

Hunter Immunology's business strategy is to partner, license or sell its product candidates at the proof of concept stage rather than establish commercial production and marketing. To this end, Hunter Immunology intends to either license, co-develop or sell HI-164OV at an appropriate point in its development where significant value has been added. A number of pharmaceutical companies have shown interest in the product if the earlier results are repeated in a larger trial.

Over 2009 and 2010, Hunter Immunology has conducted discussions with a number of large biotechnology and pharmaceutical companies, mostly under Confidentiality Agreements. Hunter Immunology believes the data from the H005 trial will be crucial in completing an appropriately valued commercial deal for HI-1640V.



### COPD and the Market Opportunity Created by the Disease

COPD is a major cause of morbidity and mortality and is projected to become the third most common cause of death in the world by 2020 as unlike many other serious health issues the death rate from COPD is rapidly increasing.

The market opportunity for this COPD therapeutic is growing, with an estimated economic cost to the Australian economy in 2010 of approximately AUD\$50 billion in both direct and indirect costs. In the United States, this disease is recognized as the fourth largest cause of death, with over 4 million patients suffering moderate to severe COPD. Within developing countries COPD is recognized as one of the most rapidly growing health issues facing already stretched health systems. Hunter Immunology is positioning itself to embrace this significant global market opportunity with a unique and proprietary vaccine which is undergoing clinical validation, and is targeted for the prevention of severe exacerbations of COPD (defined as those requiring systemic corticosteroid therapy and/or admission into hospital). The Company has commenced a significant clinical trial with in excess of 300 patients across Australia enrolled in a statistically powered clinical evaluation of its leading product, HI-164OV.

### Other Therapeutic Opportunities around HI-1640V

In parallel with the COPD trial, Hunter Immunology has been approached by a world recognized Centre of Excellence to embark upon a further statistically powered trial of HI-164OV when used in patients with treatment resistant asthma.

This exciting opportunity to diversify the indications for HI-164OV, whilst not in the previously stated disease state of COPD could bring additional opportunities for commercialization of this novel vaccine into another chronic and disabling respiratory disorder.

It is Hunter Immunology's intention to further explore the opportunities that exist within the broader respiratory infections and disease states that may be able to leverage HI-164OV or related products. The Company may further explore initial findings that HI-164OV significantly decreases antibiotic treatment, which offers significant clinical value in providing alternative treatments for bacterial infections.

For further information on Hunter Immunology and its activities, you are referred to Hunter Immunology's web-site – www.hunterimmunology.com.

## **Hunter Immunology's Directors**

lan Mutton, LLB (Non-Executive Chairman)	David Radford, BSc (Hons), MBA, GAICD  Managing Director
Emeritus Professor Robert Clancy (AM); B.Sc Med (Hons), MB.BS (Hons), PhD, FRACP, FRCPA (Non-Executive Director)	Glenn Crisp, B.Comm, LLB (Non-Executive Director)
Jeremy Curnock-Cook, (Non-Executive Director)	<b>Dr Doug Wilson</b> , MB, ChB, PhD, FRACP, FRCPA (Non-executive director)
Kevin Healy, PhD (Non-Executive Director)	



It is expected that Messrs Mutton, Radford, Curnock-Cook and Wilson would become members of the board of Probiomics.

No director, or any associate of a director, of Hunter Immunology is also a director of Probiomics. Furthermore, no shareholder of Hunter Immunology is a related party of Probiomics.

## **Capital Structure of Hunter Immunology**

As at the date of this announcement, Hunter Immunology has the following capital structure (including shares expected to be issued prior to completion of the merger.

	Number	%
Shares		
Total existing Shares	168,993,393	56.3%
Shares to be issued in consideration for payment of accrued interest on Convertible Notes – to be issued subject to Probiomics shareholder approval	5,034,303	1.7%
Hunter Immunology Executive – to be issued subject to Probiomics shareholder approval	16,335,450	5.4%
Shares to be issued on conversion of existing Convertible Notes (Existing Notes)	50,000,000	16.6%
Shares to be issued on conversion of proposed issue of Convertible Notes (New Notes)	60,000,000	20.0%
Total (undiluted capital)	300,363,146	100.0%
Options		
Hunter Immunology Executive options	16,985,000	
Options issued to investors in Hunter Immunology	4,360,862	
Options to be issued to Hunter Immunology's Financial Adviser	5,000,000	
	26,345,862	

## It is intended that:

- (a) all Hunter Immunology Shares will be acquired under the Acquisition and by means of the takeover bid;
- (b) all Existing Notes and New Notes will be converted into Hunter Immunology shares and acquired under the Acquisition and by means of the takeover bid; and
- (c) all Hunter Immunology options will be cancelled and replaced with options in Probiomics on a restructured and post Share Consolidation basis.

Hunter Immunology also anticipates undertaking a final round of fundraising (by way of an Excluded Offering) in advance release of the Target Statement, by means of the issue of the New Notes. It is expected that this fundraising will provide the funding necessary to carry Hunter Immunology through to the completion of the Phase IIB clinical trials currently underway.



#### 4. CHANGE OF NAME

If the relevant shareholders resolutions are passed at the Meeting, it is intended that Probiomics will change its name to "Bioxyne Limited".

#### 5. SUSPENSION AND RE-ADMISSION

The proposed Acquisition and Public Offer will constitute a significant change to the scale of the Company. Accordingly, it will be necessary for the Company to apply to ASX, immediately prior to the convening of the meeting of Probiomics shareholders (**Meeting**) at which the necessary approvals will be sought, for the suspension of the quotation of Probiomics' shares. In addition, if the relevant shareholders resolutions are passed at the Meeting, trading in Probiomics shares will be suspended from the day of the Meeting until ASX has accepted that the requirements of Chapters 1 and 2 of the Listing Rules have been satisfied.

Immediately after the Meeting, and irrespective of whether or not the relevant shareholder resolutions are passed at the Meeting, Probiomics will apply to ASX for Probiomics to be re-admitted to the Official List and for the termination of that suspension.

If the relevant shareholders resolutions are passed at the Meeting, it is expected that the proposed Acquisition and Public Offer will continue on to completion. However, as stated above Probiomics' readmission and termination of the suspension of its shares trading on the market operated by ASX (**Readmission**) will only occur when and if ASX has accepted that the requirements of Chapters 1 and 2 of the Listing Rules have been satisfied.

## 6. EXCLUDED OFFER

To enable Probiomics to pay for the professional costs and expenses that it is likely to incur in the course of effecting the Acquisition and Public Offer, Probiomics proposes to effect an excluded offer to a small number of sophisticated investors to raise \$200,000.00 through the issue of shares at \$0.006 per Probiomics share (Excluded Offer). The Probiomics directors feel that the discount in the price being offered under the Excluded Offer to those investors is justified as they will be assuming significant transaction completion risk, in contrast to any of the Hunter Immunology shareholders who participate in the Acquisition or any participants in the Public Offer.

## 7. TIMING OF ACQUISITION AND PUBLIC OFFER

A provisional timetable of the relevant steps in the overall process of the Acquisition and Public Offer is attached to this announcement.

However, the Probiomics directors wish to stress that the dates in the attached timetable are made in good faith but are only estimates of when the relevant steps referred to therein will actually occur. Accordingly those dates are subject to change, and in some instances, are likely to change as a result of matters outside the control of Probiomics or its directors.



# **PROBIOMICS LIMITED**

# **WORKING TIMETABLE**

Task Name	Date*
ASX announcement of proposed Takeover Bid – 1 day suspension from quotation of Bidder	Tues 11/10/11
Bidder's Statement, Target's Statement and Prospectus lodged with ASIC	Fri 28/10/11
Notice of General Meeting lodged with ASX	Fri 28/10/11
ASIC Prospectus review period and ASX Notice of General Meeting review period	Thurs 03/11/11
ASIC review period in respect of proposed issue of Options to Bidder Directors	Fri 11/11/11
Bidder's Statement dispatched to Target and Target's Statement dispatched to Bidder	Mon 14/11/11
Dispatch to Target shareholders of:	Tues 15/11/11
Bidder's Statement;	
Independent Expert's Report;	
Target's Statement; and	
Prospectus	
Dispatch to Bidder shareholders of:	Tues 15/11/11
Bidder's Statement;	
Target's Statement;	
Notice of General Meeting (including Independent Expert's Report) and	
Prospectus	
Commencement of Takeover Offer period	Tues 15/11/11
Commencement of Public Offer period	Tues 15/11/11
Commencement of notice period for Bidder Shareholder Meeting	Tues 15/11/11
Bidder Shareholder Meeting	Wed 14/12/11



Task Name	Date*
Notify ASX of results of Bidder Shareholder Meeting	Wed 14/12/11
Lodge application to ASX for re-admission of Bidder – assume 15 working days. If it takes longer, Bidder may have to extend Offer Period <sup>1</sup>	Thurs 15/12/11
ASX grants permission for quotation of Bid Consideration and re-admission of Bidder	Tues 10/01/12
Close Takeover Offer period <sup>2</sup>	Tues 17/01/12
Issue of all Bid Consideration	Wed 18/01/12

<sup>\*</sup> all dates set out above are good faith estimates of when the corresponding event may occur and are subject to change. In the event of a change in any material date, Probiomics will notify ASX accordingly.

<sup>&</sup>lt;sup>1</sup> The Offer Period may need to be extended if it appears to Bidder Directors that ASX will not give permission for re-admission and quotation to PCC within the period referred to in Section 625(3)(c)(ii) ie within 7 days after the end of the Offer Period <sup>2</sup> Ibid