



## MEDLAB – SHAREHOLDERS NEWSLETTER – FEBRUARY 2017

Dear Shareholder

### Introduction

Since our last newsletter, Medlab has made considerable progress in furthering its research program, so in this newsletter we provide an update as well as information on the context surrounding our work. Research progress is especially encouraging with cannabis, statins and depression. The cannabis and statins trials are also in conjunction with development of our small particle medicine delivery system, Nanocelle™.

A number of shareholders have also been wanting information about the medicinal cannabis market. While we do not have access to reliable statistics on the Australian market, a recent independent research report on the North American market provides some interesting facts. Its information on market size, growth rate and projections indicate it becoming a significant industry sector.

On the topic of cancer pain, it is also interesting to note conclusions from worldwide research, especially as Medlab is preparing to begin a human trial of cannabis as a therapy for oncology patients with intractable pain. In many countries, not only is cancer pain becoming more widespread but it is also undertreated. These symptoms apply to pain management more generally and this is the focus of Medlab's R&D with cannabis.

### Half year financial results

Medlab's results for the half year to December 2016 reflect the current orientation of management focus towards the research and development program. This adds to costs but they are offset by sales from nutraceuticals and an Australian government research grant, showing the benefits of our business model of combining these two complimentary operations.

Results are as follows:

CURRENT REPORTING PERIOD: PREVIOUS CORRESPONDING PERIOD:	Half-Year Ended 31 December 2016 Half-Year Ended 31 December 2015 Amount \$	Up/Down	Movement
<b>KEY INFORMATION</b>			
Revenue from ordinary activities	2,123,668	up	83.4%
(Loss) from ordinary activities after tax attributable to members	(1,704,884)	up	1.4%
Net (loss) attributable to members	(1,704,884)	up	1.4%

Medlab's research programs have advanced well ahead of schedule, adding to the cost impact. While revenue growth is encouraging, you will also see below Medlab is in advanced discussions with an Australian company to enter into a joint venture which presents an opportunity to increase nutraceutical sales.

## Research program

Medlab's research program is currently concentrated on three projects.

### 1. Cannabis trial, using Nanocelle™

Medlab's human trial of its cannabis medicine for oncology patients with intractable pain will be the first of its kind in Australia. While commencement of the trial awaits approval from the ethics committee at Royal North Shore Hospital, there has been considerable work in the lead up to this point.

Medlab has obtained licences to import cannabis and is now working with Health Canada to finalise movement of the material, with this clearance expected in the near future. The cannabis material is a combination of the two most active cannabis ingredients, formulated by Medlab and being supplied by Canadian licenced producer of medical marijuana, Aphria Inc. The formulation is designed to achieve a consistency of product which is essential in developing a medicine for a clinical trial and for subsequent commercialisation.

Medlab has appointed a contractor in Melbourne, licenced for controlled substance manufacture, and the imported cannabis material will be delivered there for assembly with Medlab's small particle medicine delivery system, the patent pending buccal spray, called Nanocelle™. This spray introduces the medicine into the buccal (cheek cavity) as a way of increasing the absorption of a medicine directly into the bloodstream. With the contractor, Medlab will establish a drug manufacturing method that will be the prescribed template for future production.

Medlab has invested considerable effort into preparing a trial protocol for evaluation by the hospital ethics committee and has had ongoing engagement with the committee over recent months and this is continuing.

Medlab believes this trial will validate its belief in this much needed unique medicine for pain relief. Establishment of a production method will allow, after completion of a successful clinical trial, commercial production, subject to approval from Therapeutic Goods Administration.

### 2. Statins

Medlab is currently developing a protocol to test its Nanocelle™ buccal spray using Atorvastatin, a market leading statin which is now off-patent. Conducted under TGA guidelines, the study is intended to test bio-equivalence, in particular that a few sprays of Medlab's material could have the same effect as large statin tablets. Medlab is calling its product "Nanostat" and the study will examine whether its more direct form of delivery of statins might enable smaller doses of active ingredient than a tablet offers, with the possibility of reducing reported statin side effects in the process. Medlab is finalising arrangements with a licensed contractor to undertake this study and work is expected to commence this coming quarter.

The size of the statins market worldwide has been estimated at US\$12 billion in 2018<sup>1</sup>, with it dominated by tablets. Outcomes from Medlab's study will also be a pointer to applying the technology to other major off patent drugs.

---

<sup>1</sup> Research report news release, <http://www.prweb.com/releases/statins-drugs-market/analysis-forecast-2018/prweb10367278.htm>

### **3. Depression study proceeding to Phase 2a**

Medlab's human trial of its product, NRG Biotic, for the treatment of patients with drug resistant depression, is proceeding to Phase 2a sooner than originally planned.

Ethics submission has been prepared and has been submitted for evaluation.

The completed Phase 1 trials were supervised by Dr Matthew Bambling at the Mater Hospital in Brisbane and he will conduct the forthcoming Phase 2a trial at Princess Alexandra Hospital in Brisbane.

Phase 1 showed that NRG Biotic taken in conjunction with standard therapy gave a superior result compared with taking the standard therapy alone.

NRG Biotic has a patent pending and is in Medlab's nutritional range.

Depression is one of Australia's leading chronic diseases and it is believed it affects approximately 20% of Australians 16 years and over.

#### **Nutritional products**

Medlab is aiming for a distinctive positioning with its nutritional products, with many being research and evidence based to enable substantiation of claims that are made about their effectiveness. This approach is different to many nutritional companies and yet is increasingly important in the current market as the TGA is looking more closely at regulation of complementary medicines and manufacturer claims.

In addition to its 14 existing products, Medlab has eight new products in the pipeline which are the outcomes of its research program. It takes time to develop the formulas for these products and to test them, with the extent of this effort warranting applying for patents and publication of our research in peer reviewed journals. From completion of R&D it can take 16 weeks before a product is actually ready for the market.

There is a crossover with Medlab's nutraceutical research and drug development work and so both elements of the business benefit from the extent of investigation we undertake. The combination of this research, patenting work for our nutraceuticals and our current emphasis on the clinical trial program explains a slower than expected increase in nutraceutical sales.

For some time, Medlab has been receiving offers from a number of local and overseas companies wanting to distribute our nutritional/nutraceutical products. To date, Medlab has rejected these approaches for numerous philosophical reasons. However, in recent months, Medlab has been in advanced discussions with an Australian company which shares Medlab's philosophy and strategies regarding health issues. These discussions have centred around a possible joint venture for distribution of Medlab's current and other new products emanating from our R&D program. The proposed joint venture would present an opportunity to increase sales significantly, and if it is successfully concluded, would lead to release of products in domestic markets late 2017. We will advise shareholders and the market of the progress of this development.

#### **The cannabis market context**

Developments in the cannabis market in the US and Canada provide an interesting pointer for the potential of Medlab's work in this area – the market is fast growing and heading towards being substantial.

In the November 2016 elections in the United States, nine states included voting on legalisation of marijuana, some just for medical use and others for wider adult use.

Four states – California, Massachusetts, Nevada and Maine - voted in favour of recreational marijuana use, joining other states, including Washington, Colorado, Oregon and Alaska, which had passed similar laws since 2012.

On the medical side, in 2016 five states – Pennsylvania, Ohio, Florida, North Dakota and Arkansas – legalised the use of medical cannabis to treat certain ailments such as epilepsy, cancer and glaucoma.

So now, 28 US states and the District of Columbia have made or are about to make cannabis legal.

The economic effects are also significant - as industry researcher, [Arcview Market Research](#) notes in a recent study (you can download a summary [here](#)) of Legal Marijuana Markets across Canada and the US:

“The legal cannabis industry accelerated at a remarkable pace in 2016. North American consumers spent US\$6.9 billion on legal cannabis products, up 34% from 2015.”

Arcview expects these trends to continue, especially since one of the states which has approved adult use of marijuana, California, is the sixth largest economy in the world, with it already representing 31 per cent of the 2016 legal market in North America.

With the legal cannabis industry having grown at a compound annual growth rate (CAGR) of 40 per cent from 2014 to 2016, Arcview is forecasting a US\$21.6 billion industry by 2021, based on CAGR of 26 per cent and assuming that by 2021 there will be 30 US states legal and including Canada.

On a population basis, since the November election, Arcview notes 87 per cent of Americans live in medical use states and 18 per cent in adult use states.

Adding to the growth story, Arcview reports that Canada has started the formal process of legalising adult use and the Senate in Mexico has voted overwhelmingly to send a medical use legalisation bill to the lower house.

When [Forbes](#) magazine reported on the Arcview research, it quoted Arcview editor-in-chief Tom Adams, about comparable growth rates:

“The only consumer industry categories I've seen reach \$5 billion in annual spending and then post anything like 25% compound annual growth in the next five years are cable television (19%) in the 1990's and the broadband internet (29%) in the 2000's.”

Two interesting sidelights to the cannabis growth story are a corresponding decline in the illegal cannabis industry and a rise in state based revenue from cannabis taxes

With Colorado estimated to have earned US\$70 million in FY15 and a likely US\$135 million in FY16 from taxes on cannabis use, it seems there is a tax based motivation for states to continue trends towards legalisation.

Cannabis industry growth trends haven't escaped the attention of investment banks either, as these reports show:

- [Bank of America Merrill Lynch](#) notes “medical marijuana has high POTential”

- [Cowen and Company](#) predicts the recreational cannabis industry could grow to \$US50 billion by 2026
- [Ackrell Capital](#) sees a potential US\$100 billion cannabis market by 2029, assuming federal legalisation and wider medical uses

The implications of all this for Medlab will become known over time but it does provide a positive surrounding context for its impending cannabis human trial.

### **Research references around intractable cancer pain**

In assessing a body of research from around the world on cancer pain, there are two common conclusions – cancer pain is an increasingly widespread condition and generally, it is undertreated.

Additionally there appears to be a lack of an Australian research contribution in relation to cancer pain, with all these factors tending to substantiate the importance of Medlab’s forthcoming trial.

Cancer pain is quite a distinct area from non-cancer pain. Sometimes causes of cancer pain can be easily identified while often it cannot be isolated from the disease itself. Anti-cancer treatment from radiotherapy can assist with pain control but generally there is no active treatment for cancer pain, with some patients needing to manage it for the rest of their lives.

The World Health Organisation has developed a three step analgesic ladder to guide cancer pain management worldwide, starting with no-opioid drugs, then weak opioids followed by stronger opioids.

Despite these WHO recommendations though, cancer pain is still a major problem. One research paper<sup>2</sup> which pooled data from 52 studies highlighted the widespread existence of pain for cancer patients:

- 64 per cent in patients with metastatic or advanced stage disease
- 59 per cent in patients on anticancer treatment
- 33 per cent in patients after curative treatment

More than one third of these patients with pain graded it as moderate or severe.

With an increasing number of cancer survivors living to an advanced age, there is a growing need to seek a way of reducing the prevalence of pain at all stages of the disease process.

A number of studies from around the world have highlighted the extent of under treatment of cancer pain.

One review of 26 separate studies showed that not only was pain a major health care problem for cancer patients but, despite the existence of guidelines for cancer pain management, under-treatment was a widespread problem. The review found nearly one in two patients with cancer pain was undertreated.<sup>3</sup>

---

<sup>2</sup> Van den Beuken-van Everdingen MHJ, de Rijke JM, Kessels AG, Schouten HC, van Cleef M, Patijn, J, 2007, *Prevalence of pain in patients with cancer: A systematic review of the past 40 years*. Ann Oncol 18(9): 1437-1449

<sup>3</sup> Deandrea S et al, *Prevalence of under-treatment in cancer pain: A review of published literature*. Annals of Oncology 19: 1985-1991, 2008

In a large study in Italy, under-treatment was found to be affecting 25 per cent of the sample and up to 55 per cent in some subgroups.<sup>4</sup>

A US study<sup>5</sup> across a large sample of 3,023 cancer patients has confirmed similar pain under-treatment trends.

It showed that 67 per cent of patients reported having pain or needing analgesics at initial assessment and of these patients, 33 per cent were receiving inadequate analgesic prescribing.

The study concluded that in the US, pain was as prevalent in ambulatory oncology patients with common solid tumours as it was more than 20 years ago, despite opioid prescribing in the US having increased more than tenfold since 1990.

In Australia, according to the government's National Pain Strategy of 2010: "Despite the ready availability of effective pain control strategies and guidelines for controlling cancer pain, there is strong evidence that cancer pain is undertreated." However, this conclusion is based on some of the studies mentioned above and to date there have been no Australian studies in adults.

The cost to the Australian economy of pain has been the subject of one piece of research<sup>6</sup> in 2007, finding it to be \$34.3 billion or \$10,847 for each person affected.

These surrounding factors add to the timeliness of Medlab's impending human trial, with it taking place when there is increasing recognition of the widespread nature of cancer pain, the extent to which it is undertreated and the rising economic costs of the lack of a resolution to these issues.

## Conclusion

In late 2016, Medlab received its financial year end research grant of approximately \$900,000 from the Australian government and we are greatly appreciative of this support. There are great scientists in Australia and this support helps them and helps Medlab.

We believe significant progress has been made in recent months, especially in getting our cannabis trial close to starting, taking our depression trial to the next stage, progressing further with our work in obesity and development of new nutraceuticals. Discussions about a possible joint venture to advance sales of our nutritional/nutraceutical products are also promising and we will advise progress on this as soon as there are developments.

We want to thank you, our shareholders, for your ongoing support.

Yours sincerely

SEAN HALL

CEO

MICHAEL HALL

Chairman

---

<sup>4</sup> Apolone G et al, *Pattern of care in cancer pain management: Results from the cancer pain outcome research study group*. British journal of cancer (2009) 100, 1566-1574

<sup>5</sup> Fisch M, Cleeland C et al, *Prospective, Observational study of pain and analgesic prescribing in medical oncology outpatients with breast, colorectal, lung or prostate cancer*, Journal of Clinical Oncology, Vol 30, Number 16, June 1 2012

<sup>6</sup> MBF foundation in collaboration with the University of Sydney Pain Management Research Institute, *The high price of pain: The economic impact of Persistent Pain in Australia*, November 2007