

20th April 2018



## CHAIRMAN'S LETTER

Dear Shareholder,

It gives me great pleasure at this exciting time in Medlab's history to enclose our first Shareholder Update for the 2018 year. As shareholders are well aware, the State and Federal Health Departments have simplified the approval for distributing Medical Cannabis via Medical Practitioners. Furthermore, the Federal Health Minister met with state and territory health ministers recently and they agreed to support the Federal Government to progress the development of a single national online application pathway to access unregistered medicinal cannabis products (<https://www.racgp.org.au/newsGP/Professional/National-health-priorities>). This simplification by the Health Departments has enabled us at Medlab to progress our original plans for Nanabis™ (Medlab's new medical cannabis product) by some 12-18 months.

Obviously to comply with the Health Department's approval procedures we needed to manufacture Nanabis™ via a licensed TGA approved Pharmaceutical facility (PPP in Melbourne) and naturally we have experienced some minor delays in manufacturing a high quality validated product. However, I am pleased to advise shareholders that these minor hold-ups are well behind us and **Nanabis™ is now ready for sale and delivery to the Royal North Shore Hospital (RNSH) for the "intractable pain trials"**.

In answer to a number of Shareholder queries I wish to reiterate that YES, we can sell Nanabis™ prior to the completion of the RNSH trial results. This decision to sell Nanabis™ immediately is in line with the State and Federal Government's SAS approvals and as a result our executive team are already on the road training Doctors and Pharmacists. To enable us to fast-track all of the foregoing as well as other trials, research and development and the planned growth in Nutraceutical product sales we need at this time to thank our brokers Bell Potter and APP Securities for the successful capital raising they undertook on Medlab's behalf in January 2018. Medlab raised approximately \$22.68m after costs from the share placement and is now well cashed up to fund our future strategies well into the future.

The following information in this "Letter to Shareholders" should bring shareholders up to date on progress at Medlab as at 20th April 2018. However, we are in a very exciting time of our development and thus when a company such as Medlab is totally focused on "the positive improvement and quality of life for patients suffering chronic illnesses" we do face very quick changes in our achievements be they good due to successful R&D results or disappointing due to delays in other areas which are often, outside our control.

As a number of our shareholders would be aware, on Tuesday 17th April, the Greens sought support for a Cannabis legalisation bill for recreational use. Medlab supports the Federal, NSW State Government and the Australian Medical Association's (AMA) stance in not supporting such a bill. Medlab's work is to develop much needed pharmaceuticals for patients with unmet needs. Our NanaBis™ program meets all health and Government requirements for a schedule 8 medicine (non-ARTG). The current human trial at RNSH is designed to demonstrate efficacy for the use of NanaBis™.

The AMA's position statement can be found at: <https://ama.com.au/position-statement/cannabis-use-and-health-2014>. Medlab's position is that all drugs have the potential for side effects, and Cannabis is no exception. Therefore, use must be controlled under medical supervision and supported through the rigours of scientific investigation.

May I take this opportunity in conclusion to thank all Shareholders for their continuous support.

Kind regards

Michael Hall  
Chairman



## LETTER TO SHAREHOLDERS

APRIL 2018

ASX: MDC

### CANNABIS

#### Opioids crisis puts cannabis in the spotlight

The statistics around the opioids crisis, in the US and Australia, are astounding. It also places cannabis at the centre of a search for a non-opioid alternative for pain management.

**"2015 was the worst year for drug overdose deaths. Then 2016 came along"**

**The opioid epidemic, explained**

2015 was the worst year for drug overdose deaths. Then 2016 came along.

By German Lopez@germanlopezgerman.lopez@vox.com Updated Dec 21, 2017, 9:10am EST

If nothing is done, we can expect a lot of people to die: A forecast by STAT concluded that as many as 600,000 people will die over the next 10 years from opioid overdoses — more than the entire city of Baltimore. The US risks losing the equivalent of a whole American city in just one decade.

That would be on top of all the death that America has already seen in the course of the ongoing opioid epidemic. In 2016, nearly 64,000 people died of drug overdoses in America — with synthetic opioids (such as fentanyl), heroin, and common opioid painkillers (like Percocet and OxyContin) topping other causes of overdose, according to raw data from the Centers for Disease Control and Prevention. That's a higher death toll than guns, car crashes, and HIV/AIDS ever killed in one year in the US, and a higher death toll than all US military casualties in the Vietnam and Iraq wars combined.

If you want to understand how we got here, there's one simple explanation: It's much easier in America to get high than it is to get help.

- Overdoses involving opioids killed more than **42,000 people** in 2016. 40% of those deaths were from prescription opioids

Hedegaard H, Warner M, Miniño AM. Drug overdose deaths in the United States, 1999–2016. NCHS Data Brief, no 294. Hyattsville, MD: National Center for Health Statistics; 2017/CDC. Widescreening online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at <http://wonder.cdc.gov>

- That's a higher death toll than guns, car crashes, and HIV/AIDS ever killed in one year in the US, and a higher death toll than all US military casualties in the Vietnam and Iraq wars combined

Lopez G, The Opioid Epidemic Explained, 21 December 2017, article

Presentation for information purposes only. All rights reserved. For more information please contact Sean Hall +61 411603378, or [sean@medlab.co](mailto:sean@medlab.co)

as presented by Dr. Sean Hall (MD, MBA - clin. pharm) Wed. 28th Feb. 2018 at Hyatt Regency Sydney

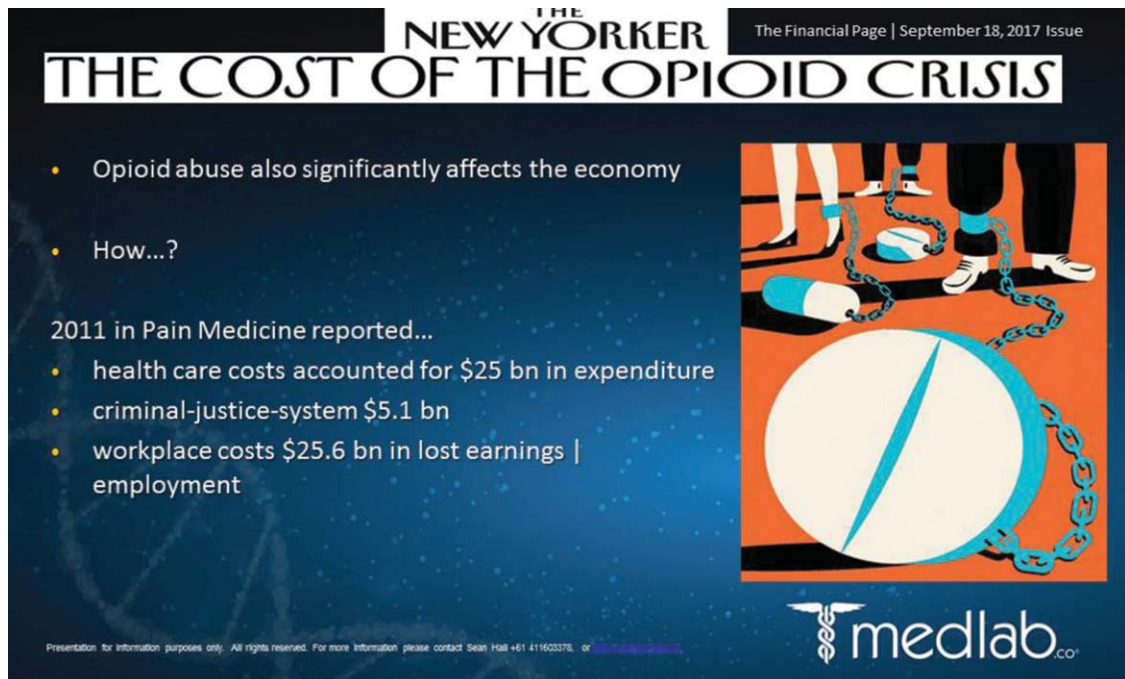
Medical cannabis has been legalised in 29 states in the US, while in Australia, medical practitioners are able to prescribe it in certain circumstances. The Australian Medical Association (<https://ama.com.au/tags/medicinal-cannabis>) is being cautious: "Medicinal cannabis has great potential for use in palliative care, juvenile epilepsy, and forms of spasticity, but doctors remain concerned about its potential diversion into the general community."

Medlab's position on this is distinctive – it is pursuing the clinical trial route for cannabis-based drug development. It has two drug candidates approved for clinical trial, with one to commence in May at Royal North Shore Hospital. The trials will provide data desperately needed by the international medical community. Its forthcoming trial with seriously ill oncology patients for pain management is believed to be the first of its kind and with the support of Therapeutic Goods Administration, it has potential to be fast tracked as a drug.

The extent of the opioids crisis provides context around the value of Medlab's work – these are the key facts from the US:

- In 2016, 2 million Americans had an addiction to prescription or illicit opioids and 175 people a day died from drug overdose
- These statistics led President Trump to declare the opioid crisis a national health emergency under federal law in October 2017
- The economic cost of the crisis was US\$504 billion in 2015 or 2.8 per cent of GDP

In Australia, the position is approaching the same level of seriousness – between 1992 and 2012, opioid dispensing increased 15-fold, annual opioid related deaths now surpass the national road toll and prescription opioids were involved in more than 70 per cent of drug related deaths in 2017.



• Opioid abuse also significantly affects the economy

• How...?

2011 in Pain Medicine reported...

- health care costs accounted for \$25 bn in expenditure
- criminal-justice-system \$5.1 bn
- workplace costs \$25.6 bn in lost earnings | employment

medlab<sup>co</sup>

as presented by Dr. Sean Hall (MD, MBA - clin. pharm) Wed. 28th Feb. 2018 at Hyatt Regency Sydney

So how did the opioids crisis arise? The US National Institute on Drug Abuse (<https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis>) puts it down to assurances by pharmaceutical companies in the 1990s that patients would not become addicted to prescription pain relievers, leading to healthcare providers prescribing them at greater rates. This resulted in widespread misuse of medications before it became clear they could indeed be highly addictive. Medical opinion is that opioids are best used for acute pain management and that wider use of them can lead to hyperalgesia which makes chronic users of opioids more sensitive to pain over time (<https://theconversation.com/fixing-pain-management-could-help-us-solve-the-opioid-crisis-90919>).

In pursuit of non-opioid alternatives, some US companies have begun research into cannabis-based pain management (<https://www.reuters.com/article/us-marijuana-fda/high-hopes-ride-on-marijuana-painkillers-amid-opioid-crisis-idUSKBN19E1NU>), targeting 100 million people in the US who suffer chronic pain and also on the basis that 60 per cent of Americans now live in states that have legalised marijuana. Providing impetus to this direction is research that hospitalisation for opioid dependence has decreased 23 per cent in US states after marijuana was permitted for medicinal purposes, with hospitalisation rates for opioid overdoses dropping 13 percent on average. Separate research also found that deaths from opioid overdoses fell by 25 percent in states that legalised medical marijuana (<https://www.reuters.com/article/us-health-addiction-medical-marijuana/would-legalizing-medical-marijuana-help-curb-the-opioid-epidemic-idUSKBN16Y2HV>).

Reuters also reported that a January 2017 National Academies study found conclusive or substantial evidence that cannabis can effectively treat chronic pain, chemotherapy-induced nausea and spasticity. The report, written by an independent panel of medical experts, found no evidence of cannabis overdose deaths.

Among measures implemented in the US have been encouragement of new drugs to counter addiction and development of non-addictive painkillers. President Trump is also providing more funding for a campaign to fight opioid abuse, with this possibly including the death penalty for drug dealers. In Australia, medicines containing codeine have been moved from over-the-counter to prescription drugs.

The clear direction from these trends in the US and Australia is that Medlab's cannabis-based drug development program comes at a time when it presents an important response to the opioids crisis. Allied to this is a heightened need for a solution to particular pain issues related to cancer, where Medlab's program is initially directed. Research has confirmed several trends in relation to cancer pain, especially that it is widespread, moderate to severe in intensity and generally undertreated. This makes cancer pain a prominent health issue and one that is prevalent and consequentially costly to society.

## Cannabis market growth

Growth of the worldwide cannabis industry also continues at a fast pace. Spending on legal cannabis worldwide is expected to hit US\$ 57 billion by 2027 with a third of this on medical marijuana. While the majority of spending will be in North America on recreational use, the fastest growth rate is outside the US. With Germany recently opening up cannabis for medical use through pharmacies, it is set to become the European market leader, with Italy not far behind. Australia is forecast to become the fifth largest market in the world, with spending to grow from US\$52 million in 2018 to US\$1.2 billion by 2027 (<https://www.forbes.com/sites/thomaspellechia/2018/03/01/double-digit-billions-puts-north-america-in-the-worldwide-cannabis-market-lead/#3a54b5a06510>).



### NanaBis™ – Our solution to Opioid Use

NanaBis™ is a whole cannabis plant extract of 1:1 ratios, CBD to THC in our proprietary nanotechnology delivery platform, NanoCelle™; indicated for advance cancer pain.

The NanaBis™ drug is built to all rigours of Australian drug manufacture and has successfully been manufactured. Validated analytical release for supply has also been completed.

NanaBis™ is currently registered for sale as an Australian TGA/ODC Special Access Drug with state licences allowing supply. Medlab is one of only nine companies federally licenced to supply medical cannabis. Medlab is the only ASX listed company licenced.

Medlab provides a unique delivery platform, manufactured in Australia and no other company licenced to supply cannabis is in the area of advanced cancer patients suffering intractable pain. (<https://www.odc.gov.au/manufacturers-and-suppliers-medicinal-cannabis-products>).

In March Medlab successfully concluded its first round of East Coast medical education evenings attracting more than 500 Doctors and Pharmacies.

First dose to patient in the Royal North Shore clinical trial is expected to start in May.

**NanaBis™ is now ready for sale and dispatch to RNSH** and our endpoint is to demonstrate effective pain management with the conjecture of reducing the reliance of, and/or replacing standard opioid use.

Upon the successful completion of the NanaBis™ trial, Medlab envisages applying for provisional TGA drug registration in the first part of 2019. Medlab welcomes recent changes to the drug registration process announced by the TGA and thus making a more expedient process. Registration as a drug is a critical endpoint for NanaBis™ as this will allow doctors to prescribe via script, without the need to apply for Government approval, currently required under the TGA's SAS.



### NanaBidual™ – Our second Cannabis solution

NanaBidual™ is similar in all ways to NanaBis™ expect the ratio is 18 parts CBD to 1 part THC, and is indicated chemotherapy nausea and vomiting (CINV) and seizures.

NanaBidual™ fits well with the overall Oncology theme and is welcomed and needed; like NanaBis™, NanaBidual™ is also currently allowed for sale as an Australian TGA/ODC Special Access Drug (<https://www.odc.gov.au/manufacturers-and-suppliers-medicinal-cannabis-products>).

NanaBidual™ is ready for manufacture, with scheduled manufacturing to occur late April/early May.

Ethics (HREC) for a safety study has been approved with commencement anticipated by the end of financial year.

## RESEARCH & DEVELOPMENT



### **NanoStat™ – NanaBis™'s delivery platform, NanoCelle™, revitalising generic atorvastatin**

NanoStat™ continues to progress well with manufacture of the actual drug to TGA standards is anticipated to occur next month. The Study to be conducted in New Zealand has been delayed, with little cost impact as drug validation models were required prior to the commencement of the Study.

These drug validation models provide Medlab with the capability of manufacturing a more regulatory compliant product and this will occur prior to human testing. Having such validation models provides Medlab with greater opportunity to commercialise not only NanoStat™ but any other potential generic drugs manufacturing using Medlab's patented NanoCelle™ delivery platform, of which the Company has a number in various stages of development.



### **NRGBiotic™ – Phase 2a Clinical Trials with Queensland University of Technology (QUT) in Depression**



With 2 prior excellent Phase 1 results, Medlab has reached agreement with QUT for a 150 person study using NRGBiotic™ (a product currently in market) as an adjuvant therapy to an SSRI (class of antidepressant).

Medlab's prior work showing significant patient improvement on the combination of NRGBiotic™ and an SSRI, as opposed to an SSRI alone. The Phase 2a study is designed to strengthen those initial findings in a wider number of patients, and ready the product to transition from a TGA listed medicine to a TGA registered medicine.

This trial has further been given grant approval from the Federal Government.

The trial has been designed to allow Medlab to access the recently announced new expedited drug approval mechanism.



### **T2Biotic™ – Phase 2a Clinical Trials in Diabetes**

Trial designs are underway to further the exceptional results seen in the prior Phase 1 trial. Like NRGBiotic™, T2Biotic™ (currently NOT in market) is an adjuvant therapy to Metformin, a first line drug used for the treatment of Type 2 Diabetes and pre-Diabetic patients.

The Phase 1 data showed considerable patient improvement on the combination of T2Biotic™ and Metformin, versus Metformin alone, this includes marked reductions in HbA1C levels.

The Phase 2a trial is expected to have about 200 patients and be conducted here in Australia – the trial has been worked up to address all 5 critical elements of the new preliminary drug approval model.

Expect more details shortly.



### **MultiBiotic™ – Mucositis Neutropenia Safety Study**

In keeping true to our Oncology area, Medlab is excited to announce ethics approval for a new study, headed by Prof Stephen Clarke at the Northern Cancer Institute.

The trial will focus on safety and tolerability for oncology patients undergoing chemotherapy in reducing intestinal inflammatory ulcerations (mucositis) that's leads to the development of diarrhoea and decreased white blood cells. Unfortunately, mucositis is extremely common and debilitating in these patients.

Multibiotic™ is already in market as a patented nutraceutical with prior work in the area of non-alcoholic fatty liver disease. Preliminary investigations are promising and at successful completion, complement other oncology endeavours Medlab is undertaking, namely NanaBis™ and NanaBidual™.

## NUTRACEUTICAL SALES

Medlab recently added new products to its range, and now has 30 products globally with more in development. The sales from the nutraceutical business is covering its associated direct selling costs.

The nutraceutical business continues to grow, with an increase of 32.3% for H1 2018 over the corresponding period in 2017 and expectations of continued growth.



Medlab's nutraceutical product range has made several significant advancements:

1. Increased core ranging with smaller Pharmacy groups
2. Reached agreement with Symbion (representing 3000 pharmacies) to be represented in their charge-through system
3. Nutraceutical product information to Pharmacies available on Minfos (Pharmacy drug reference program) (<http://www.symbion.com.au/our-businesses/community-pharmacy/minfos/>)
4. Nutraceutical product information to Doctors and Hospitals available on Mims (Medical drug reference program) (<http://www.mims.com.au/>)
5. New partner in China (inclusive Hong Kong, and Macau) in test marketing mode

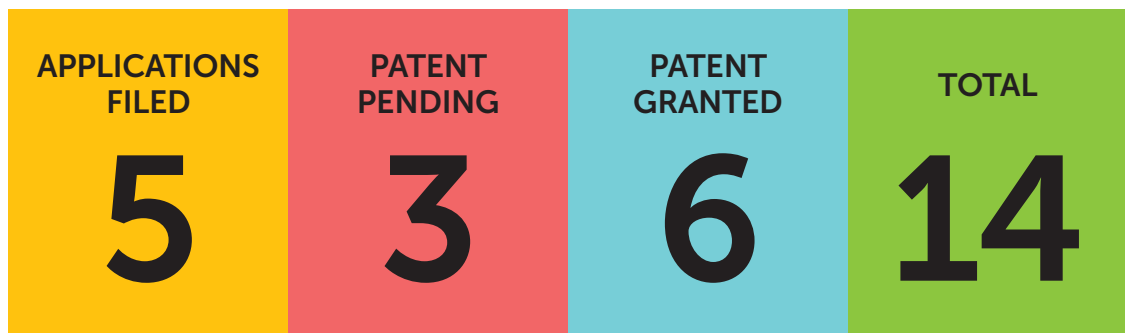
Medlab will be at the annual Pharmacy Conference APP in the Gold Coast to further the brand and commercial endeavours – initial support from Pharmacy is favourable, as Medlab offers a unique, scientific differentiation, and is gaining more support from Doctor's prescribing the product.

## CORPORATE

In January, the Company successfully completed a share placement to institutional and sophisticated investors in Australia and Asia, raising approximately \$22.68m after costs. Since listing on 14 July 2015, Medlab's market capitalisation has increased from \$32m to approx. \$100m at the time of writing. Number of shareholders has also increased from 509 at listing to 3,787 at time of writing.

At the end of March, Medlab had approximately \$21.3m in cash and on deposit.

## PATENTS



### Social Commitment – Swim for Cancer

Recently Medlab participated at the Balmoral Swim for Cancer to help raise awareness and financial support for Children’s Cancer Institute of Australia (CCIA).

2,000 people flocked to Balmoral shores and were introduced to 2 Nutraceutical offerings from Medlab, supported via the local Pharmacies.

A number of Shareholders made themselves known and welcomed seeing Medlab participate at such an event.

*Thank you to everyone who contributed to such a wonderful event.*



### Shareholder Discount

Previously we announced a shareholder discount of 25% on Medlab products, and we are happy many of our shareholders have taken up the offer. For more information, contact [investor@medlab.co](mailto:investor@medlab.co).

We would like to thank all shareholders for their loyalty and continued support.

Sean Hall  
CEO

Michael Hall  
Chairman

### For further information:

Mr Sean Hall +61 2 8203 9520  
[sean\\_hall@medlab.co](mailto:sean_hall@medlab.co)

Mr Alan Dworkin +61 2 8188 0311 (ext 116)  
[alan\\_dworkin@medlab.co](mailto:alan_dworkin@medlab.co)

About Medlab [www.medlab.co](http://www.medlab.co)