



27 April 2020

Company Announcements Office  
Australian Securities Exchange  
Exchange Centre  
20 Bridge Street  
Sydney, NSW 2000

Dear Sir/Madam

## **APPENDIX 4C – APRIL 2020**

Please find attached the Appendix 4C for the March 2020 Quarter for Medlab (ASX: MDC).

The March quarter was characterised by delivering significant milestones in its research and development programs and delivering commercial gains across its existing products in market.

The recent key highlights have been:

- **Record quarterly revenue achieved in NanaBis™ sales**, with an increase of approximately 26% over the previous best quarter and 217% over the previous corresponding period. The March quarter achieved sales in volume of over 2,000 bottles of NanaBis™ for the first time. It is important to note that as pleasing as the sales progress has been, it was despite being negatively impacted by supply restrictions which we expect to be resolved during the current June quarter.
- **Results for the Royal North Shore Hospital (RNSH) clinical trial for Cancer Pain was received.** All primary and secondary endpoints were met and in addition it was found the total cohort had meaningful pain reduction, a specific patient subset being breast or prostate cancers with bone metastasis had an average of 40% improvement in pain scores from baseline.
- **NanaBis™ Observational Study was launched in February.** Approximately 142 Australian Doctors and 373 patients have been recruited.
- **Medlab has transferred contract manufacturing and Australian chemical analysis for NanaBis to Tasmanian Alkaloids in the quarter.** Tasmanian Alkaloids are a leading global producer of regulated medicines and have extensive laboratory, production and export experience that will in future allow us to scale production to meet global demand potential.
- **Significant product packaging upgrades for NanaBis™** ahead of FDA IND filings.
- **Depression Trial using NRGBiotic™ at Queensland University of Technology was completed.** Results expected in about three months.
- **Increase in invoiced sales for nutraceutical business** for the quarter, with an increase of 42% quarter on quarter and 27% year on year. Increase in demand for immune products resulting in out of stocks.
- **COVID-19 caused supply chain disruptions** across nutraceutical and pharmaceutical businesses; action being taken to minimise disruption to one month.
- Launch of **Medlab's free telehealth services** ([clinic.medlab.co](http://clinic.medlab.co))
- Majority of Medlab staff working from home in accordance with COVID-19 guidelines.

## **RESEARCH**

Medlab's research programme in chronic diseases, (including advanced cancer pain management and depression) continues to progress well. Both programmes represent significant global earning opportunities.

### **Medical Cannabis**

Medlab's research in cannabis-based medicine (NanaBis™) through the recently completed SAD/MAD trial at Royal North Shore Hospital and the recently launched Ethics approved Observational Study, continues to make material progress in delivering clinical trials evidence with an end goal of drug registration in cancer pain management. The trial at Royal North Shore hospital was completed with very significant results:

#### **Primary Endpoints Met:**

- NanaBis™ is safe.
- NanaBis™ is tolerable. Dosage tolerance achieved at 60% of maximum dosage.
- NanaBis™ is efficacious.
- Adverse Events were predominantly mild or moderate and expected.
- NanaBis™ is demonstrated to be fast acting as it showed time to with maximum concentration in serum to be 54 minutes.
- Improvements in Quality of Life (QoL) measures, specific in role and emotional functioning and insomnia.

#### **Secondary Endpoints Met:**

- Total cohort had meaningful pain reduction, a specific patient subset being breast or prostate cancers with bone metastasis had an average of 40% improvement in pain scores from baseline.
- Breast or prostate cancers with bone metastasis showed significantly less Morphine Milliequivalent (MMEq) of dispensed opioid analgesics prescribed, than the remaining cohort.

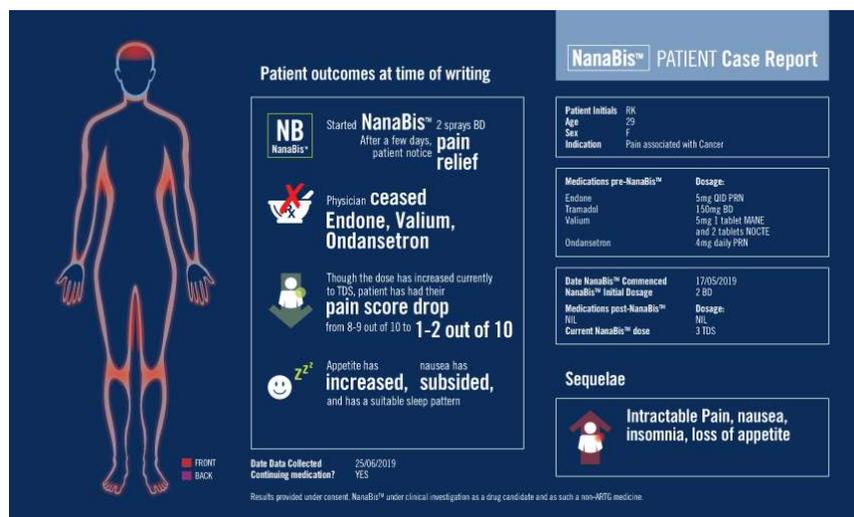
The result was a robust trial that delivered strong results allowing Medlab to focus on Phase 3 designs, specifically in the patient group, metastatic bone pain where breast or prostate are the primary cancers.

Metastatic breast or prostate cancers have a high unmet need with conservative 2017 numbers suggesting 600,000 patients in USA, Canada, Europe and Australia.

Since the completion of the Trial, the majority of patients have ethically continued on NanaBis™, free of charge.

Moving forward, Medlab will undertake secondary analysis of the data whilst canvassing with various global regulatory agencies in preparation of the forthcoming Phase 3 clinical trials.

The following is a case study to illustrate the potential of NanaBis™



Manufacture of Medlab's newest cannabinoid product using CBD from hemp has completed and awaiting transport to Australia for supply under SAS. NanoCBD™ is developed using Medlab's patented delivery platform, NanoCelle™ and is manufactured in a US FDA registered drug facility.

## Depression

As per the ASX announcement on 1 April 2020, Medlab's depression trial at Queensland University of Technology was recently completed. It was a 150 (closed at 120) participant study to follow on from previous trials investigating the use of NRGBiotic™ versus placebo as an adjuvant (used with) to an SSRI and or SNRI (common anti-depressant medications) for people diagnosed with depression that were getting little or no relief from standard medical treatment. NRGBiotic™ has several patents and is available in Pharmacy and healthcare providers.

The plan for NRGBiotic™ is to follow a drug development pathway, where Medlab would expect results publication, product optimisation and further trial work. Medlab plans at the end of this trial to continue talks with Regulatory bodies for drug pathway development which would be critical for future NRGBiotic™ plans.

The focus for the trial is an adjunct (to depression) treatment which is globally estimated to be \$864 million USD market in 2015 and is expected to reach \$1.2 billion USD by 2024<sup>1</sup>. Overall, the global depression market is estimated to be \$15.6 billion USD, growing at 2.4% CAGR.<sup>2</sup>

<sup>1</sup> <https://www.researchandmarkets.com/reports/4199131/global-treatment-resistant-depression-market>

<sup>2</sup> <https://www.globenewswire.com/news-release/2019/05/15/1825506/0/en/Anxiety-Disorder-and-Depression-Treatment-Market-To-Reach-USD-18-90-Billion-By-2026-Reports-And-Data.html>

## NanoCelle™

On the back of our Pharmaceuticals product development, our NanoCelle™ delivery platform offers commercial optionality from allowing other drug manufacturers to adopt under licence. NanoCelle™ is the proprietary delivery platform developed by MDC that allows:

- Use of nanoparticles for faster absorption.
- For increased absorption of ingredients – potentially allowing low dosages.
- Bypassing the human gastrointestinal environment – potentially reducing side effects.
- Increased product stability.
- Versatility as it can be used across several ingredients.

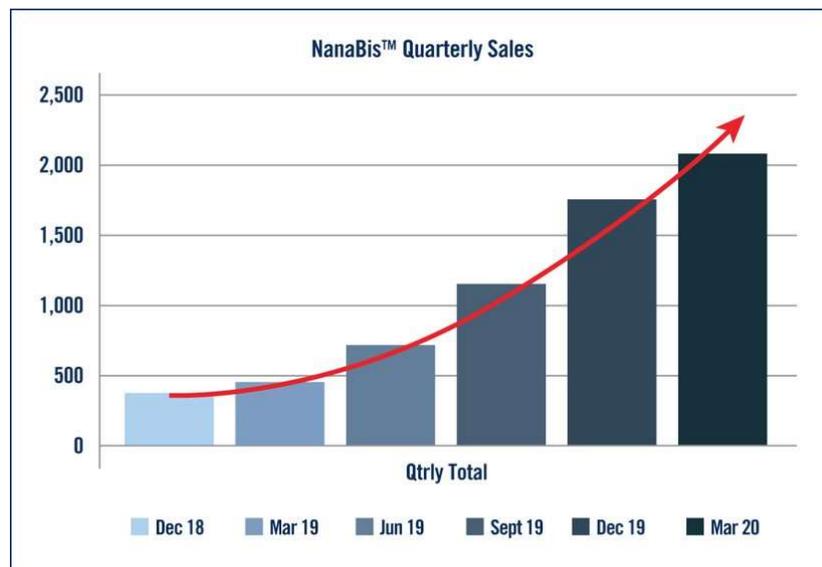
Currently NanoCelle™ is deployed in several nutraceuticals, and about 23 pharmaceutical potentials including NanaBis™ and NanoCBD™ mentioned above. It can be applied to poorly absorbed drugs and offers innovation and renewed product life for otherwise generic drugs.

As per the recent ASX announcement (21 April 2020), where Medlab through a Proof of Concept formulation, was able to complete the application of Medlab Clinical's delivery platform NanoCelle™ technology to develop a nanoparticle Chloroquine (CQ) spray delivered by the oro-buccal membrane.

## COMMERCIALISATION

While Medlab remains focused on the opportunity to deliver a novel pain management alternative to opioids in the form of drug registration (NanaBis™), the parallel commercial activities in Nutraceuticals and Medical Cannabis/Pharmaceuticals continue to deliver solid progress.

The graph below illustrates the quarterly growth in the number of NanaBis™ bottles dispensed by Medlab via the SAS.



- NanaBis™ dispensed under SAS showed solid growth with revenue up 217% year on year and 26% quarter on quarter. The number of NanaBis™ bottles dispensed for the quarter grew to over 2,000 bottles for the first time.
- Medlab continues to look for global opportunities through the supply of Cannabis products as illustrated with recent agreement in Hong Kong and UK. The first PO was received for the new

product to be manufactured combining CBD from hemp and an existing Medlab nutraceutical product, MgOptima, (named MgOptimaCBD) for UK markets

- Medlab's nutraceuticals business continues to expand into new revenue territories including the US, UK (as mentioned above) and Asia where we should see revenue flow over the next few months without material operating or capital expenditure. The Company recently announced a Heads of Agreement to expand the nutraceutical label through a potential supply agreement into India and Eastern Europe.
- The domestic Australian nutraceutical business reported a better quarter with an increase of 42% quarter on quarter and 27% year on year in invoiced sales, with lower net cash burn. The review and rationalisation of the domestic Australian nutraceuticals business after a year of expansion with wholesale distribution partners continues. Medlab will be driven by product quality, margin and not by market share. A recent increase in awareness and demand of Medlab's immune products resulted in recent out of stocks.

## OTHER

### Tele-Health

On 18 March Medlab announced the launch of a unique first, a free online clinical service, offering advice and connecting the Australian public to doctors, specialists, naturopaths and pharmacists. Medlab's Virtual Clinic is for people who are seeking advice on how nutraceuticals may be used for supportive health/medical care.

This initiative builds stronger and closer ties between the Medlab brand closer to its end users.

Medlab's complimentary healthcare practitioners are educated and audited by the company's medical team to ensure a standard of care, confidentiality and ongoing training consistent with other healthcare professionals, this includes offering unbiased advice.

Since launch, we have also now Pharmacists available to offer medication advice.

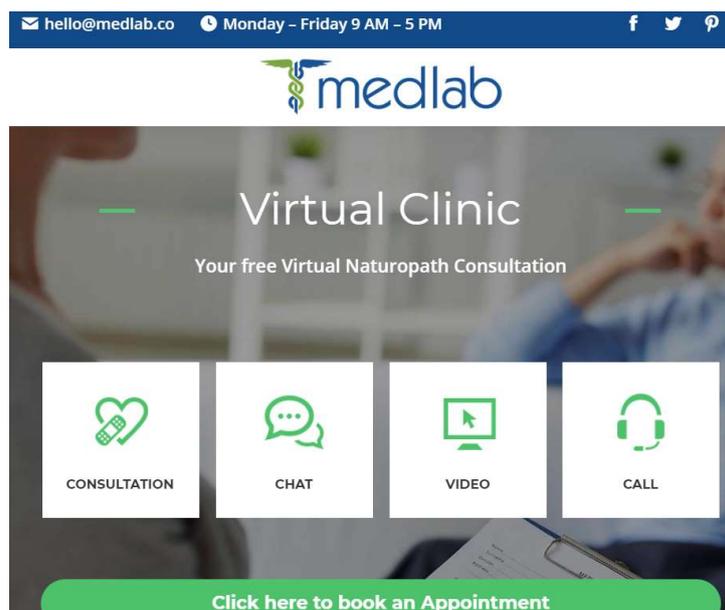


Figure 1 <https://clinic.medlab.co>

**Digital**

In an effort to increase the awareness of the nutraceutical range, Medlab recently launched a new digital selling platform at <https://shop.medlab.co/>

**CORPORATE**

Cash balance of \$6.397m as at 31 March 2020.

**SUMMARY**

Medlab has a number of catalysts signifying progression to watch out for. This progression is important as it serves as steppingstones to our ultimate goal, new approved drugs with significant global potential.

The next short-term period continues to be very exciting for Medlab with release of the Depression trial results, continued preparation of the NanaBis Phase 3 trial protocols for the US and Australia as well as FDA IND application.

In addition, Medlab will continue to pursue growth opportunities in the commercial aspects of the business, pharmaceutical and nutraceutical.

On behalf of the Board, we thank our Shareholders for their continued support.

Sincerely,



Dr Sean Hall  
Managing Director

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

MEDLAB CLINICAL LIMITED

**ABN**

51 169 149 071

**Quarter ended ("current quarter")**

31 March 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date ( 9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	1,356	5,086
1.2 Payments for		
(a) research and development	(1,506)	(3,940)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(471)	(1,603)
(d) leased assets	(283)	(689)
(e) staff costs	(873)	(3,402)
(f) administration and corporate costs	(655)	(1,957)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	13	69
1.5 Interest and other costs of finance paid	(21)	(129)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	2,100
1.8 Other (provide details if material)		
(a) payments for inventory	(630)	(4,139)
(b) IP costs	(44)	(117)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(3,114)</b>	<b>(8,721)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(22)	(166)
(d) investments	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date ( 9 months) \$A'000
(e) intellectual property	-	-
(f) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
2.3 Cash flows from loans to other entities	-	-
2.4 Dividends received (see note 3)	-	-
2.5 Other (provide details if material)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(22)</b>	<b>(166)</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	5,000
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	-	-
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(10)	(287)
3.5 Proceeds from borrowings	610	3,194
3.6 Repayment of borrowings	(762)	(4,040)
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>(162)</b>	<b>3,867</b>

Consolidated statement of cash flows		Current quarter \$A'000	Year to date ( 9 months) \$A'000
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	9,689	11,442
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,114)	(8,721)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(22)	(166)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(162)	3,867
4.5	Effect of movement in exchange rates on cash held	6	(25)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>6,397</b>	<b>6,397</b>

5. Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts		Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	6,397	9,689
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>6,397</b>	<b>9,689</b>

**6. Payments to related parties of the entity and their associates**

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter  
\$A'000**

-

-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

**7. Financing facilities**

*Note: the term "facility" includes all forms of financing arrangements available to the entity.*

*Add notes as necessary for an understanding of the sources of finance available to the entity.*

	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Banking Facility	-	-
<b>7.4 Total financing facilities</b>	<b>2,000</b>	<b>325</b>

7.5 **Unused financing facilities available at quarter end** 1,675

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (Item 1.9)	(3,114)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	6,397
8.3 Unused finance facilities available at quarter end (Item 7.5)	1,675
8.4 Total available funding (Item 8.2 + Item 8.3)	8,072
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>2.59</b>

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

## Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 27 April 2020

Authorised by: By the Board of Directors

## Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.