



31 January 2020

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

Dear Sir/Madam

## **APPENDIX 4C – JANUARY 2020**

Please find attached the Appendix 4C for the December 2019 Quarter for Medlab (ASX: MDC).

The key highlights for the period have been:

- **Record quarterly revenue achieved in cannabis sales**, with an increase of approximately 50% over the previous best quarter and 400% over the previous corresponding period. We expect sales performance to be further enhanced by recently announced production move to Tasmanian Alkaloids Pty Ltd.
- **Royal North Shore Hospital (RNSH) clinical trial has been completed** for cancer pain drug candidate, NanaBis™.
- **Impressive start to the NanaBis™ Observational Study**, prior to formal launch. Approximately 125 Australian Doctors and 250 patients have been recruited. The recruitment is ahead of the formal National rollout.
- **Agreement to manufacture NanaBis™** executed with Tasmanian Alkaloids Pty Ltd allowing an increase in manufacturing capabilities to **meet increased demands**, and more-so progress the regulatory endpoints with TGA, USFDA and EMA
- **Collections of \$1.641m**, an increase of approx. 29% over the corresponding period last year. Collections declined quarter on quarter as Nutraceuticals sales consolidated after the addition of significant wholesale distribution in previous two quarters.
- Agreement executed to expand the nutraceutical range into the US which was launched at a medical conference in December, the 27th Annual World Congress, run by the American Academy of Anti-Aging Medicine (A4M).
- Agreement executed to expand the Medlab range into the UK with first order received for new product combining CBD from hemp and MDC's nutraceutical product MgOptima, (MgOptimaCBD), in production now.

The key highlights looking forward for the March quarter:

- **Royal North Shore Hospital clinical trial** for cancer pain drug candidate NanaBis™, formal independent results expected February. Internal reviews of the data provide encouraging initial results.

## RESEARCH

Medlab's research programme in chronic diseases, including pain management and depression continues to progress well. Both chronic pain and depression represent significant earning opportunities globally.

### Medical Cannabis

Medlab's research in cannabis-based medicine (NanaBis™) continues to make material progress in delivering clinical trials evidence with an end goal of drug registration in cancer pain management. Medlab's Phase 2 trial at Royal North Shore hospital has completed. This is a significant milestone with preliminary data very encouraging as the Company develops Phase 3 trial protocols to be used in Australia and USA. Medlab intends obtaining IND status for NanaBis™ from the FDA later this year. The ultimate endpoint for NanaBis™ is an approved global drug for Cancer pain which would lead to significant commercial opportunities.

The highly significant data from the recently completed Phase 2 Clinical Trials at Royal North Shore Hospital is currently being independently evaluated and written up, with formal results expected by the end of February 2020.

With the recently announced agreement with Tasmanian Alkaloids Pty Ltd, MDC is in a very strong position to upscale its manufacturing output to meet increased demands from:

- Australian SAS approved use
- Observational Study
- Phase 3 in both Australia and USA

Manufacture of MDC's newest cannabinoid product using CBD from hemp, NanoCBD™ is nearing completion. NanoCBD™ is developed using Medlab's patented delivery platform, NanoCelle™. It is manufactured in a US FDA drug facility and first revenues via the SAS are expected in the March quarter. NanoCBD™ also represents global opportunities as potential offshore regulatory environments change through local partnerships. Our adoption of approved drug facility manufacturing and clinical trials philosophy to product development puts us in a strong position to comply with changing regulations for CBD globally as this market develops.

### Depression

Medlab's depression trial at Queensland University of Technology is progressing ahead of expectations. The trial involves MDC's multi-patented NRGBiotic™ from its nutraceutical range with current results suggesting the trial will complete earlier than originally required.

The plan for NRGBiotic™ is to follow a drug development pathway, whereby after this trial, Medlab would expect results publication, product optimisation and further trial work. Medlab plans at the end of this trial to continue talks with the TGA 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, at 2.4% CAGR.<sup>2</sup>

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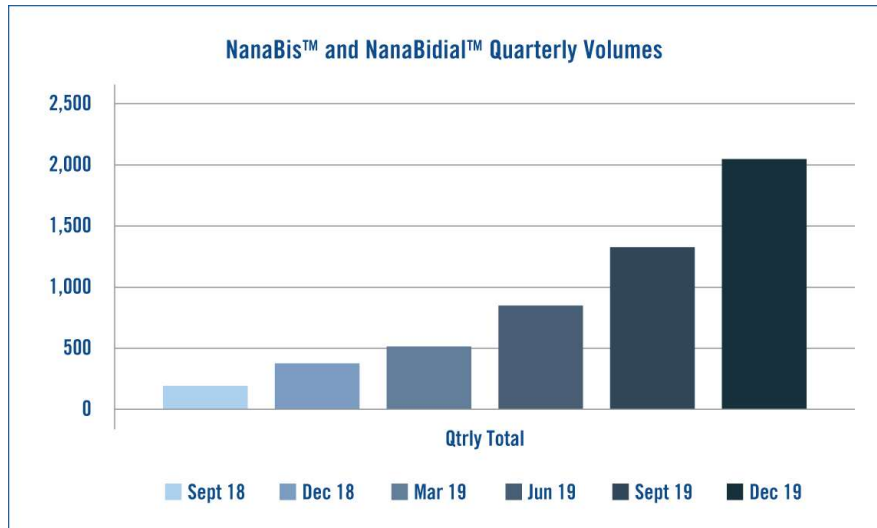
<sup>1</sup> <https://www.researchandmarkets.com/reports/4199131/global-treatment-resistant-depression-market>

<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>

## COMMERCIALISATION

While we remain focused on the opportunity to deliver a pain management alternative to opioids in the form of drug registration, the parallel commercial activities in Nutraceuticals and Medical Cannabis/Pharmaceuticals continue to deliver solid progress. Revenues from our core cannabis-based medicines (NanaBis™ and NanaBidual™) are starting to feature more prominently in quarterly incomes.

The graph below illustrates the quarterly growth in the number of Cannabis bottles dispensed by Medlab (NanaBis™ and NanaBidual™) via the SAS.



- Products dispensed under SAS showed solid growth (predominantly through the lead product, NanaBis™) with revenue up 262% year on year and 46% quarter on quarter. The number of bottles dispensed for the quarter grew to over 2,000 bottles which represents growth of over 50% quarter on quarter and 400% year on year. As pleasing as the revenue growth being made through SAS sales is, we stress that these sales are a step along the path rather than a commercialisation strategy in itself – our ultimate goal is achieving drug registration status and we expect global revenue opportunities in achieving that status to be far more material than any measure of success under the SAS.
- Global opportunities exist through recent commercial agreements providing expansion into the USA and UK. The nutraceutical range through the collaboration between MDC and American Nutritional Corp Inc was launched at the recent medical conference, the 27th Annual World Congress, run by the American Academy of Anti-Aging Medicine (A4M). In the UK, the agreement with Cultech Ltd has just resulted in the receipt of the first PO for the new product to be manufactured combining CBD from hemp and MDC's nutraceutical product, MgOptima, (MgOptimaCBD).
- MDC's nutraceuticals business is expanding 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 Australian nutraceuticals business is likely to rationalise somewhat after a year of expansion with large wholesale distribution partners and focus on better performing products – we will be driven by product quality, margin and not by market share.
- Potential further revenue opportunities exist through the commercialisation of inhouse developed technologies from royalties on blood assays developed as part of our clinical trials protocols and now available for commercial use in other clinical trials and therapeutic monitoring. Further information will be made as progress is made.

These commercial opportunities represent opportunities for significant growth, whether in the domestic pharmacy market (nutraceutical and pharmaceutical) and internationally.

## **CORPORATE**

Cash balance of \$9.689m as at 31 December 2019.

### **SUMMARY**

Medlab is committed to delivering advanced progress in the significant pain management commercial opportunity globally. Success in progress to drug registration through trials success offers a quantum change in outlook for Medlab.

Parallel opportunities including the growth in Nutraceuticals (global opportunities) and through the commercialisation of the new cannabis based products, NanoCBD™ and MgOptimaCBD, with first orders received for both.

MDC also has licensing opportunities for its NanoCelle™ delivery platform. We will keep the market updated on any contract success in the path to licensing this technology.

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

The first half of calendar year 2020 is expected to be very exciting for the Company with the release of Phase 2 trial data, preparation of Phase 3 trial protocols for the US and Australia and aiming for IND status for NanaBis™ in the USA.

We expect to deliver significant news on progress on across our businesses and exciting opportunities for our customers, our staff and our shareholders.

For and behalf of the Board.



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 December 2019

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date ( 6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	1,641	4,044
1.2 Payments for		
(a) research and development	(1,494)	(2,666)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(483)	(1,178)
(d) leased assets	(247)	(406)
(e) staff costs	(1,118)	(2,408)
(f) administration and corporate costs	(777)	(1,417)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	20	55
1.5 Interest and other costs of finance paid	(74)	(100)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	2,100	2,100
1.8 Other (provide details if material)		
(a) payments for inventory	(1,267)	(3,510)
(b) IP costs	(25)	(74)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,724)</b>	<b>(5,560)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(45)	(143)
(d) investments	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date ( 6 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</b>	<b>Net cash from / (used in) investing activities</b>	<b>(45)</b>	<b>(143)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	5,000	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	(275)	(275)
3.5	Proceeds from borrowings	784	2,584
3.6	Repayment of borrowings	(983)	(3,328)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>4,527</b>	<b>3,981</b>

Consolidated statement of cash flows		Current quarter \$A'000	Year to date ( 6 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	6,942	11,442
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,724)	(5,560)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(45)	(143)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	4,527	3,981
4.5	Effect of movement in exchange rates on cash held	(11)	(31)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>9,689</b>	<b>9,689</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	9,689	1,942
5.2	Call deposits	-	5,000
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>9,689</b>	<b>6,942</b>

6. Payments to related parties of the entity and their associates		Current quarter \$A'000
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	-

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.

	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Banking Facility	-	-
<b>7.4 Total financing facilities</b>	2,000	390

7.5 **Unused financing facilities available at quarter end** 1,610

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)	(1,724)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	9,689
8.3 Unused finance facilities available at quarter end (Item 7.5)	1,610
8.4 Total available funding (Item 8.2 + Item 8.3)	11,299
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>6.55</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: 31 January 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.