

28 October 2020

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

## CONTINUED STEADY CASH BURN AS MEDLAB ADVANCES NANABIS™ DEVELOPMENT – APPENDIX 4C

Medlab Clinical (ASX.MDC) a company with a portfolio of novel drug candidates enhanced by its drug delivery platform and used for the treatment of chronic pain and disease, is pleased to provide a business update and quarterly cash flow report for the period ended 30 September 2020 (Q1 2021).

## **Highlights**

- Preparation for global Phase III study of NanaBis™ advancing with George Medical appointed to manage US sites
- Data from real-world observation study of NanaBis™ shows 59.5% reduction in pain scores
- 1,473 bottle of NanaBis™ were dispensed during the quarter, representing an increase of 29% year on year
- Well capitalised to accelerate clinical and commercial activities with continued cash management
- Australian patent granted for NanoCelle® delivery platform
- Rationalisation of the domestic nutraceutical business continued with a recorded increase in after-discount sales of 16%

Dr Sean Hall, Managing Director of Medlab Clinical said, "This quarter we have continued to develop commercial pathways for the company and differentiate ourselves as a fast-moving biotechnology company with a global opportunity for our non-opioid alternative for the treatment of cancer-induced bone pain. Operationally we have been focused on advancing the development of our lead candidate NanaBis™ as we prepare to file an investigational new drug application with the US FDA later this year and initiate a global Phase III study.

"As one of the most clinically advanced medicinal cannabis products for the treatment of cancer-induced pain, we are attracting the interest of the global investment industry and pharmaceutical industry. In October we were invited to present at Jefferies Medicinal Cannabis summit and the BIO investor forum – two high profile international forums."

## Cannabinoid portfolio update: NanaBis™ Observational Study Progress update, signs CRO for NanaBis™ Phase III trial

Medlab published the third monitoring report for its ongoing study of NanaBis™, which is being developed as a non-opioid alternative for the treatment of cancer-induced bone pain. The study showed a 59.5% reported reduction in pain (unadjusted) based on average dose of four sprays per day. Importantly, these results are consistent with an earlier Phase I/II clinical trial completed at Royal Sydney North Shore Hospital earlier this year.

The consistent results being achieved across the clinical trials for NanaBis™ are encouraging and are a further step in achieving the goal obtaining regulatory approval and providing cancer patients with an alternative to manage pain.

During the quarter, Medlab signed an agreement with leading global CRO George Clinical Pty Ltd, to provide clinical services support for Medlab's upcoming NanaBis™ Phase III trials.

George Clinical Pty Ltd will partner with Medlab to provide site selection and feasibility, trial recruitment and ongoing site management for US trial sites of NanaBis™. They will also implement data services for all Phase III sites.

The US market is a priority for NanaBis™ Medlab has a business development team focused on US NanaBis™ deals.

Use of NanaBis™ under the Special Access Scheme in Australia provide access to a growing user base and revenue stream. Sales this quarter were 1,473 units, up 29% year on year but down slightly on the previous quarter (1,575 units, Q4). In Q2 the company experienced supply issues for NanaBis™ which has had a short-term impact on momentum of prescribed use under the Special Access Scheme. Since moving all manufacturing to TasAlk, there is sufficient supply of material to meet expected demand under SAS and for a Phase III trial.

A further 257 units of NanoCBD™ - a CBD only formulation - were sold during the quarter.

Medlab has reached the 10,000 unit milestone in products sold under the SAS.



## Australian patent granted for NanoCelle® Delivery Platform

Medlab was delighted to have an Australian patent granted for its NanoCelle® drug delivery platform during the quarter. This was the first patent granted for the technology and provides validation of the science behind NanoCelle® and its innovative mode of action.

The Australian patent provides protection until March 2036. Medlab has also filed patent applications in the US, EU, NZ, SG, HK and Canada.

NanoCelle® is used to improve drug solubility issues, making drugs more easily metabolised, absorbed and consequently utilised and has application to many prescription and over the counter medications. Medlab's NanaBis™ formulation has been optimized using NanoCelle® and provides a strong proof of concept for the effectiveness of this drug delivery platform.

Medlab continues to seek partnerships to drive value from NanoCelle®. There are significant partnership opportunities for NanoCelle® across pharmaceuticals, food technology, consumables and other industries.

## **Nutraceuticals update**

The Nutraceuticals business continued its expansion via banner pharmacies, global partners and enhanced digital sales and marketing. Sales for the quarter were \$1.11M (after discount) up 16% on the previous quarter, showing signs of recovery from the initial impact of the COVID-19 pandemic.

## Cashflow and corporate highlights

Medlab reported cash receipts of \$1.4M (steady from the previous) and net operating cash outflow of \$2.02M (vs \$1.99M in previous quarter). Excluding the government incentives, the net operating burn was \$2.584m. Cash continues to be managed responsibly.



The company's cash balance as of September 30 was \$8.38M. This included the proceeds of the Share Purchase Plan completed in July 2020 which raised \$1.57M before costs. Subsequent to the end of the quarter, the company received an R&D tax credit of \$ \$2.44m. This is not reflected in the cash balance as of 30 September 2020.

The company appointed Laurence McAllister as Non-Executive Director during the quarter. Mr McAllister is currently CEO of McPherson's Limited, a global consumer goods company in the Health, Wellness & Beauty sector with a market capitalisation of \$266 million. Mr McAllister will leverage his experience in consumer health/FMCG, global pharmaceutical industry and leading an ASX listed company to help guide the business through its next stage of growth.

A payment of \$163,000 to related parties were made. These payments were Director fees and wages, tax consulting services by Hall Chadwick (director related entity of Mr Drew Townsend) and wages to a related party of Dr Sean Hall.

**ENDS** 

Authorisation & Additional information

This announcement was authorised by the Board of Directors of Medlab Clinical Limited.

## About Medlab - www.medlab.co

Medlab Clinical is an Australian based medical life science company, developing therapeutic pathways for diagnosed chronic diseases. It is advanced in developing therapies for pain management, depression and obesity as well as earning revenue from sale of nutritional products in Australia and the United States. In pain management Medlab is developing cannabis-based medicines. The Medlab developed nano-particle medicine delivery system, NanoCelle™ is being applied to its medicines, nutritional products and off-patent drugs like statins, Medlab has a growing patent portfolio.

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## **Appendix 4C**

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

## Name of entity

MEDLAB CLINICAL LIMITED

## ABN Quarter ended ("current quarter")

51 169 149 071 30 September 2020

Con	solidated statement of cash flows	Current quarter \$A'000 (3 months) \$A'000	
1.	Cash flows from operating activities		
1.1	Receipts from customers	1,387	1,387
1.2	Payments for		
	(a) research and development	(1,750)	(1,750)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(312)	(312)
	(d) leased assets	(84)	(84)
	(e) staff costs	(910)	(910)
	(f) administration and corporate costs	(142)	(142)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	5	5
1.5	Interest and other costs of finance paid	(12)	(12)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	562	562
1.8	Other (provide details if material)		
	(a) payments for inventory	(670)	(670)
	(b) IP costs	(96)	(96)
1.9	Net cash from / (used in) operating activities	(2,022)	(2,022)

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(7)	(7)
	(d) investments	-	-

ASX Listing Rules Appendix 4C (17/07/20)

Page 1

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 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)	-	-
2.6	Net cash from / (used in) investing activities	(7)	(7)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,570	1,570
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	(42)	(42)
3.5	Proceeds from borrowings	870	870
3.6	Repayment of borrowings	(896)	(896)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material) (a) repayment of lease liability	(148)	(148)
3.10	Net cash from / (used in) financing activities	1,354	1,354

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	9,063	9,063
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,022)	(2,022)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(7)	(7)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,354	1,354
4.5	Effect of movement in exchange rates on cash held	(10)	(10)
4.6	Cash and cash equivalents at end of period	8,378	8,378

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	8,378	9,063
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	8,378	9,063

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	163
6.2	Aggregate amount of payments to related parties and their associates included in item 2	_
Direc	ctor and associates fees/wages	1

wn at nd
52
52
1,948

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.

A debtor finance facility secured over debtors was established with Scottish Pacific Business Finance in November 2017 (renewed June 2019). The facility is over a 24-month term with a discount charge of 8.04% and is for \$2m and matures June 2021

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,022)
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,378
8.3	Unused finance facilities available at quarter end (item 7.5)	1,948
8.4	Total available funding (item 8.2 + item 8.3)	10,326
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	5.11
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	8.5 as "N/A". Otherwise, a

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

8.6.1 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

8.6.2 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

8.6.3 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

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

## **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:	28 October 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.
- 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".
- 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.