



25 January 2021

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

MEDLAB CLINICAL APPENDIX 4C AND BUSINESS UPDATE

Medlab Clinical Ltd (ASX: MDC, Medlab, the Company), 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 31 December 2020 (Q2 2021).

Highlights

- US Food and Drug Administration (FDA) for Investigational New Drug (IND) application received, allows Medlab to initiate its pivotal Phase III trial of NanaBis™ at sites in the US.
- The NanaBis™ Phase III trial rollout in the UK received third-party validation, and support, from the UK National Institute of Health Research (NIHR)
- Positive results from latest audit of NanaBis™ observational study
- Sales of NanaBis™ under Special Access Scheme continue to increase quarter on quarter
- Nutraceuticals sales up 8% on previous quarter

In the December quarter, Medlab applied to the US FDA for Investigational New Drug (IND) status for its lead drug candidate, NanaBis™, for the treatment of cancer-induced bone pain. Medlab announced the FDA's grant of IND status for NanaBis™ on January 19, 2021.

FDA approval allows Medlab to initiate its pivotal Phase III trial of NanaBis™ at sites in the US. The US joins Australia and the UK as approved Phase III trial jurisdictions. Medlab is submitting a second IND for the expanded access scheme, which is similar to the compassionate use program in Australia. If successful, NanaBis™ could be the first cannabis-derived drug candidate, containing THC, that is able to be prescribed under the expanded access scheme in the US.

The approval of the IND followed the decision in Q2 by one of the world's leading healthcare research organisations, the UK's National Institute of Health Research (NIHR), to support Medlab in the UK arm of the NanaBis™ Phase III trials.

During the December quarter, Medlab also reported positive results – consistent with existing clinical data – across all criteria in its 12-month observational study of NanaBis™. The fourth monitoring report on the study demonstrated a 55% reduction in pain scores. It also indicated significant improvements in quality-of-life outcomes such as “general activities”, “sleep” and “mood”. The observational study was initiated following talks with the US FDA regarding the pathway for regulatory approval.

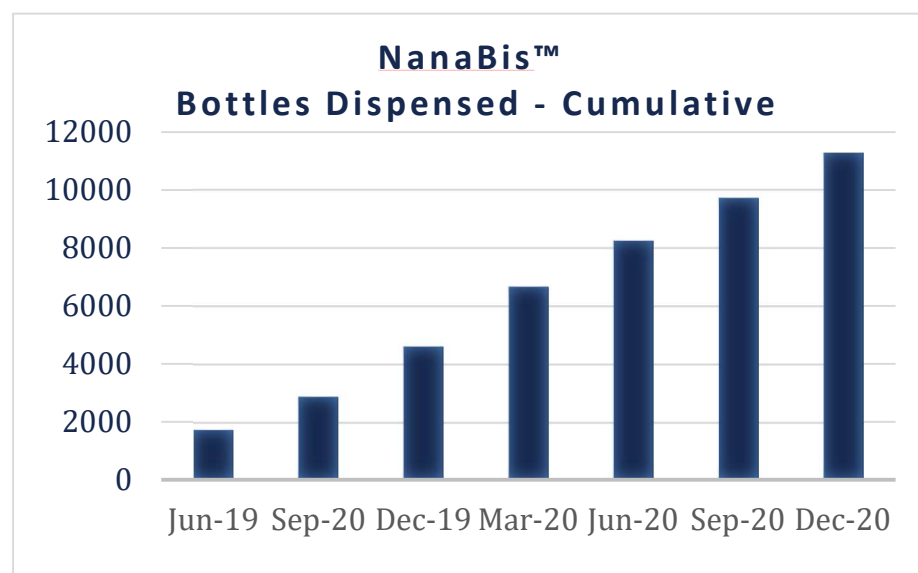
“Medlab continues to make solid progress in the development of NanaBis™, and the grant by the US FDA of IND status for NanaBis™ is a major milestone for Medlab. It puts us in a leading position when you consider that NanaBis™ is now the only cannabinoid-based drug candidate under development ready to initiate a Phase III study,” said the Managing Director of Medlab, Dr Sean Hall.

“The IND approval and support of the NIHR is an important validation, and also signifies the interest in the clinical community to see a medicinal-cannabis product that is clinically validated and providing an alternative for the management of cancer-related bone pain.

“In Q2, Medlab also made strong progress in the development of the NanoCelle® drug delivery platform, with the Company advancing applications into diverse programs. We’ve had a strong start to 2021, making solid clinical and regulatory progress that will bring commercial opportunities,” Dr Hall said.

Cashflow and corporate highlights

The number of NanaBis™ bottles dispensed rose by six per cent in Q2 compared to Q1 to 1,560 units. Demand via the Special Access Scheme continues to grow with approx. 12,000 bottles being dispensed



In Q2, Medlab’s nutraceuticals business increased invoiced sales (pre-discount) by over 8% to \$1.3m, compared to Q1. Customer advocacy is growing, with strong testimonials and rapidly increasing brand loyalty.

Medlab reported cash receipts of \$1.26 million for the December quarter. Net operating cash outflow was \$1.17 million, down from \$2 million in the September quarter. The Company received an R&D tax grant of \$2.437 million during the December quarter. Medlab recorded an additional other income of \$500,000 for Q2.

The company’s cash balance as of December 31 was \$6.877 million.

Payments totalling \$174k were made to related parties. 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 pharmaceuticals 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

51 169 149 071

Quarter ended ("current quarter")

31 December 2020

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,255	2,568
1.2 Payments for		
(a) research and development	(1,938)	(3,438)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(641)	(953)
(d) leased assets	(20)	(39)
(e) staff costs	(1,004)	(1,978)
(f) administration and corporate costs	(806)	(1,110)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	8	14
1.5 Interest and other costs of finance paid	(15)	(27)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	2,675	3,237
1.8 Other (provide details if material)		
(a) payments for inventory	(624)	(1,293)
(b) IP costs	(56)	(152)
1.9 Net cash from / (used in) operating activities	(1,166)	(3,171)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(10)	(16)
(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)	-	-
2.6	Net cash from / (used in) investing activities	(10)	(16)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	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	-	(39)
3.5	Proceeds from borrowings	580	1,450
3.6	Repayment of borrowings	(731)	(1,626)
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	(173)	(343)
3.10	Net cash from / (used in) financing activities	(324)	(1,012)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 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	8,378	9,063
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,166)	(3,171)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(10)	(16)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(324)	1,012
4.5	Effect of movement in exchange rates on cash held	(1)	(11)
4.6	Cash and cash equivalents at end of period	6,877	6,877

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	6,877	8,378
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)	6,877	8,378

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	174
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
Director and associates fees/wages		

7.	Financing facilities <i>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.</i>	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	2,000	2
7.4	Total financing facilities	2,000	2
7.5	Unused financing facilities available at quarter end		1,998
7.6	<p>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.</p> <p>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</p>		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,166)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,877
8.3	Unused finance facilities available at quarter end (item 7.5)	1,998
8.4	Total available funding (item 8.2 + item 8.3)	8,875
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	7.61
	<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
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	
	<i>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.</i>	

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:25 January 2021.....

Authorised by:By the Board of Directors.....
(Name of body or officer authorising release – see note 4)

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.