ASX Announcement

Medlab Clinical Appendix 4C and Business update – Q1 2023

SYDNEY, October 28, 2022 - Medlab Clinical Ltd (ASX:MDC) (Medlab, the Company), an Australian biotech using delivery technology to enhance medicines effectiveness is pleased to provide a business update and quarterly cash flow report for the period ended 30 September 2022 (Q1 2023).

Key Financial Highlights for Quarter

- **Cash receipts,** NanaBis / NanoCBD sales to patients via Doctors Special Access Scheme Approval $0.3M and Research and Development Grant $3.6M, received from Government - with thanks
- **Expenditure** $3.2M of which some $0.3M spent on drug development work for NanaBis at USA registered drug development facility
- **Cash at 30th September** $5.3M - expectation is approximately $1M will be recovered from this expenditure in next Research & Development grant (Sept 2023)

NASDAQ Listing & Share USA Issue

Major work for the US listing has been completed and relevant applications lodged with authorities (Securities Exchange Commission, FINRA and NASDAQ; queries received and answered, awaiting approvals). As the Shareholders approval as it relates to the EGM, was restricted to three (3) months, a time extension for a further three (3) months has been granted by the ASX (see announcement 21 Oct).

The Company's NASDAQ reserved symbol is MDLB.

NanaBis™ Work Published

The NanaBis Advanced Cancer Pain P1/P2 study conducted at the Royal North Shore Hospital, under Prof Stephen Clark has been peer-reviewed and published in PLOS ONE https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0270543.

The Company wishes to remind shareholders, the study met all primary and secondary endpoints:

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. (Numerical Pain Rating Scales (NRS): p-value 0.046 and Brief Pain Inventory (BPI) : p-value 0.04)
- Breast or prostate cancers with bone metastasis showed significantly less Morphine Milliequivalent (MMEq) of dispensed opioid analgesics prescribed, than the remaining cohort.
- No change in number of rescue medication doses during the course of the Trial.

The NanaBis™ evidence package is today fortified with data from about 1,200 Australian patients contributing to long term use, adverse events (representing 12% non-serious and 1.3% serious), impact on standard care (opioid reductions) and impact on the patient's quality of life.

Currently, the Company is completing the CMC package which is a considerable part of the new drug application and is expecting to return to clinical trials 1st ½ 2023.

What is Pain?

Classified as a chronic illness, including indirect costs with lost economic productivity costs the United States approximately US$3.7 trillion each year, per the American Action Forum. In 2010, the National Academy of Sciences estimated that more than 100 million American individuals suffered from pain, resulting in estimated costs from health care and missed work time of approximately US$3.7 trillion per year. Traditionally, pain management has centered around opioid use. Over 81,000 drug overdose deaths occurred in the United States in the 12 months ending in May 2020, the highest number of overdose deaths ever recorded in a 12-month period, according to recent provisional data from the Centers for Disease Control and Prevention.

Depression Work Now PATENTED

The Depression Phase 2 study (partly funded by government grant) was conducted at Queensland University of Technology under Prof Matthew Bambling and Prof Esben Strodl, was on the effect of our ARTG Listed Medicine "NRGBiotic" As an outcome of this study, specific chemicals were highlighted as a means to simplify the overall formulation making it far more suitable for drug registration.

The Company wishes to remind its shareholders that this study met all primary endpoints and 2/3 secondary endpoints:

The Primary Outcomes (2/2 MET) were:

1. MET–Participants taking both NRGBiotic™, and an anti-depressant had greater symptom remission over the 8 weeks period than those on an anti-depressant alone (p=0.015).
2. MET-Incidence of dysbiosis assessed by faecal analysis showed both groups were dysbiotic, holding to the premise that anti-depressant medications adversely affect the intestinal bacteria leading to an unbalanced dysbiotic gut.

The Secondary Outcomes (2/3 MET) were:

1. MET-Participants taking both NRGBiotic™ and an anti-depressant had greater proportional increase in Quality of Life (QoL) Scale from baseline to 8 weeks, than those on anti-depressants alone (p=0.015).
2. MET -Participants taking both NRGBiotic™ and an anti-depressant had greater improvement in non-clinical levels of symptoms (e.g., interpersonal, social, etc) than those on anti-depressant medications alone (p=0.003)
3. NOT MET-Proportion of participants with a reduction in lipopolysaccharides (LPS^) showed no noticeable differences between the groups.

Lab work (in vitro work) has commenced at our facilities for a simplified NRGBiotic contain 1 drug substance encapsulated into our NanoCelle® delivery platform.

The Company is very pleased to announce New Patents protecting this IP, are being granted:

Jurisdiction	Patent	Type of Patent	Patent/Application Number	Status	Patent Expiry
Australia	Treatment for depression and depressive disorders	Use	2015337800	Granted	28/10/2035
Europe	Treatment for depression and depressive disorders	Use	15854029.4	Granted	28/10/2035
New Zealand	Treatment for depression and depressive disorders	Use	731151	Granted	28/10/2035
United States	Treatment for depression and depressive disorders	Use	11135181	Granted	28/05/2037
Canada	Treatment for depression and depressive disorders	Use	2964971	Granted	28/10/2035
With the following Territories still pending:					
Singapore	Treatment for depression and depressive disorders	Use	11201703193X	Pending	28/10/2035
Hong Kong	Treatment for depression and depressive disorders	Use	17109856.5	Pending	28/10/2035

NRGBiotic™ as an ATRG Listed Medicine is patented in several regions and is subject to several executed partnering arrangements.

What is Major Depressive Disorder (MDD)?
We believe mental health continues to be recognized as a growing issue globally. Like opioids, the global mental health problem was exacerbated by some 25% due to the recent COVID-19 pandemic.
We believe currently available antidepressant therapies do not effectively control or cure depressive symptoms. Furthermore, refractory major depressive disorder is characterized by recurrent, long-lasting cycles of severe, often suicidal depressive episodes that do not remit using multiple types of antidepressant therapies.

Given that major depressive disorder ("MDD") is a leading cause of disability worldwide; only 50% of patients with MDD respond to the first trial of an antidepressant, and 36.8% of patients achieve remission after a first course of antidepressant treatment. Patients with MDD who respond partially to an adequate trial of antidepressant often need an augmentation agent to further optimize the response.

Medlab settles into UNSW campus laboratory and closes Alexandria facility

The Company has settled into its new laboratory on campus at University of New South Wales (UNSW). This change will reduce overheads and put our Research people into a good work environment. Our major work will be developing the new depression formula, and testing and working with the two universities (UNSW and Macquarie University) on the Nasal RNA program.

4.7C.3 Ruling

Pursuant to ASX Listing Rule 4.7C.3, the Company advises that during the quarter, payments made to related parties and their associates in the aggregate amount of **$0.2M**. As already noted in item 6 of Appendix 4C, these payments were for Director fees and wages, tax consultancy services by Hall Chadwick (Director-related entity of Mr Drew Townsend) and wages to related parties of Dr Sean Hall (CEO).

- ENDS -

Authorisation & Additional information
This announcement was authorised by the Board of Directors of Medlab Clinical Limited.

About Medlab Clinical:

Medlab Clinical Ltd (ASX:MDC) is pioneering the use of NanoCelle® a proprietary, patented delivery technology using water soluble nanoparticles®, allowing for enhanced medical properties, including increased efficacy, safety, patient compliance and stability.

Medlab's investigative drug pipeline comprises several small and large molecules from repurposing generic medicines to enhancing the delivery of immunotherapies.

Patented lead drug candidate NanaBis™ is being developed for cancer bone pain as a viable alternative to opioid use. Data to date, strongly suggests NanaBis™ may be equally effective in non-cancer neuropathic pain. Medlab operates in Australia (Head Office), USA, and the UK.

For more information, please visit www.medlab.co

Medlab – *better medicines, better patient care*

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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 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	262	262
1.2	Payments for		
	(a) research and development	(1,420)	(1,420)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	(263)	(263)
	(e) staff costs	(1,205)	(1,205)
	(f) administration and corporate costs	(807)	(807)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	5	5
1.5	Interest and other costs of finance paid	(1)	(1)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	3,588	3,588
1.8	Other (provide details if material)		
	(a) payments for inventory	0	0
	(b) IP costs	(74)	(74)
1.9	**Net cash from / (used in) operating activities**	**84**	**84**

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

Consolidated 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**	**0**	**0**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
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	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
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	-	-
3.10	**Net cash from / (used in) financing activities**	**0**	**0**

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	5,191	5,191
4.2	Net cash from / (used in) operating activities (item 1.9 above)	84	84
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	17	17
4.6	**Cash and cash equivalents at end of period**	**5,291**	**5,291**

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	5,291	5,191
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)**	**5,291**	**5,191**

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	191
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
Director and associates fees/wages		

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		
7.4	**Total financing facilities**		

7.5	**Unused financing facilities available at quarter end**	

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 2021). The facility is over a 24-month term with a discount charge of 8.04% and is for $2m and matures August 2022

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	84
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,291
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	5,291
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	*N/A*

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.

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: Yes, entity expects to have future funding to meet future net operating cash flows.

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: Yes, entity has AU shareholder approval to raise finance on US markets.

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: Yes, based on raising future working capital through US markets, and on future licencing agreements.

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: ..... **28th October 2022** .....

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.