



20 April 2021

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

## **MEDLAB APPENDIX 4C / STRATEGIC HIGHLIGHTS – AMENDED**

**Medlab Clinical LTD (ASX:MDC) apologises for a clerical error in the prior 4C filing effectively removing the last page of the 4C financial template. Please excuse the oversight and find the complete 4C [here](#).**

Medlab (ASX:MDC), an Australian Biotech using delivery platforms to enhance medicines particularly in the field of oncology and pain management is pleased to provide a business update and a quarterly cashflow report for the period ended 31 March 2021 (Q3 FY21).

- **4C expectations marginally ahead** (see below summary and detailed tables)
- **NanaBis™ Observational Study (OBS) report confirms continued improvement in pain scores**
- **EU & UK Patent Office Notice of Intention to grant NanoCelle© patent, has now been granted as of 15<sup>th</sup> April**
- **Capability investment step-change, with our structure is now mirroring our strategy, with a revised Board and Executive appointments to strengthen experience of global Pharmaceutical & oncology markets to assist our focus on US clinical and Northern Hemisphere partnering opportunities**
- **Heads of Agreement (HoA) with Arrotex to accelerate NanoCBD™ pharmacy access in Australia via a Schedule 3, proposition progressing through regulatory channels**
- **US FDA IND for lead candidate NanaBis™ experiencing technical process / electronic corruption interference. NB: Technical disclosure point**
- **North America interest & engagement with Jefferies Conference invitation for Medlab CEO (Dr Sean Hall) presentation in June, supported by US / Edison coverage**
- **Medlab receives positive NRGBiotic™ Phase IIa Depression trial independent preliminary results**
- **\$15 million share placement/capital raise to support the above strategies**

### **CASHFLOW & FINANCIAL COMMENTARY**

In the quarter, revenues from Special Access Sales (SAS) sales of NanaBis™ and NanoCBD™ continued to grow further supporting proof of concept. Sales for NanaBis™ in Australia show steady growth under the TGA Special Access Scheme.

Medlab's nutraceutical business continued to undergo a period of rationalization in the quarter with brick-and-mortar sales continuing to build on the improvement and recovery seen in the H1 FY2021. Proceeds from issues of equity securities \$11.611m

The company's cash balance as of 31 March 2021 was \$14.032m million.

Medlab's pursuit of a differentiated path to market for its medicinal cannabis products, undertaking comprehensive clinical trials and pursuing global opportunities, continues to yield success.

In the quarter, the company completed a successful \$15 million share placement with funds raised to be used to commence NanaBis™ PIII trials in the US, UK and Australia and provide for market access on the prospect of a potential US Expanded Access IND for NanaBis™. Funds raised will also provide working capital for a minimum of 12 months to continue research programs and partnering discussions, particularly around Medlab's proprietary NanoCelle® delivery technology. The Company placed 62,500,000 new fully paid ordinary shares at 24 cents per share and was supported by new and existing institutional and sophisticated investors.

Significant progress was also made in the development of lead candidate NanaBis™ for the treatment of cancer-induced bone pain with pending IND approval in the US by the FDA and advancement toward pivotal US Phase III trial. Medlab continues to focus on partnering activities in parallel with NanaBis™ clinical development with key appointments in the quarter strengthening Medlab's business development and partnering capabilities which will be instrumental to US and UK clinical and commercial pathways.

Mrs Cheryl Maley was appointed independent Non-Executive Director during the quarter. Mrs Maley joins the Medlab Board with strong pharmaceutical experience and global focus on the oncology market, currently serving as Managing Director of Oncology for global healthcare company Novartis (Australia and New Zealand). Previously based in North America & South East Asia within major Pharma.

Mr Naresh Patel was appointed Global Business Development Manager and will explore further partnering and licensing opportunities with a particular emphasis on the Northern Hemisphere. Prior to joining Medlab, Naresh held Business Development roles with companies such as Clarity Pharma and Biomap.

Mr Robert Jenson was appointed Medical Science Liaison in the US and will work with Medlab to advance compassionate access to NanaBis™ via an Expanded Access Investigational New Drug pathway. Robert joins Medlab with extensive experience in retail pharmacy previously working as a Pharmacy Manager with CVS Pharmacy in the US.

#### **R&D PIPELINE PROGRESS IN THE QUARTER**

**US FDA IND for NanaBis™ Pending:** Medlab was advised that due to a file/upload corruption issue resulting in the Medlab "XML backbone" of FDA records, that clinical IND status for NanaBis is still pending. Medlab, its FDA lawyers and the FDA are working together to resolve this technical discrepancy, however the FDA has advised that Medlab will be required to refile the application after the XML issue is repaired.

[clinicaltrials.gov](https://clinicaltrials.gov) the US public facing database for all trials, cites a National Clinical Trial Identifier (NCT04808531) issued for the forthcoming NanaBis™ Phase III study. The Phase III trial will investigate NanaBis™ as a monotherapy metastatic cancer-induced bone pain (CIBP), the most common type of cancer pain. NanaBis™ is currently the only cannabinoid-based pipeline candidate in development for cancer pain initiating Phase III trials in the US, which now joins Australia and the UK as NanaBis™ Phase III trial jurisdictions.

Medlab continues to work towards submission of a second IND application to the US FDA for the expanded access scheme, similar to the compassionate use program in Australia. If successful, NanaBis™ could be

the first cannabis-derived pipeline candidate that is able to be prescribed under the expanded access scheme in the US.

**NanoCelle® EU / UK Patent:** Post quarter close, Medlab received an upgraded notice from Intention to Grant to Decision to Grant from the European Patent Office<sup>i</sup> for its patent covering the use of the Company's NanoCelle® sub-micron delivery platform in Europe, including the UK. Patent EP 16 759 419.3 titled Transmucosal and transdermal delivery systems, provides protection until 2036. This second patent approval further validates the NanoCelle® drug delivery platform, supports Medlab's R&D pipeline and commercial focus and extends protection in one of the world's largest markets. An Australian patent was granted in September 2020 and further patent applications have been made in the US, New Zealand, Singapore, Hong Kong, and Canada.

**Continued improved in pain scores in 12-Month Observational NanaBis™ study report (OBS):** Post quarter close saw release of the fifth monitoring report<sup>ii</sup> on the ongoing 12-month real world observational study of NanaBis™ which launched in 2020. This demonstrated a 55% reduction in pain scores, consistent with prior updates on the study and the earlier Phase I/II study undertaken at the Royal North Shore Hospital. 805 of 2,000 (40.2%), patients are now enrolled in the study (HREC Approval ID: H0052E\_2019) building further confidence in the evidence recorded to-date. This monitoring report is also the first include patients (n=119) in the study who have completed a 6- or 12-month observation period and demonstrates continued improvement in pain scores.

These results continue to support the safety, tolerability, and efficacy of NanaBis™ for pain management in a real-world setting. Consistent with the growing body of clinical and real-world evidence supporting NanaBis™ the building longitudinal evidence gives the Company greater confidence in the quality of data and outcomes reported. The latest results support the Company's clinical pathway and FDA strategy, particularly in preparing to initiate the potential IND Phase III study in the US, UK and Australia.

**Agreement with Arrotex to accelerate NanoCBD™ pharmacy access in Australia via Schedule 3:** An Australian exclusive non-binding Heads of Agreement was signed with Arrotex Australia Group Pty Ltd (Arrotex) for the development and distribution of Medlab's proprietary cannabinoid formulation NanoCBD™ to Australian pharmacies. Arrotex is the largest dispensary and OTC supplier in Australia and this agreement will both companies to fast-track development of the clinical package required for lodgement and approval by the Australian regulator TGA for a Scheduled 3 (S3) or pharmacist only medicines schedule approved pharmaceutical.

**Positive Preliminary NRGBiotic™ depression trial data:** Preliminary analysis by Queensland University of Technology and the Queensland Medical Research Institute (QMRI) of the NRG Biotic™ Phase IIa depression trial data showed a significant reduction in depression and improvement in quality of life from baseline. It was also demonstrated to be safe and tolerable, with no reported adverse effects. COVID-19 restrictions had delayed results read out of the trial which was completed in March 2020 with 120 of 150 patients treated. Full analysis of the trial data continues, with COVID-19 further impacting timing.

Commenting on the quarter, Medlab's CEO and Managing Director, Dr Sean Hall said "Medlab has achieved significant milestones in the quarter. With strong US interest, a strong development pathway and encouraging partnering opportunities, we have positive momentum across all activities and continue to see solid progress that will generate commercial opportunities."

**ENDS**

#### **Authorisation & Additional information**

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

#### **About Medlab – [www.medlab.co](http://www.medlab.co)**

Medlab Clinical LTD (ASX:MDC) is pioneering the development and commercialisation of a delivery platform, allowing for enhanced medical properties, including increased efficacy, safety, patient compliance and stability.

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

Medlab's Patented lead drug candidate, NanaBis™ has been 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.

NanaBis™, as it moves in global P3 trials is public facing on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) NCT04808531.

NanoCelle©, the patented delivery platform is wholly owned by Medlab Clinical and developed in Medlab's owned OGTR Registered Laboratory. NanoCelle© is designed to address known medication problems, addressing global unmet medical needs.

Medlab operates in Australia (Head Office), USA, and the UK.

Medlab – *better medicines, better patient care.*

For further information contact:

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<sup>i</sup> 7 April ASX Announcement.

<sup>ii</sup> 12 April ASX Announcement.

## 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 2021

<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	1,203	3,771
1.2 Payments for		
(a) research and development	(1,109)	(4,547)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(317)	(1,270)
(d) leased assets	(65)	(104)
(e) staff costs	(1,452)	(3,430)
(f) administration and corporate costs	(393)	(1,503)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	15
1.5 Interest and other costs of finance paid	(23)	(50)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	121	3,358
1.8 Other (provide details if material)		
(a) payments for inventory	(1,111)	(2,404)
(b) IP costs	(58)	(210)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(3,202)</b>	<b>(6,373)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(4)	(20)
(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)	-	-
2.6	<b>Net cash from / (used in) investing activities</b>	<b>(4)</b>	<b>(20)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	11,611	13,181
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	(766)	(805)
3.5	Proceeds from borrowings	495	1,945
3.6	Repayment of borrowings	(777)	(2,403)
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	(193)	(536)
3.10	<b>Net cash from / (used in) financing activities</b>	<b>10,370</b>	<b>11,382</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	6,877	9,063
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,202)	(6,373)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	(20)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	10,370	11,382
4.5	Effect of movement in exchange rates on cash held	(9)	(20)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>14,032</b>	<b>14,032</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> 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	14,032	6,877
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>14,032</b>	<b>6,877</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	216
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
Director and associates fees/wages		

<b>7.</b>	<b>Financing facilities</b> <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>	<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	2,000	2
7.4	<b>Total financing facilities</b>	2,000	2
7.5	<b>Unused financing facilities available at quarter end</b>		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>		

<b>8.</b>	<b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,202)
8.2	Cash and cash equivalents at quarter end (item 4.6)	14,032
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)	16,030
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	5.00
	<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: 20 APRIL 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.