



ASX Announcement

Medlab Clinical Appendix 4C Administrative Clarification – Q3 2022

SYDNEY, April 14, 2022 - Medlab Clinical Ltd (ASX:MDC) (Medlab, the Company), an Australian biotech using delivery technology to enhance medicines effectiveness is announcing a correction to Appendix 4C cash balance.

Medlab has recognised an administrative correction is required to the Appendix 4C announcement made on 13th April 2022 and we alerted the ASX to this on review.

In item Point 4.6 – Year to Date (9 months) column total, this number should read **\$8,634**, not \$11,220. This will match the same Current Quarter column total number of \$8,634, which was already disclosed in Appendix 4C and covering letter.

Medlab apologises for any confusion caused.

- 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 development and Commercialisation of a delivery technology, allowing for enhanced medical properties, including increased efficacy, safety, patient compliance and stability. Medlab's pipeline comprises several small and large molecules from repurposing generic medicines to enhancing the delivery of immunotherapies.

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.

NanoCelle®, the patented delivery platform is wholly owned by Medlab 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.

For more information, please visit www.medlab.co

Medlab – better medicines, better patient care

For further information contact:

Mr. Kerem Kaya
CFO Medlab Clinical Ltd
T: +61 2 7201 0096
kerem_kaya@medlab.co

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 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	889	5,688
1.2 Payments for		
(a) research and development	(559)	(2,092)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(83)	(579)
(d) leased assets	(244)	(664)
(e) staff costs	(1,483)	(5,123)
(f) administration and corporate costs	(860)	(3,095)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	3	10
1.5 Interest and other costs of finance paid	(9)	(37)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	201	3,343
1.8 Other (provide details if material)		
(a) payments for inventory	(343)	(2,660)
(b) IP costs	(86)	(363)
1.9 Net cash from / (used in) operating activities	(2,574)	(5,571)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(9)	(15)
(d) investments	-	-

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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	Net cash from / (used in) investing activities	(9)	(15)

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 (9 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	11,220	13,432
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,574)	(5,571)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(9)	810
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(2)	(37)
4.6	Cash and cash equivalents at end of period	8,634	8,634

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	8,634	11,220
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)	8,634	11,220

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	188
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
	Director and associates fees/wages	

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	-	
7.2 Credit standby arrangements	-	
7.3 Banking facility	2,000	66
7.4 Total financing facilities	2,000	66
7.5 Unused financing facilities available at quarter end		1,934
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 June 2022	

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,574)
8.2 Cash and cash equivalents at quarter end (item 4.6)	8,634
8.3 Unused finance facilities available at quarter end (item 7.5)	1,934
8.4 Total available funding (item 8.2 + item 8.3)	10,568
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.1
<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: **14th April 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.

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ASX Announcement

Medlab Clinical Appendix 4C and Business update – Q3 2022

SYDNEY, April 13, 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 31 March 2022 (Q3 2022).

Please view the attached investor presentation deck.

Key Financial highlights:

- **Cash receipts from customers** amounted to \$0.9m for the quarter, reflecting improved **operating revenues** of \$1.3M
- The month of March cash burn was \$0.3M with the March quarter cash burn at \$2.6M
- **Cash position** as at end of March 2022 was \$8.6M, with sufficient cash and significant **global partnering opportunities** anticipated to generate revenue, supporting future cash flow
- Confirmed ~\$5M **cash receipts from revenues** for balance of calendar year 2022, excluding any potential partnering deals Medlab is currently working on
- **70+ partnering engagements** to which **five partnership agreements** are in discussions/term sheet generation

Business Operations Update

1. As was recently announced, **NanoCBD™** is ready to be exported to UK for compassionate use. Medlab is currently awaiting final import approval from the UK government, with all other necessary licenses granted. Doctors' distribution network established.
2. **NanaBis™** (Investigative cannabinoid program for patients with cancer bone pain) has shown significant success in improving patient outcomes. With just over 1,000 Australian patients under clinical management we continue to **see positive signals** that demonstrate pain reduction and improvements in quality of life. Progress has been made in preparing the US FDA (Food and Drug Administration) application
3. The final granting of **global patents** for **NanoCelle** in 43 countries ensures exclusivity and protection of intellectual property for 15 years. This achievement has generated particular interest from pharmaceutical companies, demonstrated by the very positive commercial prospects that emerged at the recent UK Jefferies Biotech Health Conference
4. Under an accelerated regulatory model **NanoCBD™** would be approved for over-the-counter Australian pharmacy sales. Advanced joint venture discussions are currently underway with a key significant distribution/manufacturing pharmaceutical company to expand the availability of **NanoCBD™**, with potential for globalisation
5. The establishment of joint ventures with both the **UNSW** and **Macquarie University** together with a government grant for preliminary research into **NanoCelle®** as a means of delivering RNA vaccines **nasally** is a development in Medlab's penetration of the vaccine space
6. Post **commercial deal completion with The Cann Group (ASX:CAN)**, Medlab has commenced charging a monthly fee for service to educate and support physicians for selected Cann's cannabis products to complement the existing Medlab portfolio (NanaBis™ and NanoCBD™)

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 -

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For more information, please visit www.medlab.co

Medlab – *better medicines, better patient care*

For further information contact:

Mr. Kerem Kaya
CFO Medlab Clinical Ltd
T: +61 2 7201 0096
kerem_kaya@medlab.co



ASX:MDC

COMPANY UPDATE

Understanding the value indicators

“ The NanoCelle® drug enhancement and bio-delivery technology;
applicable to a vast range of new and existing medicines, with initial
targets in pain and mental health medication ”

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WHO IS MEDLAB

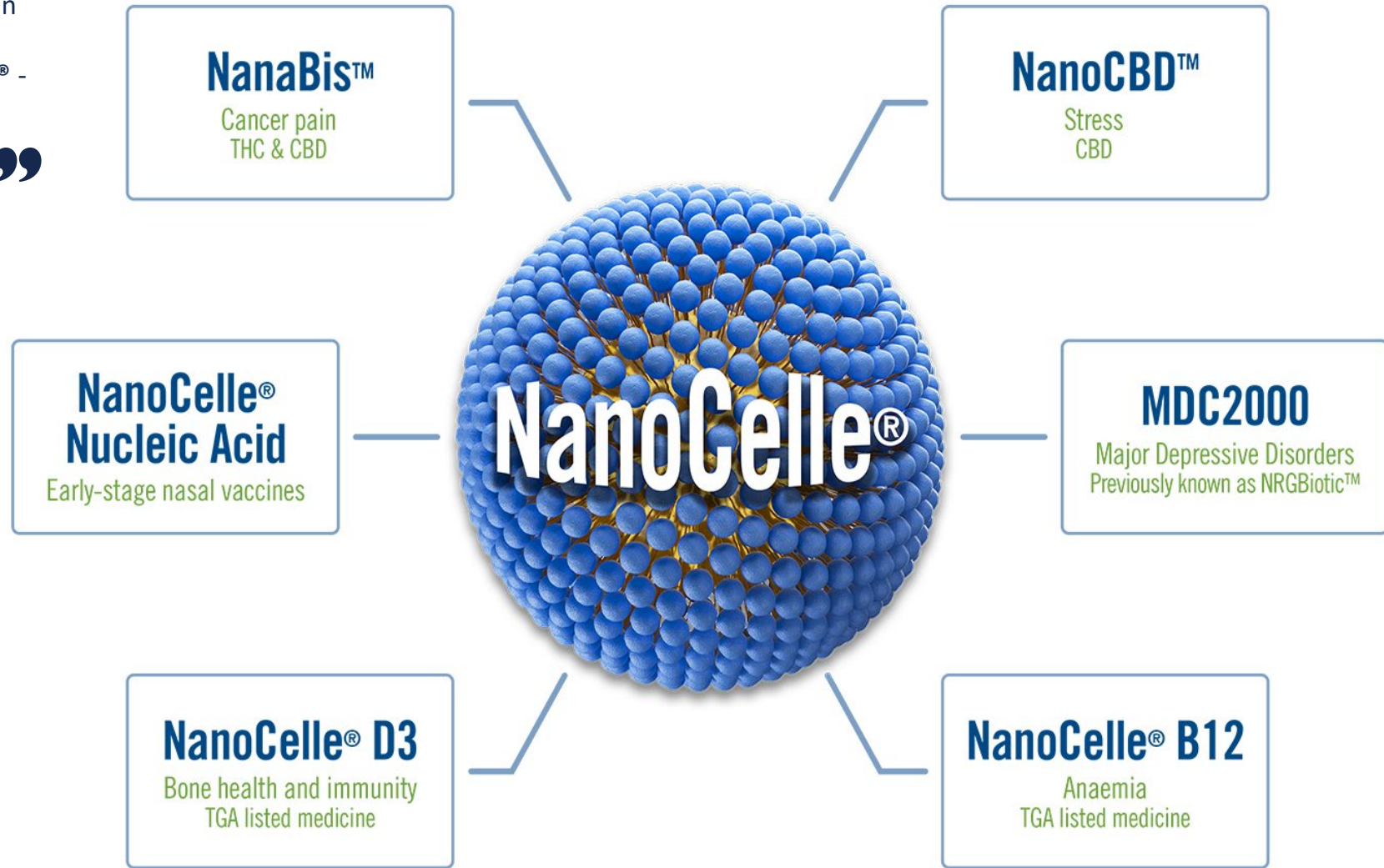
“ Medlab Clinical Ltd is a globally recognised Australian Biotech company, built on a proprietary drug processing and bio-delivery technology – **NanoCelle®** - that enhances the effectiveness, safety and reaction speed of new and existing medicines. Initial therapeutic focus includes pain and mental health. ”



Our revenue model is partnering. MDC is actively engaging with over 70 partnering opportunities through Royalties, Joint Ventures & Asset Sales with priority focus on 5 major partnering deals currently in advanced negotiations



NanoCelle®: Our validated delivery platform is patented and protected in all western regions until 2036



WHAT IS NANOCELLE® AND WHY IS IT SO IMPORTANT



<https://vimeo.com/611215328>

“ NanoCelle® has a diverse use, but principally it is designed to improve a medicines bioavailability and improve patient compliance, which includes a reduced risk profile effectively making the medicine safer and more tolerable ”

01

NanoCelle® is the registered name of our clinically validated, patent protected delivery platform, that uses nanoparticles to significantly enhance medicines. Medicine delivered by oral buccal mouth, topical or nasal spray

02

NanoCelle® bypasses the gastrointestinal tract, known as 1st pass metabolism, this means we can administer a lot less of a medicine, vastly reduce the patient's exposure to harmful side effects, whilst conferring the intended therapeutic benefits

03

NanoCelle® is a key differentiator to our programmes, such as the cannabinoid cancer pain program - NanaBis™

04

The NanoCelle® technology optimises the bioavailability of medicines, making compounds more easily and rapidly absorbed by the body

05

The NanoCelle® process can additionally **improve** the **stability** of medicines, such as removing the expensive requirement of storing vaccines at sub-zero temperatures.

UNDERSTANDING THE CATALYSTS

2021 Produced significant validation for Medlab

01



NanaBis™

- Ethics approval for the NanaBis™ Phase III trials in AU & UK.
- AU Government agreed to future expenses on NanaBis™ development.

02



NanoCelle®

- Patent protection for NanoCelle®.
- NSW Government funded NanoCelle® use with two Universities for a Nanoparticle, Nasal COVAX. This is a significant validation of the NanoCelle® technology and its many commercial applications across a broad range of medical therapeutic products. The collaboration incurs no expense to Medlab under a non-refundable, non-dilutive NSW Health grant.

03



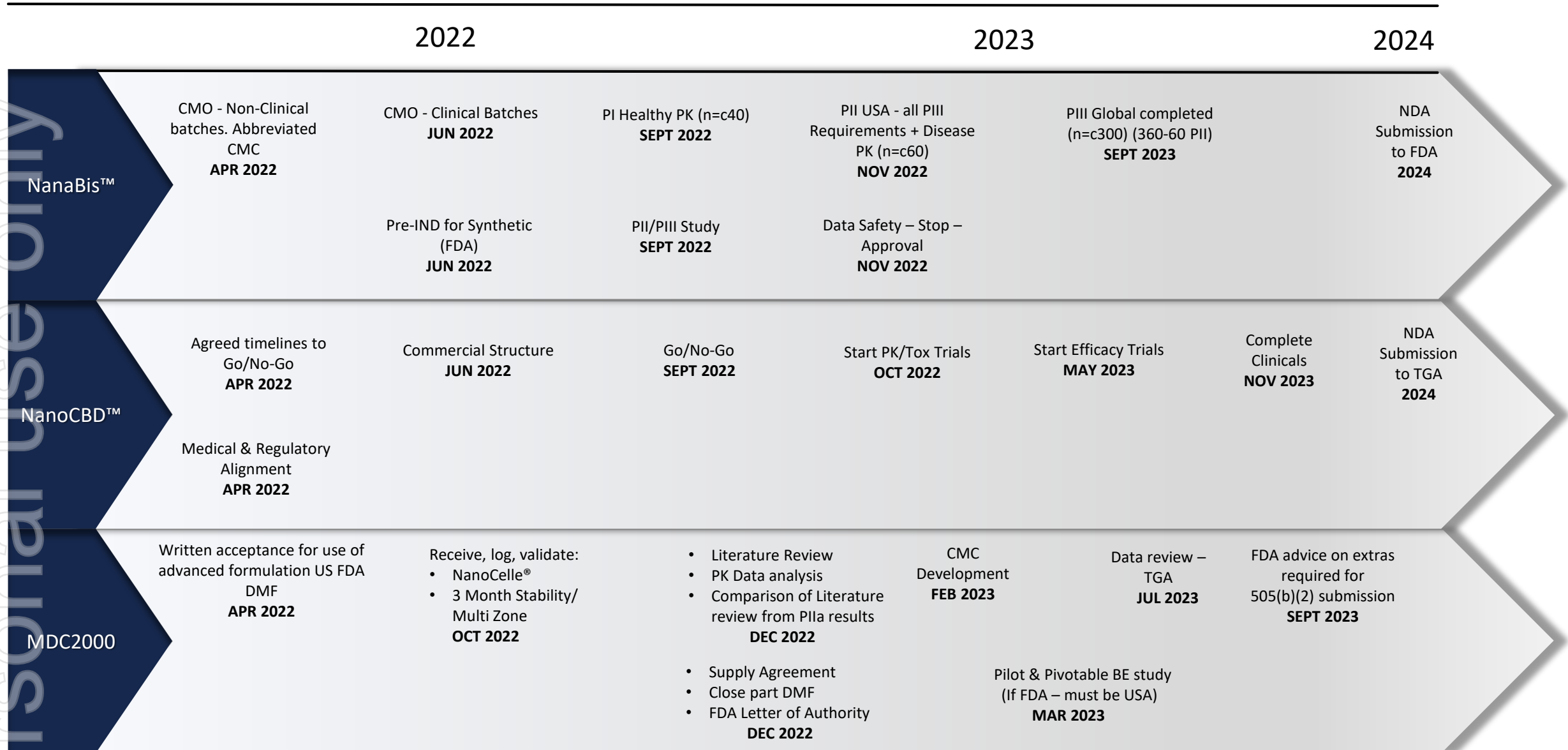
- Medlab is addressing significant **unmet medical needs** globally. The work to meet successful drug registration is extremely technical and detailed.
- **Medlab significantly progressed** 4 of the 5 essential modules required for the NanaBis™ NDA package for **final submission to the FDA**. Much of this work can also be directly applied to the NanoCBD™ package, saving time and money.

04



- **Synthetic THC and CBD Drug Master Files** now recognised by the US FDA – the recent technological ability to move to synthetics is an extremely positive step which further de-risks the NanaBis™ and NanoCBD™ New Drug Applications (NDA's).

UNDERSTANDING THE PRODUCT DEVELOPMENT CATALYSTS - TIMELINE



GLOBAL RESEARCH ANALYSIS

EDISON

Medlab Clinical

Novel drug delivery and cannabinoids against pain

Initiation of coverage
Pharma & biotech

12 July 2021

Price A\$0.16
Market cap A\$55m

Net cash (A\$m) at end of calendar Q121 13.8
Shares in issue 342.2m
Free float 90%
Code MDC
Primary exchange ASX
Secondary exchange NIA

Medlab's proprietary platform, NanoCelle, is a patented nanomicellar formulation that can improve the delivery of drugs. Medlab's lead product is NanaBis, a combination of THC and CBD (1:1) cannabinoids encapsulated in NanoCelle particles, which enable a convenient buccal spray formulation. A recent breakthrough was Medlab's announcement that it had successfully produced a synthetic version of NanaBis, which will allow it to move away from a botanical extract. Once the product reformulation is completed (guidance is eight to 10 months), NanaBis will re-enter clinical development (potentially Phase III) as a fully synthetic, non-opioid pain relief drug optimised with proprietary delivery technology aimed at a vast market. Our valuation of Medlab is A\$201m or A\$0.59/sh.

BLUE OCEAN EQUITIES MEDLAB CLINICAL LTD (MDC)

MEDLAB CLINICAL (MDC)
Research Initiation: Material valuation upside on offer from completion of Phase III trials

Analyst Philip Pope
Email philippope@boeq.com.au
Phone +61 2 8072 2921
Date 1 September 2021

Thomas Brunton
Thomasbrunton@boeq.com.au
+61 2 8072 2920

We say Buy Share Price Price Target
0.175 0.55

MDC is well positioned to potentially become a first mover within the cannabinoid cancer pain medication market. Assuming Phase III NanaBis trials are successful, we expect MDC to benefit from the growth of the global cannabinoid market, which is projected to surpass US\$45b in the USA alone by 2025. Further, the GW Pharmaceuticals takeover suggests a material valuation uplift is on offer should MDC successfully complete its Phase III trials. We initiate with a BUY rating, PT \$0.55/s.

SHARE PRICE CHART MDC SALES POTENTIAL COMPANY DATA & RATIOS

EDISON

Medlab Clinical

Transforming into a pure-play biotech

Company update
Pharma & biotech

27 January 2022

Price A\$0.13
Market cap A\$44m

Net cash (A\$m) at end-November 2021 (after the completion of the transaction) 13.0
Shares in issue 342.2m
Free float 90%
Code MDC
Primary exchange ASX
Secondary exchange NIA

In its former shape, Medlab used the cash flows from selling innovative nutraceuticals to fund pharmaceutical research. With lead product NanaBis (NanoCelle encapsulated 50:50 THC:CBD for pain) preparing to enter a Phase III trial in pain, management has decided to fully focus on therapeutics development and divested its nutraceuticals portfolio in November 2021. As a pure-play biotech, Medlab is also focused on optimising its R&D portfolio, which has many initiatives. Historically, Medlab has explored its proprietary drug delivery technology NanoCelle in combination with various generic active pharmaceutical ingredients (APIs), extracts and other products. The management is now prioritising the likely winners, with NanaBis leading the pack. Our valuation has increased to A\$239m or A\$0.70 per share.

morgans
Stocks | Wealth Management | Superannuation

Medlab Clinical

MDC AU SPEC BUY
Price A\$0.16
Price target A\$0.39

27 January 2022

Result reaction: Neutral
Reporting date: 31/08/2021

Iain Wilkie
+61 7 3334 4521
ian.wilkie@morgans.com.au

Analyst(s) own shares in the following stock(s) mentioned in this report: N/A

Earnings guidance and result expectations
Earnings guidance/outlook provided: No guidance.
Result expectations: Financial results largely guided to in 4Q21 cashflow statement.

Earnings forecasts (A\$m)

	H20A	H20A	FY20A	H21A	H21F	FY21F	H21F % chg on pcp	FY21F % chg on pcp
Revenue	1.3	1.5	2.8	2.0	2.7	4.7	74.9%	65.0%
Gross profit	-1.5	-0.2	-1.7	0.1	0.1	0.0	72.3%	59.4%
Gross profit margin (%)	-1.1	-0.1	-0.6	0.0	0.0	0.0	254.9p	5972.9p
Operating expenses	6.9	6.7	13.6	6.7	8.1	14.8	20.9%	9.1%
Opex % of sales	522.6%	437.8%	477.1%	332.0%	302.6%	315.3%	-1351.8bp	-16181.0p
EBITDA	6.6	5.8	-12.3	4.8	6.3	-11.1	-9.0%	18.0%
EBITDA margin (%)	-497.4%	-371.1%	-432.9%	-237.0%	-235.1%	-236.2%	14207.5p	19677.2p
EBIT	7.0	6.3	-13.3	5.3	5.9	-11.2	6.1%	15.1%
EBIT margin (%)	-532.3%	-409.9%	-466.7%	-269.2%	-222.4%	-238.3%	18752.0p	22838.0p
Underlying NPAT	-7.1	-6.3	-13.4	-5.3	-5.7	-11.0	8.4%	17.8%
EPS (cps)	-3.3	-2.7	-5.9	1.9	-5.5	-3.6	-106.8%	26.4%
DPS (cps)	0.0	0.0	0.0	0.0	0.0	0.0	#N/A	#N/A

Source: Morgans research, company

- Multiple research reports from US and AUS see the nutraceutical divestment of the small Australia-only division to PharmaCare as an intelligent move. It uncomplicates our messaging, makes more efficient use of resources, and positions Medlab as a pure play biotech
- Research reports available on request identify strong upside with different positive valuations, and provide a deep dive into NanaBis™ as our investigative drug for cancer pain
- Research reports clearly state that beyond the obvious scientific validation, partnering is a critical validation model for commerciality
- Email us for a copy of reports – investor@medlab.co

IN SUMMARY

A globally recognised Biotech company addressing significant unmet patient needs; an ethical investment with vast global revenue opportunities in:

Name	Indication	Market potential	
NanaBis™	Cancer bone pain	US \$1.22B (2010)	CAGR 5.4%
NanaBis™	Non-cancer pain	US \$69.3B (2017)	CAGR 6.4%
NanoCBD™	Stress	US \$10.9B (2020)	CAGR 7.2%
MDC2000 (NRGBiotic™)	Depression	US \$11.67B (2019)	CAGR 2.9%

ITS NOT JUST INVESTMENT RESEARCH ANALYSIS

One of our potential Partners recently undertook an in-depth and significantly expensive Due Diligence and subsequent Independent Expert analysis on NanaBis™ suited to their potential territories.

What we can share at this time is:

- Due Diligence focused on Europe with the EMA as the central regulatory agency
- NanaBis™ is much needed and would be well received
- The time to peak sales is shorter than expected and volumes are hugely significant
- Pricing placed NanaBis™ in the early 200€ a bottle
- NanaBis™ subject to re-imburement in given territories



Battling anxiety and depression, as well as pain, can be exhausting. The right treatment can offer a new outlook on life, as in Jinhee's case. [Read Jinhee's story..](#)



For Catherine, Endometriosis presented as intense pelvic pain, nausea and light-headedness/ dizziness leading up to her period. [Read Catherine's story..](#)



When prostate cancer spreads, it most frequently goes to the bones and this is what happen in Josef's case. [Read Josef's story..](#)

FINANCIALS AND CORPORATE PERFORMANCE

As at end of March 31, 2022, Medlab **cash in the bank was \$8.6M**, with a \$2.7M cash burn for the quarter. Operating revenue for the quarter amounted to \$1.3M.

Expected future monthly cash burn rate to be less than \$1M, as we optimise savings from divesting / licencing out the AU nutraceuticals business.

Majority of the expenditure, including salaries, are R&D related and hence subject to rebate claimable R&D Grants.

Revenue already confirmed for the balance of 2022 includes:

- \$0.2M extraordinary income in April
- \$3.8M R&D Grant income in September
- \$0.25M Pharmacare Licence Royalty in November
- \$0.4M Amortised Service Income – April to December

This is short of any potential partnering deals Medlab is currently working on.

By continuing to generate revenues and optimise costs Medlab can focus its core Pharma strategies. Future spend on R&D Claim (to include international costs) is approved for NanaBis™ development with circa \$12M cash back annualized over 3 years against future expenses of the program.



THE NEXT 12 MONTHS

01

Expanded ethical compassionate sales of NanaBis™ and NanoCBD™ in AUS, with UK coming now and USA later in 2022.

02

NanaBis™ trial progression with FDA meetings on CMC data - estimated July/August 2022

03

NanoCBD™ trial progression with partner estimated September 2022

04

Stronger and clearer investor engagement in AUS and USA

05

Active engagement with over 70 partnering opportunities and significant progress on 5 major partnering deals

06

Expecting AU Government readout on NanoCelle® siRNA COVAX collaboration – estimated October 2022





THANK YOU

HEAD OFFICE

Medlab Clinical
Units 5 & 6 11 Lord St, Botany
NSW 2019, Australia

P +61 2 8188 0311

E Kerem_kaya@medlab.co

M +61 405 299 402

CALIFORNIA OFFICE (USA)

Medlab Clinical US, Inc
30021 Tomas
Suite 150
Rancho Santa Margarita,
CA 92679, USA

P +1 949 202 1088

US INVESTOR RELATIONS

Edison Group
1185 Avenue of the Americas,
New York NY

P: +1 646 653 7035

E: lyonker@edisongroup.com

ersonal use only

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APPENDIX I:
SYNTHETIC NANABIS™ & NANOCBD™

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APPENDIX – NANABIS™ AND NANOCBD™ PROGRESSION

NanaBis™ Synthetic Importance & Progression

Our planned development for NanaBis™ Synthetic is well underway, with expectations of being back with the FDA in a few months. The synthetic program for NanaBis is key for us at a regulatory level as both the FDA and the EMA have expressed a preference for synthetic compounds due to the unavoidable impurities and inherent chemical variations from one batch to another in botanicals.

Why did we start in botanical and then move to synthetic THC?

2 significant reasons;

- First a 100% Dronabinol (the synthetic name for THC) was not technically possible to produce or commercially available until last year.
- Second, when we started we modelled work from GW Pharma (the only company globally that has to date received FDA approval for a cannabinoid product); we had purified botanicals to 97% and in our FDA IND meetings it was recommended that we do one of 2 things; either increase the purity of the botanical to minimum 98% purity or better yet, move to 100% pure synthetics for absolute purity control.

We embarked on a 2 pronged approach - searching for capabilities to create the 100% Dronabinol, whilst continually improving the purity index for botanicals. From the botanical aspect, this directly translated to more work and expense at every level of manufacturing and chemistry work; more time and increased costs.

During 2021 we (with the help from our biosynthetic partners) developed the 100% Dronabinol synthetic, and today we have what is known as Drug Master File (DMF) recognition at the FDA for both a 100% CBD and a 100% Dronabinol (THC). From a regulatory step, this is significantly superior to what we had in the botanicals – additionally, yields vastly improved, impurity issues no longer existed, and production risks were negated. We cannot overstate the value and importance of acquiring these DMFs for the progression of our NDA application.

What we have developed over the course of 2021 is a stronger Chemical, Manufacturing and Controls (known as a CMC) package. This CMC package is common to all western regulatory authorities and is absolutely fundamental in a new drug application.

APPENDIX – NANABIS™ AND NANOCBD™ PROGRESSION

NanaBis™ Synthetic Importance & Progression (continued)

It's important to know that a drug application is traditionally made up of 5 key modules:

- Module 1 is region specific, and addresses why the product is needed.
- Module 2 is summary data with an emphasis on quality (driven from the CMC package and essential for regulatory approval).
- Module 3 is the CMC package itself
- Module 4 is the non-clinical data (elements of the CMC package are also present here) .
- Module 5 is the clinical reports (as in clinical trials and the final phase 3 endpoints report)

All 5 modules come together to make what is referred to as a Common Technical Document of Drug Dossier (<https://www.ich.org/page/ctd>) - the huge and ultimate application document required to apply for any pharmaceutical drug registration and subsequent commercialisation.

The point we are wanting to highlight is that too often the focus in biotech and New Drug Applications is on the clinical trials – and to some extent that makes sense simply because of the visibility in medical journals and the broader commercial pharmaceutical market. What we are demonstrating from the above is that there is a significant amount of work that is required in addition to the final clinical trials in order to format a final drug registration package.

Since COVID presented real risks and legitimate public health barriers to accessing patients which prevented us from initiating our Phase 3 trial, we have instead focused heavily on developing the other larger areas of the drug application dossier.

APPENDIX – NANABIS™ AND NANOCBD™ PROGRESSION

NanaBis™ Synthetic Importance & Progression (continued)

So how detailed is a CMC package?

In short it is a huge, detailed document – in order to provide a sense, please review the FDA link:

www.fda.gov

We have leveraged the NanaBis™ CMC package work, both current and future so that NanoCBD™ shares significant process optimisation, production efficiencies and cost reductions, including US FDA recognised Drug Master Files (DMF), US manufacturing and Packaging components and CMC components - this reduces time and money in the development of the drug.

We learnt a lot from the Botanicals, they gave us our fundamental evidence that provides confidence in moving forward; and our Botanical based products continue to be available to compassionate markets for ethical use.

As for clinical development for both programs, we have a good line of sight on the future and both programs are currently in due diligence for our partnering discussions. Clearly, we can't talk too much about partnering as we are under confidentiality, but we can disclose that these negotiations are active and progressing rapidly now that full patent protection has been granted across all major western markets.



APPENDIX 2:
FREQUENTLY ASKED QUESTIONS

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APPENDIX – FREQUENTLY ASKED QUESTIONS

Does Medlab have sufficient finances to continue operations without raising capital?

Medlab retains a strong cash position of \$8.6 million cash as at 31 March 2022. Preapproved future R&D claims providing an additional \$12 million funding rolling forward over 3 years.

We have confirmed additional revenues and royalty receipts that are due throughout the 2022 calendar year, with around \$5 million expected without including any potential proceeds from new commercial partnerships, overseas R&D rebates or exercise of options.

Whilst a falling share price directly affects our market capitalisation on paper, our financial position remains unchanged and our top 20 investors still retain circa 60% of all shares on issue.

There hasn't been any recent news on partnering activities – are these still happening and when can you announce something?

Partnering is very active, very promising, and progressing at pace

We are actively engaged in new commercial partnership deals that we will announce as soon as they become binding and we are permitted to do so.

Due to the technical nature of the assets we are partnering, the due diligence involves not just monetary considerations, but significant elements of medical, regulatory and future forecasting.

These discussions have advanced significantly in light of the patent protections we now hold globally and we anticipate being able to update the market further in the coming months.

Why has Medlab been engaged in roadshows and talking to brokers recently?

Medlab is developing and actively implementing improved communication and marketing strategies to keep our investors and the broader market better informed.

As a first step, we are currently engaged in non-deal roadshows (NDRs) and investor webinars to update investors, analysts and institutions on Medlab's recent milestones, and to outline the 2022 roadmap and the near term catalysts to improve the share price.

Additionally we have recently launched a bi-monthly global Investor Newsletter and we invite shareholders to subscribe by emailing "Subscribe" to investor@medlab.co

APPENDIX – FREQUENTLY ASKED QUESTIONS

What’s happening with NanaBis™? Has the program been delayed or stopped altogether?

The NanaBis™ program has by no means stopped; in fact, considerable progress has been achieved in 2021. NanaBis™ is now in a far superior position due to the vast amount of regulatory work completed over the last 12 months.

In-depth details of this work are provided in Appendix 1.

Why did you sell the nutraceutical business when it was your only profitable division?

We have not sold our nutraceutical business; we’ve only divested the Australian rights and sold warehoused inventory.

The divestment of nutraceuticals to PharmaCare for \$1.6m in upfront payments and ongoing royalty payments through the licensing of domestic Australian rights has significantly reduced our operating costs and aligns with our business model of generating revenue through multiple commercial partnerships.

Medlab retains all global rights to our nutraceutical range beyond the Australian market.

We are working to replicate this commercialisation model internationally with upfront payments and ongoing royalties scaled to each regional market, and little to no further investment required on Medlab’s part.

Removing the financial- and time-intensive requirements of supporting a sales force, distribution infrastructure and marketing activities for these products by moving to a licensing business model enables Medlab to focus clearly on the priority development of new commercial partnerships for our patented NanoCelle® technology and our lead drug candidate NanaBis™ as it progresses to phase 3 trials and final regulatory approvals.

APPENDIX – FREQUENTLY ASKED QUESTIONS

What has Medlab achieved in 2021?

Medlab has been very active in 2021;

- We successfully delivered long term patent protection for NanoCelle® in all Western countries. This legal protection has allowed us to accelerate multiple commercial partnership deals by opening our NanoCelle technology up to the necessary external auditing and due diligence examinations.
- We gained Ethics approvals for NanaBis™ Phase 3 for Australia and the United Kingdom.
- We obtained a firm commitment of circa \$12M for future and overseas work as it relates to NanaBis™ from AusIndustry.
- We received a non-refundable, non-dilutive grant to work with UNSW and the Woolcock Institute of Medical Research (MQ) for a NanoCelle® nasal siRNA covid vaccine.
- We have also significantly progressed or completed 4 of the 5 essential modules required for the NanaBis New Drug Application (NDA) package for final submission to the FDA and EMA. While the covid pandemic prevented us from initiating the “hands on” P3 clinical studies component with at-risk patients, we have used this time to forge ahead the vast amount of supplemental work required for the final NDA.

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