

## Q1 FY23 QUARTERLY ACTIVITIES REPORT & APPENDIX 4C

Distribution growth and therapeutic advancement driving towards strong results

### Key Highlights

- **66% growth in distribution partnerships over the last 6 months delivering the foundations for continued revenue growth**
  - Formal distribution expansion activated with Europe's largest pathology company SYNLAB (FRA: SYAB)
  - Growth in pipeline of new global distribution partners with >20 active leads, 10 qualified opportunities, 2 in draft terms, and 3 in final agreement stage
  - New distribution partnerships (Genova, G42, Midnight Health) now live in the US, Middle East and Australia with initial sales and revenue achieved, driving towards meaningful new revenue in H2 FY23 as sales momentum builds.
  - New healthcare practitioner products on track for full feature launch in November 2022
- **Therapeutic program advancement**
  - An important catalyst in the sector - Rebiotix and Seres Therapeutics progressing towards first microbiome drug approvals with the FDA, signalling the start of a therapeutic revolution.
  - Inflammatory Bowel Disease program - successful scale-up production of MAP 315 completed delivering on manufacturing requirements to support upcoming Phase I trial. Pre-IND meeting requested with the FDA.
  - Immuno-oncology program – 3 leads progressed into pre-clinical animal models. First results expected February - March 2023.
  - Autoimmune disease program – significant biobank strains delivered, characterisation activities underway with Ginkgo Bioworks (NYSE: DNA). First data expected January - March 2023.
- **Additional achievements for the quarter**
  - Second data package delivered in research partnership with International Flavors & Fragrances Inc. (NYSE: IFF) delivering therapy leads for food allergy and atopic dermatitis
  - Q1 FY23 unaudited revenue totalled \$0.92m, above internal budget for the period and tracking towards positive growth for FY23
  - Q1 FY23 cash receipts totalling \$1.79m representing 31% growth on prior quarter
  - Two R&D Tax Incentive Advanced Overseas Findings received, providing additional cash rebates of up to \$5,829,000 across financial years 2022, 2023 and 2024
- **\$26.4 million in cash or equivalents as at 30 September 2022, and FY22 R&D Tax Incentive claim lodged and expected to be received in Q2 FY23 - the Company remains well funded to support revenue growth and therapeutic program advancement**
- **The Company will host an investor webinar, Monday 31 October 2022, at 10.30am AEDT / 9.30am AEST.**  
[https://us02web.zoom.us/webinar/register/WN\\_B0\\_RqfbzQdm6yMp4OEV2AQ](https://us02web.zoom.us/webinar/register/WN_B0_RqfbzQdm6yMp4OEV2AQ)

**Microba Life Sciences Limited** (ASX: MAP) ("Microba" or the "Company"), a precision microbiome company, is pleased to provide a summary of its activities for the quarter ended 30 September 2022.

**CEO Dr Luke Reid said:**

*"We are exceeding our FY23 budget towards another year of positive growth. For Microba's testing services, our advancement with SYNLAB represents an important leap forward for our distribution throughout Europe and Latin America which we expect to translate into new country agreements across the next quarter. In addition, pleasingly our pipeline of new prospective distribution partners for our testing technology is both growing and progressing through to new distribution agreements. For Microba's therapeutics, the field is on the cusp of the first FDA approved microbiome drugs which is an important catalyst for the sector. A clear path to market for microbiome drugs, and Microba's progress into the clinic with MAP 315 provides critical momentum as we continue to advance our pipeline towards out-licensing deals on these high value therapeutic assets".*

**First FDA approvals – the start of a therapeutic revolution**

As Microba transitions into a clinical stage company, there has been some important progress in the microbiome therapeutics sector. Live microbial cell therapies, also known as "Live Biotherapeutic Products" (LBPs) represent an entirely new class of drug. These drugs represent an attractive new treatment option for patients with potential novel therapeutic activities and strong safety profiles, however there are no U.S. Food and Drug Administration (FDA) approved LBPs available today. This year the first Phase 3 trials were completed by both Seres Therapeutics (Nasdaq: MCRB) and Ferring-Rebiotix demonstrating positive results for their First Generation<sup>1</sup>, donor derived, microbiome treatments for recurrent C. difficile infection (rCDI). Aligned to this Seres Therapeutics, Inc. (Nasdaq: MCRB) in September completed a rolling Biologics License Application (BLA) submission to the FDA for SER-109 for the prevention of rCDI, and announced they anticipate approval in H2 FY23. Further, an FDA advisory committee voted in favour of approving RBX2660 from Ferring-Rebiotix for rCDI treatment, which is anticipated to translate into a full FDA approval in Q3/Q4 FY23. A clear regulatory path to market is critical for drug developers and big pharma companies to invest with confidence to bring these drugs to patients. The first full FDA approval of a microbiome drug represents an important catalyst for the sector and supports a path to market for Microba's next-generation<sup>2</sup> microbiome drugs.

**Leading in Europe with SYNLAB**

SYNLAB (FRA: SYAB) is the largest European clinical laboratory and medical diagnostic services company by revenue and number of tests, servicing around 100 million patients annually. In 2020, Microba entered into a master agreement with SYNLAB International GmbH and an agreement with SYNLAB Diagnosticos Globales to deliver Microba's testing solution to Healthcare Providers in Spain, with an option to formalise distribution agreements across their affiliate organisations. With positive sales results in Spain, in October SYNLAB further activated their rights to pursue formal expansion into additional countries across Europe and Latin America. Aligned to this, Microba and SYNLAB executed a major amendment to the master agreement (refer to ASX announcement on 20 October 2022) to enable this distribution expansion including; a new agreement framework for SYNLAB countries; an extended distribution term to 31 December 2028, and an expanded field to include sales direct to Consumers as well as Healthcare Providers. This amendment to the master agreement exemplifies SYNLAB's conviction and long-term commitment to the partnership and formally advances this distribution relationship to the next phase to expand access to Microba's testing across SYNLAB's territories.

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<sup>1</sup> Human fecal donor derived drug products which are reliant on ongoing donor material supply to manufacture

<sup>2</sup> Single strain LBP or microbiome derived small molecule drugs amenable to scalable cGMP manufacturing

### **Expanding international distribution**

Microba's growth strategy for the Company's personal testing services continues to execute through a global, scalable, distribution partnership model. This Software as a Service (SaaS) model enables leading partners with deep channels into market to quickly launch an advanced microbiome testing solution powered by Microba's technology. Over the last six months we have seen growth from 3 partners to 5 partners representing 66% growth in the distribution partner network. Over the last quarter Microba has seen significant demand from prospective partners seeking to launch a microbiome testing solution. This has led to a strong pipeline of partners with more than 20 active leads, 10 qualified opportunities, 2 in draft terms, and 3 in final agreement stage. Aligned to this Microba expects to sign and announce new distribution partners across the remainder of the financial year, focused on both opening up new regions and expanding distribution in existing regions.

In addition, Microba's recently commenced partnerships with Genova Diagnostics (USA), G42 Healthcare (GCC) and Midnight Health (AUS) have all achieved first sales of their Microba powered products. Over the last month, Genova Diagnostics have engaged over 40 key opinion leading physicians across North America as the initial phase of a staged sales roll out of their Microba powered microbiome test. With the defined sales and marketing plans for these partners and anticipated signing of new partners, Microba is expecting another year of positive revenue growth weighted to the second half of the financial year.

### **New healthcare products preparing for full product launch**

A core component of Microba's strategy is to advance the clinical utility of microbiome testing to ultimately become embedded as a routine part of health and disease management. Over the last quarter Microba's next generation product for health professionals progressed successfully through beta with positive feedback from a group of healthcare professionals. Microba is now preparing for a full product feature launch in November and will be delivering to market a suite of 3 new tests leveraging Microba's ISO15189 accreditation and diagnostic testing solutions. The new products will enable health professionals to comprehensively assess gut microbiome biomarkers and other gastrointestinal markers to identify opportunities to intervene through diet, lifestyle and supplementation. In addition, the product suite will enable comprehensive diagnostic testing for gastrointestinal pathogens. These new products will be initially launched in Australia and then rolled out through Microba's growing international distribution networks. These new products will significantly advance the clinical utility of microbiome testing in a healthcare setting, and expand the total addressable market for Microba's testing products.

### **Allergy treatment partnership with global leader IFF**

During the quarter a second data package was delivered to International Flavors & Fragrances Inc. ("IFF") (NYSE: IFF) in a joint discovery project which seeks to identify novel allergy treatments leveraging Microba's proprietary Databank. The new data package identified multiple microbial therapy leads for food allergy and atopic dermatitis. This builds on the first data package delivered in June 2022 for asthma and allergic rhinitis and marks a step towards a potential longer-term commercial relationship between the parties, leveraging Microba's Therapeutic Platform to develop novel allergy treatments. This program further demonstrates Microba's repeatable, scalable data-driven Therapeutic Platform with the ability to partner with large multinational health and pharmaceutical companies to discover and develop novel microbial cell therapies.

### **IBD Program - MAP315 progressing towards Phase I**

Microba is rapidly progressing its novel microbial cell therapy lead candidate, MAP 315, into its first in human Phase I clinical trial. Over the quarter, manufacturing of MAP 315 further progressed with Bacthera in Switzerland with production of engineering batches at full-scale which enables GMP production for Microba's Phase I clinical program. In addition, Microba requested a Pre-IND meeting with the FDA to support rapid advancement of the clinical program, with a formal meeting anticipated for Q2/Q3 FY23. MAP 315 is being developed for the treatment of Ulcerative Colitis, a debilitating form of Inflammatory Bowel Disease with >50% of patients unable to achieve sustained remission. The global market for Ulcerative Colitis treatments was valued at \$7.5B in 2021.

### **Immuno-Oncology Program – Driving towards pre-clinical efficacy data**

Following the recent discovery of therapeutic leads, the team has successfully isolated 3 of these and commenced pre-clinical animal model experiments with Eurofins with first results expected February - March 2023. This work will provide important pre-clinical efficacy data on the potential of these novel microbial cell therapy leads to increase response to immune checkpoint inhibitor (ICI) therapy. Microba's immuno-Oncology program is targeting the development of a therapeutic to improve response rates in cancer patients receiving immune checkpoint inhibitor (ICI) therapy. Global immune checkpoint inhibitor sales have grown substantially since Microba has commenced the program, with Merck announcing sales of the market leading drug Keytruda in excess of \$5bn USD in Q2 2022<sup>3</sup>.

### **Autoimmune Disease Program – tracking ahead of schedule towards first data**

Microba has now supplied a significant number of bacterial strains from the Company's biobank to strategic shareholder and partner Ginkgo Bioworks (NYSE: DNA) for assessment. Characterisation and screening activities are now active at their laboratories in Boston, USA. An in-person update meeting in October 2022 indicated that the program is tracking ahead of schedule with first in vitro screening data expected to be available in January to March 2023. Microba's Autoimmune Disease program is targeting three autoimmune disorders lupus, psoriatic arthritis and autoimmune liver diseases. The global market for autoimmune disease treatments was estimated to be US\$53.2 billion in 2019 and forecast to grow to US\$90.7 billion by 2024<sup>4</sup>.

### **Financial Update**

Unaudited revenue for the September 2022 quarter totalled \$0.92m. Cash receipts for the September 2022 quarter totalled \$1.79m representing 31% growth on the prior quarter. These financial results are ahead of internal budgets and are tracking towards another year of positive growth for the Company. As messaged last quarter, the financial year's growth is expected to be weighted to the second half of the financial year aligned to timing of sales ramp up of new distribution partners, launch of new healthcare product, seasonality of service demand, and aligned revenue recognition.

Net cash outflows during the quarter amounted to \$4.49 million.

As at September 30 2022, Microba had \$26.4 million in cash or equivalents, and had lodged its FY22 R&D Tax Incentive claim which is expected to be received in Q2 FY23. This puts the Company in a strong position to execute its growth strategy and provides a solid runway to support advancement of the Company's therapeutic programs.

In accordance with Listing Rule 4.7C, payments made during the quarter to related parties and their associates included in item 6.1 of the Appendix 4C was \$112,000 and included Director fees.

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<sup>3</sup> [https://s21.q4cdn.com/488056881/files/doc\\_financials/2022/q2/v2/Q2-2022-Merck-Earnings-Deck-\(update-8.9.2022\).pdf](https://s21.q4cdn.com/488056881/files/doc_financials/2022/q2/v2/Q2-2022-Merck-Earnings-Deck-(update-8.9.2022).pdf)

<sup>4</sup> BCC Research. Autoimmune Disorder Therapies: Global Markets (2020).

## Use of Funds

In section 7.4 of the Microba Life Sciences Prospectus, the Company provided a proposed use of funds statement for 24 months from listing. The table below only shows use of funds from IPO to the end of the most recent quarter, 30 September 2022.

Use of Funds	Sep-22 Qtr	Prior Total	Total Expenditure	Prospectus
Global market penetration and sales growth	732	758	1490	7,200
Data driven drug discovery	2,028	2,206	4,233	13,100
Platform technology advancement	486	405	890	2,500
Administrative and working capital	1,248	979	2,227	4,700
Costs of the offer	-	2,429	2,429	2,500
<b>Total</b>	<b>4,493</b>	<b>6,777</b>	<b>11,270</b>	<b>30,000</b>

During the three-month period ended September 2022, overall expenditure remained in line with the estimated use of funds as set out in the Prospectus.

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*This announcement has been authorised for release by the Board.*

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## About Microba Life Sciences Limited

Microba Life Sciences is a precision microbiome company driven to improve human health. With world-leading technology for measuring the human gut microbiome, Microba is driving the discovery and development of novel therapeutics for major chronic diseases and delivering gut microbiome testing services globally to researchers, clinicians, and consumers. Through partnerships with leading organisations, Microba is powering the discovery of new relationships between the microbiome, health and disease for the development of new health solutions.

**For more information visit: [www.microba.com](http://www.microba.com)**

Microba encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group, whose contact information is housed on the Investor Relations page of the Company's website.

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## Appendix 4C

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

**Name of entity**

Microba Life Sciences Limited, and controlled entities

**ABN**

82 617 096 652

**Quarter ended ("current quarter")**

30 September 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	1,798	1,798
1.2 Payments for		
(a) research and development	(1,645)	(1,645)
(b) product manufacturing and operating costs	(817)	(817)
(c) advertising and marketing	(219)	(219)
(d) leased assets	(150)	(150)
(e) staff costs	(2,453)	(2,453)
(f) administration and corporate costs	(742)	(742)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	14	14
1.5 Interest and other costs of finance paid	(4)	(4)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	18	18
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(4,200)</b>	<b>(4,200)</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	(112)	(112)
(d) investments	-	-
(e) intellectual property	(69)	(69)
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(181)</b>	<b>(181)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
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	(112)	(112)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(112)</b>	<b>(112)</b>
<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	30,581	30,581
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,200)	(4,200)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(181)	(181)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(112)	(112)
4.5	Effect of movement in exchange rates on cash held	374	374
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>26,462</b>	<b>26,462</b>

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	22,988	26,230
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other - Restricted Cash* (current)	3,474	4,351
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>26,462</b>	<b>30,581</b>

\*Relates to cash held in a Microba escrow account for the purposes of satisfying Ginkgo Bioworks R&D activities during FY23

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**	(112)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		

\*\*Payments included in item 6.1 above relate to Director Fees and Consulting Fees paid to Directors of Microba Life Sciences Limited during the period.



<b>7.</b>	<b>Financing facilities</b> <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>	<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	Other (please specify)	(225)	(225)
7.4	<b>Total financing facilities</b>	<b>(225)</b>	<b>(225)</b>
7.5	<b>Unused financing facilities available at quarter end</b>		-
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>An unsecured insurance premium funding arrangement was entered into to finance the Group's annual insurance premiums. The balance originally drawn was \$425k, the balance drawn at quarter end was \$225k, and is repayable over 11 equal monthly instalments, with a fixed interest rate of 3.093%.</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)	(4,200)
8.2	Cash and cash equivalents at quarter end (item 4.6)	26,462
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	26,462
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	6.3
	<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: .....

Authorised by: .....  
(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.