



ASX Announcement

30 Oct 2024

Quarterly Cashflow Report & Business Update – Period ending 30 September 2024

Cambium Bio Limited (ASX:CMB) (Cambium Bio or Company), a clinical-stage regenerative medicine company focusing on the development of innovative biologics for ophthalmology and tissue repair applications, today released its quarterly cash flow report and business update for the period ending 30 September 2024 (the quarter).

Elate Ocular® Development Progress

Cambium Bio continues to make substantial progress in preparing for the registration-enabling Phase 3 trials of Elate Ocular®, its lead product candidate for dry eye disease. The trials will be conducted across multiple sites in Australia, the United States, and Taiwan.

- **Chemistry, Manufacturing, and Controls (CMC)**

The Company has successfully advanced the development of bioactivity and potency assays for Elate Ocular® in preparation for the Phase 3 trials. The comprehensive assay data package is scheduled for FDA submission in December 2024. Cambium Bio is working in close collaboration with a Contract Development and Manufacturing Organisation (CDMO) to initiate cGMP investigational drug manufacturing for the Phase 3 programme.

- **Clinical Trial Setup**

The Company is in advanced discussions with leading Contract Research Organisations (CROs) in the United States and Australia regarding the execution of the Phase 3 programme. These discussions encompass detailed budget planning, protocol refinement, and strategic site selection. A significant portion of patient recruitment is planned for Australian sites to optimise the overall programme costs while maintaining the highest clinical trial standards.

Subject to funding availability, Cambium Bio remains on track to dose the first patient in April 2025, with initial top-line data expected in mid-2026.

- **Regulatory Development**

During the quarter, Cambium Bio submitted a Fast Track Designation application to the U.S. Food and Drug Administration (FDA). If granted, this designation would provide several significant benefits, including enhanced FDA guidance, organisational commitment, priority review eligibility, and the potential for rolling review of the future Biologics License Application (BLA).

Additionally, the Company is actively exploring a Conditional Approval pathway in Taiwan under the country's recently enacted Regenerative Medicine Act. This pathway could potentially accelerate market access for Elate Ocular® in Taiwan ahead of other markets.

Board and Executive Management

Following the successful integration of Cambium Medical Technologies, LLC, the Company continues to strengthen its leadership team. During the quarter, Cambium Bio made two key appointments:

- Dr. Louis Tong joined the Scientific Advisory Board, bringing extensive expertise in ocular immunology and dry eye disease. Dr. Tong is a Senior Consultant at the Singapore National Eye Centre and an internationally renowned clinician-scientist with over two decades of experience in ophthalmology.
- Dr. ChiTai Chang was appointed to the Board of Directors as a representative of Orient EuroPharma. Dr. Chang brings significant pharmaceutical industry experience and currently serves as Chief Strategy Officer at Orient EuroPharma. His expertise in steering clinical programmes to successful market entry will be invaluable as Cambium Bio progresses towards FDA BLA approval for Elate Ocular®.

Financial Summary

As of 30 September 2024, Cambium Bio held cash reserves of \$1.32 million. The Company's cash outflow for the quarter was \$1.5 million, which included several one-off expenses related to the merger completion, settlement of overdue liabilities, and prepayments for specific R&D activities.

Aggregate payments to related parties during the quarter totalled \$674,000, comprising directors' fees, consulting fees, and a retainer and incentives to CEO Karolis Rosickas.

Financing Update

In preparation for the pivotal Phase 3 trials, Cambium Bio has appointed a lead manager to coordinate additional capital raising activities. The Company's management has commenced investor meetings in Australia and overseas, receiving strong initial interest. The Board, management, and key shareholders remain confident in the Company's ability to secure adequate funding for the next stages of Elate Ocular® development.

-ENDS-

About Cambium Bio Limited

Cambium Bio Limited (ASX:CMB) is a Sydney-based clinical-stage regenerative medicine company focusing on the development of innovative biologics for ophthalmology and tissue repair applications. The Company's proprietary technology, based on human platelet lysate, is being leveraged to create a pipeline of novel therapeutics, with a primary focus on ophthalmology. Cambium Bio's lead product candidate, Elate Ocular[®], is being developed to address significant unmet medical needs in the treatment of dry eye disease. In addition, the Company's stem cell platform, Progenza[™], is being applied to the development of therapies for knee osteoarthritis and other tissue repair indications. Cambium Bio is committed to advancing its pipeline through clinical development and commercialisation, with the goal of providing transformative treatments to improve patient outcomes. For more information about the Company and its programs, please visit www.cambium.bio.

Authorisation & Additional information

This announcement was authorised by the Board of Directors of Cambium Bio Limited.

For further information, please contact:

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Corporate Secretary
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1 300 995 098

Appendix 4C

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

Name of entity

Cambium Bio Limited

ABN

13 127 035 358

Quarter ended ("current quarter")
30th September 2024

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	256	256
1.2 Payments for		
(a) research and development	(331)	(331)
(b) product manufacturing and operating costs	(92)	(92)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs (including Directors)	(665)	(665)
(f) administration and corporate costs	(717)	(717)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	14	14
1.5 Interest and other costs of finance paid	(6)	(6)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(1,541)	(1,541)
1.2 (a) Research and development costs in relation to the production of Elate Ocular, Progenza and Sygenus technologies		
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses	-	-
(c) property, plant and equipment	(4)	(4)
(d) investments	-	-
(e) intellectual property	-	-
(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 (Loan repayment from shareholders)	-	-
2.6	Net cash from / (used in) investing activities	(1,545)	(1,545)
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)	-	-
3.10	Net cash from / (used in) financing activities	-	-
4. Net increase / (decrease) in cash and cash equivalents for the period			
4.1	Cash and cash equivalents at beginning of period	2,865	2,865
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,541)	(1,541)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	(4)

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)	-	-
4.5	Effect of movement in exchange rates on cash held	(5)	(5)
4.6	Cash and cash equivalents at end of period	1,315	1,315

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	1,315	2,865
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)	1,315	2,865

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	674
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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.

6.1 Aggregate payments to related parties

- payments to Directors – Consulting fees and Directors fees (include payments to Sherman Group Pty Ltd, a company of which with Barry Sechos is a director, for services provided)
- Retainer and incentives paid to Mr. Karolis Rosickas

7. Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	451	451
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	451	451
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.		
<p>Cambium Medical Technologies, LLC (CMT) entered into a Senior Note Purchase Agreement with Georgia Research Alliance, LLC, in April 2017. It's an unsecured loan of US\$250,000 at a 5% interest rate per annum. US\$152,000 matures on 7 April 2026, and US\$98,000 matures on 7 August 2026. A New Note of US\$37,500 is payable upon CBL raising at least US\$1.0M.</p>		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9) (net of receipt)	(1,541)
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,315
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	1,315
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	0.85
<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?	
<p>Answer: No. The current quarter included one-off cash outflows related to the merger with Cambium Medical Technologies, LLC, repayment of overdue liabilities, and prepayments for certain one-off R&D activities.</p>	
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?	
<p>Answer: Yes. The company retained a lead manager for the planned fundraising process. Investor meetings have been initiated with strong initial interest.</p>	

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 interest from potential new investors and existing shareholders, the Company believes it will be able to raise additional capital to fund its Phase 3 development activities.

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:30 Oct 2024.....

Authorised by:By the Board.....
(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.