

Public Announcement

ASX Code: 1AI

# **December Quarterly Activities Report and Appendix 4C Cash Flow Statement**

## Highlights:

- Development of AI driven biopharmaceutical prediction platform, known as Algorae Operating System, continues at UNSW AI Institute
- Receives CSIRO grant for three PhD candidates to assist with development and iterative upgrades of Algorae Operating System over a period of three years
- Continues preclinical studies in Al-116 for dementia and Al-168 for cardiovascular disease at La Trobe and Monash Universities
- Strategic review of the NTCELL program continues.

Melbourne, Australia – 30 January 2024: Algorae Pharmaceuticals Ltd (ASX Code: 1AI) ("Algorae" or "the Company") is pleased to provide its quarterly activities report and appendix 4C for the period ended 31 December 2023.

## **Development of Algorae AI Operating System with UNSW**

During the quarter, Algorae executed an agreement with University of NSW ('UNSW') to develop a proprietary artificial intelligence ('Al') enabled platform for biopharmaceutical prediction of both combination drug leads and repurposed drug leads agnostic to medical indication.

Known as Algorae Operating System ('AlgoraeOS'), the platform under development, in collaboration with Al experts from UNSW Al Institute, will predict synergistic drug combinations using machine learning, deep learning, and neural network algorithms over a multitude of extensive and multi-disciplinary public and private databases. Existing past and present registered drugs and other potentially therapeutic molecules are being included in the databases. AlgoraeOS will encompass a specialisation in predicting therapeutic utility of cannabinoid combination drug targets - a key differentiating aspect of the platform to those being developed by international peer companies.

Algorae retains 100% ownership rights to all project intellectual property, including synergistic combination drug targets. The first version of AlgoraeOS, available in Q2 or Q3 of CY2024, will be immediately capable of deriving insights for the Company and will be enhanced in iterative upgrades by incorporating additional data, data modalities and adopting the latest AI technology.

AlgoraeOS will develop an Al-generated and Al-enhanced drug development pipeline for the Company. Ongoingly, insights from the platform will enhance the development of those drug targets. Algorae also intends to seek licensing, development and commercialisation partnerships over Al-generated drug targets and medical indication specific insights.

## Algorae Becomes Participant to CSIRO Next Generation AI Graduate Program Grant Funding

In October 2023, Algorae become an industry participant to the Next Generation AI Graduate Program ('NGAIGP'), established and operated by Australia's national science agency, CSIRO. Under the agreement, UNSW has recruited three PhD candidates for the purpose of advancing various components of AlgoraeOS.

The candidates are supervised and managed by lead investigator and AI expert, Associate Professor Fatemeh Vafaee, and Dr Muhammad Heydari, who is a full time post-doctoral officer assigned to the project. The hand-selected PhD candidates form part of the research and development team for the AlgoraeOS project and are co-funded by CSIRO and Algorae.

CSIRO provides approximately 2/3rds of the funding required for the candidates, with Algorae providing approximately 1/3 of funding over the three-year term of the scholarships. The NGAIGP was established to deliver partnerships with industry and universities to invest in home-grown, job-ready graduates to unlock the immense economic opportunity offered by artificial intelligence and other emerging technologies.

#### AI-116 Drug Candidate for Dementia

Preclinical studies associated with Al-116 continued at La Trobe University ('LTU') during the quarter. Al-116 comprises a cannabinoid and another off-patent pharmaceutical drug. The preclinical studies being undertaken employ a suite of state-of-the-art experimental techniques, which are expected to provide valuable insights into the mechanism of action of Al-116, including by comparing the efficacy of Al-116 to an existing class of drugs used to treat dementia.

*In vitro* studies have commenced, and results are anticipated in multiple deliverable time frames to be announced to ASX as they are received and analysed. The results will guide the next steps in the R&D program for AI-116 and potentially serve to underpin further patent applications to develop intellectual property assets that align with the Company's commercial interests.

Dementia is a term used to describe a decline in cognitive function that affects a person's ability to perform daily activities. A person with dementia has two or more specific difficulties, including decline in memory, reasoning, language, coordination, mood and behaviour. Causes of dementia include Alzheimer's disease, vascular dementia, lewy body dementia, frontotemporal dementia, Parkinson's disease and Huntington's disease. The global dementia drugs market size was valued at more than US\$8.7B in 2021 and is projected to reach US\$19.7B by 2031, growing at a CAGR of  $8.5\%^1$ .

### AI-168 Drug Candidate for Cardiovascular Disease

During the quarter, Algorae executed a research agreement with Monash University ('Monash') to undertake an extensive range of preclinical studies to further assess the Company's cannabinoid-based combination drug, known as Al-168, in various cardiovascular models.

Al-168 includes a cannabinoid and another pharmaceutical drug. In performing the preclinical studies, the models undertaken by Monash are expected to provide an understanding of the mechanism of action of Al-168 across a range of cardiovascular diseases ('CVDs'). The preclinical efficacy of Al-168 will be compared to existing classes of drugs used to treat CVDs. Algorae has filed a provisional patent application over Al-168 to establish a priority date for the invention ahead of potential competitor companies.

CVDs encompass a range of conditions affecting the heart and blood vessels. These diseases collectively represent a significant global health burden, with millions of people affected worldwide. CVDs are a leading cause of morbidity, mortality, and healthcare expenditure. The potential market for new drugs targeting CVDs is substantial as the global population continues to age and lifestyles contribute to an increase in cardiovascular risk factors. Additionally, emerging economies with improving healthcare infrastructure are also witnessing a growing need for advanced cardiovascular treatments. The market for new drugs is not only driven by the prevalence of CVDs but also by the continuous pursuit of more effective and safer treatments. New drugs that offer improved outcomes, reduced side effects, and enhanced patient compliance have a vast market potential.

### Algorae Engages HL Pharma to Warehouse Cannabinoid Compounds

In December, Algorae executed an agreement with HL Pharma to import and warehouse company-owned cannabinoids and other compounds for distribution to its research partners as and when required, minimising drug access lead times.

HL Pharma holds relevant licenses to import and supply pharmaceutical ingredients, including schedule 2 to schedule 9 substances. Under the agreement with Algorae, HL Pharma will be responsible for the importation, storage, supply, and distribution of compounds to the research partners of Algorae, while ensuring compliance with Good Distribution Practice (GDP).

The pharmaceutical ingredients ordered to date comprise a range of under-studied alternative cannabinoids (not CBD or THC) for research in a range of medical indications either alone or in combination with other pharmaceutical compounds.

The additional cannabinoids are intended to be integrated into existing programs being undertaken by our research partners La Trobe and Monash University. Under-studied alternative cannabinoids will also be used to enhance the predictive capabilities of AlgoraeOS.

#### **NTCELL for Parkinson's Disease**

The Company continued to progress a scientific review of the NTCELL clinical trial protocol and development plan with a primary focus on assessing potential enhancements to the therapeutic value of NTCELL. The NTCELL scientific review has been significantly advanced by Dr Belinda Di Bartolo whose 12-month contract with the Company was not renewed after the end of the December quarter. Further review will be undertaken by the Company's chief scientific officer Dr James McKenna.

#### **Corporate Activities**

At December 31, 2023, Algorae recorded A\$3.62M in cash at bank. R&D expenditure comprised payments to the Company's research partners at La Trobe, Monash and UNSW. Algorae is eligible to receive an annual cash rebate equivalent to approximately 43.5% of all monies spent on R&D in Australia. Algorae expects a tax rebate associated with R&D expenditures made in the previous financial year (FY23) in the current March quarter. Item 6.1 of Appendix 4C (below) represents amounts paid to directors and related parties.

This announcement has been approved for release to ASX by the Algorae Board of Directors.

For further information: www.algoraepharma.com

#### **Corporate and Media Enquiries**

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#### **About Algorae Pharmaceuticals Limited**

Algorae is a pharmaceutical development company focused on discovering and developing novel treatments for medical conditions with under met medical needs. Algorae has a highly proficient internal scientific team and academic collaborations with esteemed universities that assist the Company to achieve its goals. Existing

drug candidates include Al-116 combination drug candidate for dementia, Al-168 for cardiovascular disease and NTCELL for Parkinson's disease. Algorae intends to increasingly use artificial intelligence to assist its scientific and commercial endeavours, including by using Al to generate drug targets. The Company is listed and publicly traded on the Australian Stock Exchange (ASX: 1Al) and in the United States (OTCQB: LVCLY).

For more information visit www.algoraepharma.com or follow @algoraepharma on Twitter or LinkedIn.

#### References

<sup>1</sup> https://www.alliedmarketresearch.com/dementia-drugs-market-A12014

#### **Forward-looking statements**

This document may contain certain forward-looking statements, relating to Algorae's business, which can be identified by the use of forward-looking terminology such as "promising," "probable", "plans," "anticipated," "will," "project," "believe," "forecast," "expected," "estimated," "targeting," "aiming," "set to," "potential," "seeking to," "goal," "could provide," "intends," "is being developed," "could be," "on track," or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other health authorities' requirements regarding any one or more product candidates, nor can there be any assurance that such product candidates will be approved by any health authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, and new clinical data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated, or expected. Algorae is providing this information and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.

# Appendix 4C and Quarterly cash flow report for entities subject to Listing Rule 4.7B

# Name of entity

Algorae Pharmaceuticals Limited	
ABN	Quarter ended ("current quarter")
14 104 028 042	31 December 2023

Con	solidated statement of cash flows	Current quarter \$A	Year to date (6 months) \$A
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(161,715)	(297,771)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(21,031)	(23,197)
	(d) leased assets	-	-
	(e) staff costs	(65,451)	(205,763)
	(f) administration and corporate costs	(282,655)	(512,986)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	15,714	31,123
1.5	Interest and other costs of finance paid	-	-
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	(515,138)	(1,008,594)

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

	(f) other non-current assets	-	-
Con	solidated statement of cash flows	Current quarter \$A	Year to date (6 months) \$A
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	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	562,805
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	7,125
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(49,260)
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	-	520,670

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,137,607	4,111,074

4.2	Net cash from / (used in) operating activities (item 1.9 above)	(515,138)	(1,008,594)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
Cons	solidated statement of cash flows	Current quarter \$A	Year to date (6 months) \$A
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	520,670
4.5	Effect of movement in exchange rates on cash held	(33)	(714)
4.6	Cash and cash equivalents at end of period	3,622,436	3,622,436

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	Previous quarter \$A
5.1	Bank balances	622,436	1,137,607
5.2	Call deposits	3,000,000	3,000,000
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)	3,622,436	4,137,607

6.	Payments to related parties of the entity and their associates	Current quarter \$A
6.1	Aggregate amount of payments to related parties and their associates included in item 1	46,600
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.

Payments of directors and consultancy fee.

7.	Financing facilities  Note: the term "facility' includes all forms of financing arrangements available to the entity.  Add notes as necessary for an understanding of the sources of finance available to the entity.	Total facility amount at quarter end \$A	Amount drawn at quarter end \$A
7.1	Loan facilities		

7.2	Credit sta	indby arrangements		
7.3	Other (ple	ease specify)		
7.4	Total fina	ancing facilities		
7.5	Unused	financing facilities available at qua	arter end	
7.6	rate, mate facilities h	the box below a description of each urity date and whether it is secured on have been entered into or are propo- note providing details of those facili	or unsecured. If any add sed to be entered into af	itional financing
8.	Estimat	ed cash available for future op	erating activities	\$A
8.1	Net cash from / (used in) operating activities (item 1.9)		(515,138)	
8.2	Cash and cash equivalents at quarter end (item 4.6)		3,622,436	
8.3	Unused finance facilities available at quarter end (item 7.5)		-	
8.4	Total available funding (item 8.2 + item 8.3) 3,62		3,622,436	
8.5	Estimate item 8.1)	d quarters of funding available (it	em 8.4 divided by	7.0
		entity has reported positive net operating cas e estimated quarters of funding available mu		m 8.5 as "N/A". Otherwise, a
8.6	.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:		ring questions:	
		loes the entity expect that it will cont ash flows for the time being and, if n		level of net operating
	Answer:			
	С	las the entity taken any steps, or doe ash to fund its operations and, if so, elieve that they will be successful?		
	Answer:			
		Ooes the entity expect to be able to c bjectives and, if so, on what basis?	ontinue its operations an	d to meet its business
	Answer:			

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

- 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 January 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.