

SEPTEMBER 2022 QUARTERLY ACTIVITY REPORT

HIGHLIGHTS

- **Submission of Phase I Clinical Trial for HREC approval:** This was followed by the HREC providing a decision that the study was not approvable at this stage
- **Multiple activities underway to resubmit HREC application:** NSB has engaged international experts to resubmit HREC application in 1H CY 2023
- **CEO resignation:** the Company is conducting a search for a new leadership with deep experience in clinical trials & regulatory work
- **Receipt of R&D Tax Incentive Refund:** NSB received ~\$1.16m for FY 2021
- **Cash as at 30 September 2022:** Cash position of A\$4.14m as at 30 September 2022

NeuroScientific Biopharmaceuticals Ltd (ASX: NSB) (“**NeuroScientific**” or “**the company**”) today submitted its Appendix 4C and quarterly activity report for the period ended 30 September 2022.

QUARTERLY ACTIVITY REPORT

Submission of Phase I Clinical Trial

Early in the September 2022 quarter, NeuroScientific reported that it submitted an application for Human Research Ethics Committee (HREC) review of a Phase I clinical trial of lead drug candidate EmtinB™ scheduled to be run in Australia. Unfortunately, mid quarter, the company was notified that the HREC did not believe that the supporting documentation sufficiently addressed the risk-benefit profile of the product to initiate a Phase I clinical trial.

The committee had concerns across three core areas which included:

- Impurity profile of the manufactured EmtinB™ product, particularly regarding the identification of all impurities and a query on overall purity.
- Local injection site tolerability was not satisfactorily demonstrated. The Company does note however that systemic safety was not raised as a core concern.
- An efficacy animal model referred in the submission was not accepted due to a dimer form of EmtinB used in this model compared to a dendrimer form that is planned to be used in future clinical studies.

The Company is addressing the issues identified by the HREC committee by specifically focussing on the manufacturing, safety and efficacy concerns as raised.

This includes the engagement of leading experts in the fields of regulatory compliance and toxicology to ensure that future HREC submissions for clinical trial approval for EmtinB have been rigorously prepared to best industry standards.

In addition, the Company plans to conduct a scientific meeting with an overseas regulatory agency (for example, UK's MHRA) to confirm that the Company's work is appropriate to support a Phase I trial.

CEO Resignation

Neuroscientific advised the market during September 2022 that Non-Executive Chairman, Paul Rennie had accepted the resignation of Former CEO and Managing Director, Matt Liddelow effective immediately.

The company advised following this that there would be a search for an appropriately qualified CEO and may appoint an interim CEO to oversee the next 3-6 months.

Receipt of Research and Development Tax Incentive Refund

In August 2022, Neuroscientific received an R&D Tax Incentive Refund of approximately \$1,158,480 in cash from the federal government in relation to eligible R&D activities undertaken by the Company during the 2020/2021 financial year. This cash will be reinvested into R&D programs that are currently being undertaken by the company.

Outlook for Q4 2022 / Q1 2023

The Early-Phase Clinical Trial that was initiated in June 2022 (Phase 0) will provide important information on the effect of EmtinB™ on peripheral inflammation as well as inform investigations that may be included in the planned Phase I clinical trial.

The company has a goal to have all information following purity, safety and efficacy investigations that are currently ongoing or in planning and will advise at the investigation's completion. We expect data from these activities will fill the gaps raised in the initial ethics review of the Phase I Clinical Trial. This will allow us to plan for a resubmission in 1H 2023. The Company will provide an update to the market once there is more visibility in the timeline.

Quarterly Cash Flow Summary

NeuroScientific's cash position was \$4.14 million as at 30 September 2022. The Company has maintained a strong cash position during the initial execution of its clinical development program and corporate expenses continue to be carefully managed.

Net operating cash outflows for the quarter were \$3.076m. Research and development activities payments totalled \$3.715m for the quarter. This included several significant non-repeatable costs including a manufacturing cost of approx \$1.5m AUD for GMP product ahead of clinical trials, \$302k for R&D expenses related to research programs and \$100k for clinical trial expenses.

Staff costs for the quarter were \$255k. Administration and corporate costs were \$265k. During the quarter, the company spent \$29k in advertising and marketing costs.

Payments to related parties during the September 2022 quarter totalled \$208k and relate to Director fees, salaries and superannuation (\$179k) and Administration and Management fees (\$29k).

The level of net cash burn for the December 2022 quarter is expected to be significantly lower going forward, due to the Company incurring some high, non-recurring costs in the September 2022 quarter, in addition to a thorough review of operations to preserve cash in the coming months as the work towards a new Phase I submission continues. Additionally, the Company is currently completing the 2022 tax return in order to access the R&D tax incentive refund for the 2022 financial year expenses.

This announcement is authorised by the Board of NeuroScientific Biopharmaceuticals Ltd.

-ENDS-

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About NeuroScientific Biopharmaceuticals Ltd

NeuroScientific Biopharmaceuticals Limited (ASX: NSB) is a company developing peptide-based pharmaceutical drugs that target a number of neurodegenerative conditions with high unmet medical demand. The company's product portfolio includes EmtinB™, a therapeutic peptide initially targeting Alzheimer's disease and glaucoma, as well as other Emtin peptides (EmtinAc, EmtinAn, and EmtinBn) which have demonstrated similar therapeutic potential as EmtinB™. For more information, please visit www.neuroscientific.com

About EmtinB™

EmtinB™ is a peptide-based compound that binds to surface-based cell receptors from the LDLR family, activating intracellular signalling pathways that stimulate neuroprotection, neuroregeneration and modulate neuroinflammation. EmtinB™ is modelled on a specific active domain of the complex human protein called Metallothionein-IIA, which is produced as part of the human body's innate immune response to cell injury.

Our preclinical research has established that EmtinB™ is highly specific and selective for its target receptor, safe and well tolerated at high concentrations, and is able to penetrate the blood brain barrier. A series of Phase I clinical studies will be conducted to establish the safety profile of EmtinB™ in humans.

Appendix 4C

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

Name of entity

NeuroScientific Biopharmaceuticals Limited

ABN

13 102 832 995

Quarter ended ("current quarter")

30 September 2022

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	-	-
1.2 Payments for		
(a) research and development	(3,715)	(3,715)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(29)	(29)
(d) leased assets	-	-
(e) staff costs	(255)	(255)
(f) administration and corporate costs	(265)	(265)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	30	30
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,158	1,158
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(3,076)	(3,076)
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	-	-

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)	-	-
2.6	Net cash from / (used in) investing activities	(0)	(0)

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	(0)	(0)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	7,216	7,216
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,076)	(3,076)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

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	-	-
4.6	Cash and cash equivalents at end of period	4,140	4,140

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	187	291
5.2	Call deposits	3,953	6,925
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)	4,140	7,216

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	(208)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	
<p><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></p> <p>Item 6.1 above includes Director salaries, fees & superannuation (\$179k) and management & administration fees (\$29k)</p>		

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	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-
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.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,076)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,140
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,140
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.3
	<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: No, the company expects to have significantly lower net operation cash flows in future quarters. The September 2022 quarter included several significant non-repeatable costs including a manufacturing cost of approx \$1.5m AUD for GMP product ahead of clinical trials, \$302k for R&D expenses related to research programs and \$100k for clinical trial expenses.	
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: The Company has commenced the tax return for 2022 financial year in order to apply for the R&D Tax Incentive Refund, which will provide a cash boost in the coming months.	

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, in light of non-repeatable expenses as detailed above and expected receipt of the R&D Tax Incentive Refund.

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: 31 October 2022

Authorised by: The Board of Directors