

## **JUNE 2022 QUARTERLY ACTIVITY REPORT**

### **HIGHLIGHTS**

- **Completion of Safety & Toxicity Program:** All preclinical safety and toxicology studies required by regulatory agencies prior to use of EmtinB™ in humans were successfully completed.
- **Clinical Trial Progress:** With all safety studies completed, NeuroScientific was granted HREC approval to commence an Early-Phase Clinical Trial for EmtinB™ and has also submitted for HREC approval to commence a Phase I Clinical Trial to investigate the safety and tolerability of EmtinB™ in healthy human volunteers.
- **Promising signals of efficacy of EmtinB™ in MS animal study:** EmtinB™ was evaluated in an industry gold standard animal model for Multiple sclerosis.
- **Expansion of the clinical team:** The Company expanded its clinical management team.
- **Cash as at 30 June 2022:** Strong cash position of A\$7.2M as at 30 June 2022.

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

### **QUARTERLY ACTIVITY REPORT**

Throughout the June 2022 quarter, NeuroScientific reported several key milestones as the Company successfully progressed its lead drug candidate EmtinB™ into clinical development, highlighted by the landmark achievement of receiving ethics approval to commence the very first clinical trial for EmtinB™. The Company has maintained a strong cash position and is positioned for further success during the September quarter 2022.

#### **Successful completion of Preclinical Safety and Toxicology Program for EmtinB™**

During the June 2022 quarter, the Company reported positive safety outcomes from its preclinical Safety and Toxicology Program for EmtinB™, with the safety data from pivotal toxicology studies demonstrating daily doses up to 20x above the predicted effective dose-range in humans being well-tolerated with no reported significant adverse findings in multiple animal species. The preclinical Safety and Toxicology Program was undertaken to support the advancement of EmtinB™ into clinical trials for the Company’s neurology indications, leading with Alzheimer’s disease and Multiple sclerosis, which represent large markets with unmet medical needs.

### **Commencement of the Clinical Development Program for EmtinB™**

NeuroScientific reported a number of historic company milestones during the June 2022 quarter, including Human Research Ethics Committee (HREC) approval to commence its first clinical trial for EmtinB™, an Early-Phase Clinical Trial involving the assessment of biomarkers in human blood samples, and the subsequent milestone of recruitment of the first subject for this clinical trial. The Early-Phase Clinical Trial is an important initial component of the clinical development program for EmtinB™ as the Company seeks to develop biomarker data to indicate proof of the mechanism of activity of EmtinB™ in humans for the purpose of guiding efficacy outcomes during future clinical trials in patients.

### **Positive preliminary results in Multiple sclerosis animal studies**

Also during the June quarter, NeuroScientific reported highly promising preliminary results from its preclinical Multiple sclerosis (MS) Program, conducted in a gold-standard animal model for MS, the myelin oligodendrocyte glycoprotein-induced experimental autoimmune encephalomyelitis (MOG-EAE) mouse model. The study evaluated EmtinB™ across 4 dose groups (5mg/kg, 10mg/kg, 20mg/kg, and 40mg/kg) in comparison to an untreated control group, with the drug administered daily for a period of 30-days following the onset of initial symptoms. Most importantly, the results from this study determined that the 10mg/kg and 20mg/kg EmtinB dose groups were the most effective in this MS animal model and both dose groups will be further validated in a larger animal study to be undertaken during the 2H CY2022.

### **Expansion of the Clinical Development Team**

Another key event during the June 2022 quarter involved the enhancement of the NeuroScientific management team to include additional clinical development expertise. Dougal Thring was promoted from the role of VP of Clinical Development to Chief Operating Officer and Simon Scott was appointed as Director of Clinical Development. With this management structure in place, NeuroScientific is well-positioned for future success as a clinical-stage drug development company.

### **Outlook for 2H 2022**

With the Early-Phase Clinical Trial for EmtinB™ underway, NeuroScientific has since, as announced on 12 July 2022, submitted an application for HREC approval to commence a Phase I Clinical Trial for EmtinB™ in healthy volunteers. The planned Phase I clinical trial will seek to establish the safety profile, pharmacokinetics and pharmacodynamics of EmtinB™ in up to 88 healthy adult volunteers. Achieving HREC approval for the Phase I Clinical Trial will be another landmark milestone for the Company and in the progression of EmtinB™ as a first-in-class treatment with disease modifying potential for Multiple sclerosis and Alzheimer's disease.

NeuroScientific is also planning to undertake additional animal studies in gold-standard models for MS as part of its preclinical MS Program. These studies will aim to further validate the *in vivo* therapeutic effect of EmtinB in MS and will be undertaken in models that represent different stages of the disease, such as the relapse-remitting stage of MS and the more advanced progressive stage of MS. Successful completion of these planned studies will support the advancement of EmtinB into a future Phase II Clinical Trial in MS patients.

The Company will also continue to progress its Ophthalmology R&D Program for EmtinB™, with important preclinical 13-week ocular toxicity studies scheduled for completion during the 2H CY2022.

### **Quarterly Cash Flow Summary**

NeuroScientific's cash position was \$7.2 million as at 30 June 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 \$681,000. Research and development activities payments totalled \$239,000 for the quarter. Staff costs for the quarter were \$252,000. Administration and corporate costs were \$179,000. During the quarter, the company spent \$33,000 in advertising and marketing costs.

Payments to related parties during the June 2022 quarter totalled \$184,000 and relate to Director fees, salaries and superannuation (\$155,000) and Administration and Management fees (\$29,000).

The level of net cash burn for the September 2022 quarter is expected to be higher than the June 2022 quarter due to the Company progressing its planned clinical development program, with the Early-Phase Clinical Trial already underway and the Phase I Clinical Trial expected to commence during the September 2022 quarter.

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

-ENDS-

For more information please contact:

Matthew Liddelow  
CEO and Managing Director  
ml@neuroscientific.com  
+ 61 8 6382 1805

Lucas Robinson  
Investor Relations  
Corporate Storytime  
[lucas@corporatestorytime.com](mailto:lucas@corporatestorytime.com)  
+ 61 408 228 889

### **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](http://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 June 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(239)	(5,038)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(33)	(98)
(d) leased assets	-	-
(e) staff costs	(252)	(939)
(f) administration and corporate costs	(179)	(935)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	22	68
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)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(681)</b>	<b>(6,942)</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	(1)	(4)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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>(1)</b>	<b>(4)</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	-	-
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>(0)</b>	<b>(0)</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	7,898	14,162
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(681)	(6,942)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1)	(4)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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	<b>Cash and cash equivalents at end of period</b>	<b>7,216</b>	<b>7,216</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	291	495
5.2	Call deposits	6,925	7,403
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>7,216</b>	<b>7,898</b>

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	(184)
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 &amp; superannuation (\$155k) and management &amp; administration fees (\$29k)</p>		

<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)	-	-
7.4	<b>Total financing facilities</b>	-	-
7.5	<b>Unused financing facilities available at quarter end</b>		-
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.		

<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)	(682)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,215
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,215
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	10.6
<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: 29 July 2022

Authorised by: The Board of Directors