NeuroScientific
BIOPHARMACEUTICALS
ASX:NSB

**ASX ANNOUNCEMENT**
**28 JULY 2023**

# JUNE 2023 QUARTERLY ACTIVITY REPORT

## HIGHLIGHTS

- **NeuroScientific continues R&D work on lead drug compound EmtinB™ to address safety, purity & efficacy issues to enable HREC submission for phase I clinical trial.**
- **Work includes the development of an improved EmtinB™ drug product formulation with *in vitro* testing confirming desirable attributes for subcutaneous administration & phase-appropriate stability.**
- **Improved EmtinB™ drug product formulation displays positive *in vivo* local toxicity safety for a range of concentrations following the completion of an exploratory local toxicity study in dogs.**
- **Leading regulatory consultancy supports the purity of EmtinB™ following their independent review of manufacturing and toxicology data.**
- **EmtinB™ early phase clinical trial completed database lock, with data now undergoing analysis.**
- **Cash balance of A$4.9m as at 30 June 2023.**

NeuroScientific Biopharmaceuticals Ltd (ASX: **NSB**) (**"NeuroScientific"** or **"the company"**) today submitted its Appendix 4C and quarterly activity report for the period ended 30 June 2023.

## QUARTERLY ACTIVITY REPORT

### Formulation Redevelopment Progress

The limited localised toxicity seen in previous animal toxicology studies was determined as mostly likely attributable to the previous drug product formulation for EmtinB™. During the June quarter, there was significant progress in the redevelopment of the EmtinB™ drug product formulation. This formulation has been developed to minimise the risk of injection site pain and other localised toxicities that were seen with the previous EmtinB™ drug product formulation.

*In vitro* experiments confirmed that EmtinB™ in this improved formulation has phase-appropriate stability in this form and the chemical attributes of the formulation should ensure a very low risk of localised (injection-site) toxicity.

**Animal Study Shows Localised Injection Site Safety of Improved EmtinB™ Formulation**

The newly developed improved formulation of EmtinB™ was administered to 4 Dogs to explore the *in vivo* local injection site toxicity.

Each dog received a dose of EmtinB™ every 2 to 3 days, which increased in concentration with every dose. This allowed a determination of the no adverse event concentration range. Note that this study was not powered for statistical significance, but this exploratory investigation is critical in determining the next steps to attain a formulation ready for human administration.

On completion of this study, the NeuroScientific technical team in consultation with a toxicology specialist and formulation specialist observed no adverse events in the dogs. The company believes that the study will provide the necessary confidence to move this formulation forward into further preclinical studies and may be appropriate for use in human dosing in a Phase I study.

**Leading Regulatory Consultancy Supports Purity of Manufactured EmtinB™**

NeuroScientific commissioned a leading product development and regulatory consultancy to conduct an independent review of all EmtinB™ manufacturing and related data combined with all phase I trial enabling preclinical toxicology studies conducted under good laboratory practice.

As part of this review, a regulatory position paper has been developed that supports the purity of manufactured EmintB™ for clinical use is phase appropriate for a first-in-human study.

Additionally, the position paper confirms that the related compounds within the manufactured product, that are identified as related impurities, have been appropriately qualified for safety in the completed preclinical toxicology studies.

This position paper has been finalised within the June quarter, with the intention to include it as part of the phase I clinical trial HREC submission that is planned.

**EmtinB™ Phase I Clinical Trial HREC Submission**

NeuroScientific has initiated discussions with clinical research organisations, specialist clinicians and other specialists to assess the outputs of the additional work that has been carried out to date across safety, purity and efficacy and to determine its sufficiency to apply for HREC review of material to progress to a phase I study.

**EmtinB™ Early Phase Clinical Study Data Base Lock**

An early phase clinical trial was initiated in 2022 to exploratorily evaluate the inflammatory modulatory effect of EmtinB™ via *ex vivo* stimulation of collected human blood samples. Within the June quarter, the final clinical study visits were completed. With all blood samples having now been processed and clinical visits completed and monitored, NeuroScientific locked the database of this clinical study. The data that has been collected is now awaiting formal exploratory analysis to determine the outcomes of the study.

Interpretation of the results of this study are expected in Q3 CY 2023, with the aim of providing information to assist in designing future studies and identifying promising patient sub-populations that may benefit from treatment with EmtinB™.

**Quarterly Cash Flow Summary**

NeuroScientific's cash position was $4.9 million as at 30 June 2023. The Company has maintained a strong cash position during the initial execution of its R&D program and corporate expenses continue to be carefully managed.

Net operating cash inflows for the quarter were $482k, in light of a GST refund of $296k relating to the import of R&D technologies. Research and development activities payments totalled $532k for the quarter.

Staff costs for the quarter were $163k. Administration and corporate costs excluding the GST refund were $100k. During the quarter, the company spent $15k in advertising and marketing costs.

Payments to related parties during the June 2023 quarter totalled $107k and relate to Director fees, salaries and superannuation ($72k) and Administration and Management fees ($35k).

The level of net cash burn for the September 2023 quarter is expected to be at similar levels as for the June 2023 quarter, as the company continues to preserve cash in the coming months as the work towards a new EmtinB™ Phase I clinical trial submission continues.

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** | **Quarter ended ("current quarter")** |
| 13 102 832 995 | 30 June 2023 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (12 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | - | - |
| 1.2 | Payments for | | |
| | (a) research and development | (532) | (5,683) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | (15) | (69) |
| | (d) leased assets | - | - |
| | (e) staff costs | (163) | (813) |
| | (f) administration and corporate costs | 196 | (995) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 32 | 107 |
| 1.5 | Interest and other costs of finance paid | - | - |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | - | 4,953 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(482)** | **(2,304)** |

| **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 (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) | - | - |
| **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 | 5,394 | 7,216 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (482) | (2,304) |
| 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 (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** | **Cash and cash equivalents at end of period** | **4,912** | **4,912** |

| 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 | 612 | 1,127 |
| 5.2 | Call deposits | 4,300 | 4,267 |
| 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)** | **4,912** | **5,394** |

| 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 | (107) |
| 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.*

Item 6.1 above includes Director salaries, fees & superannuation ($72k) and management & administration fees ($35k)

| 7. | **Financing facilities**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*Add notes as necessary for an understanding of the sources of finance available to the entity.* | **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)<br>*(** excluding R&D tax Incentive Refund)* | (482) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 4,912 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 4.912 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 10.2 |

*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.*

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 |

*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: 28 July 2023

Authorised by: The Board of Directors