



NOVEL DRUG THERAPIES FOR NEURODEGENERATIVE CONDITIONS

INVESTOR UPDATE

SEPTEMBER 2022 - ASX: NSB

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NSB INVESTOR UPDATE ON EMTINBTM HREC SUBMISSION

STRUCTURAL FORMULA OF EMTINETM



Figure 1 Structural formula of EmtinB H—Ser—Ala—Gly—Ser—Cys—Lys—Cys—Lys—Glu—Ser—Lys—Ser—Thr—Ser H—Ser—Ala—Gly—Ser—Cys—Lys—Cys—Lys—Glu—Ser—Lys—Ser—Thr—Ser Lys—β-Ala—NH₂ H—Ser—Ala—Gly—Ser—Cys—Lys—Cys—Lys—Glu—Ser—Lys—Ser—Thr—Ser H—Ser—Ala—Gly—Ser—Cys—Lys—Cys—Lys—Glu—Ser—Lys—Ser—Thr—Ser

EmtinB™ is a peptide derived from Metallothionien-II

HREC SUBMISSION REFUSED ON THREE MATTERS



NSB understands the HREC decision. The HREC explained the three reasons for the refusal were safety, purity of EmtinBTM and efficacy.

- Safety- local injection site tolerability was not satisfactorily demonstrated, with systemic safety not noted as a concern.
- **Purity of EmtinB™** lack of clear identification of impurities and overall purity of the product was questioned. Peptide manufacturing is complex and holds no clear guidance on overall purity requirements.
- **Efficacy** Key efficacy animal model was not accepted due to a different form of the EmtinB being used in this study from planned clinical product.

NSB NEXT STEPS FOR EMTINB™ (3-6 months)



- **Safety:** Two independent toxicologists (one US board certified and one with both US and EU board certification) to perform a thorough GAP analysis. Following completion of all required toxicology, a formal independent toxicology report opinion will be provided for revised HREC submission.
- Purity of EmtinB™: Currently in discussion with two manufacturers regarding the further purification of available GMP material and full characterization of impurities. The Company is also conducting a full CMC regulatory GAP analysis.
- **Efficacy.** NSB will present efficacy data on the preclinical multiple sclerosis model. The data and the final report are due from the external provider by 28 February 2023.

NSB NEXT STEPS FOR EMTINB™ (3-6 months)



• Interim CEO: Potential to appoint an interim CEO to oversee the next 3-6 months.

- Potential new asset licensed into NSB: The Company plans to file at least 2 new patents on EmtinB and potentially licensed in a new technology to expand the Company's pipeline.
- Re-submission plans: Once all items of concern that were raised through our initial submission attempt are satisfactorily addressed, and confirmed through independent expert review, NSB will re-submit to the Australian HREC or an alternant Geography, such as the MHRA (UK), to undertake the Phase I clinical trial.



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