Neuren (NEU) – ASX Announcement **27 August 2025**

H1 2025 profit after tax A$15 million, up from A$8 million in H1 2024

Highlights:

- **H1 profit after tax A$15.0 million, up from A$8.0 million in H1 2024**
- **H1 royalties from DAYBUE® (trofinetide) A$28.3 million, up from A$24.3 million in H1 2024**
- **H1 basic earnings per share 11.9 cents, up from 6.3 cents in H1 2024**
- **A$50 million share buyback completed at average price of A$12.27 per share**
- **A$300 million cash and short-term investments at 30 June 2025, up from A$222 million at 31 December 2024**
- **H1 net sales of DAYBUE reported by Acadia US$180.7 million, up from US$160.5 in H1 2024**
- **Acadia full year 2025 DAYBUE US net sales guidance of US$380 - 405 million, implying full year 2025 US royalty income for Neuren of A$62 - 67 million, compared with A$56 million in 2024**
- **Acadia submitted Marketing Authorisation Application for trofinetide in EU and initiated named patient supply programs in Europe through Clinigen, Israel through Rafa and Rest of the World through Farmamondo**
- **Primary endpoints for a single pivotal Phase 3 trial of NNZ-2591 in Phelan-McDermid syndrome agreed with FDA and first US site initiated in Phase 3 trial**
- **NNZ-2591 in Pitt-Hopkins syndrome received FDA Fast Track designation and allowance of US patent to 2040**
- **Development initiated for NNZ-2591 in Hypoxic Ischemic Encephalopathy (HIE) and *SYNGAP1* related disorder added to NNZ-2591 pipeline**

Melbourne, Australia: Neuren Pharmaceuticals (ASX: NEU) today reported its H1 2025 financial results, announcing profit after tax of A$15.0 million, up from A$8.0 million in H1 2024. The increase was mainly driven by royalty income from DAYBUE® (trofinetide), which grew to A$28.3 million from A$24.3 million in H1 2024. DAYBUE, which is marketed in the United States to treat Rett syndrome, is licensed exclusively worldwide to Acadia Pharmaceuticals (Nasdaq: ACAD).

Acadia reported DAYBUE net sales in H1 2025 of US$180.7 million, up from US$160.5 in H1 2024. Acadia's full-year 2025 DAYBUE US net sales guidance is US$380 - 405 million, which would result in full-year 2025 US royalty income for Neuren of A$62 - 67 million (assuming US$/A$ exchange rate of 0.65), compared with A$56 million in 2024.

During the half-year, Acadia submitted a Marketing Authorisation Application for trofinetide in the European Union, with potential approval anticipated in Q1 2026. Acadia has also initiated named patient supply programs in Europe through Clinigen, Israel through Rafa and Rest of the World through Farmamondo.

There is substantial potential for future growth in the US with two-thirds of the 5,500 to 5,800 diagnosed Rett patients yet to try DAYBUE. Outside the US, Acadia continues to build its European commercial team in anticipation of approval of the marketing application.

During H1 2025, Neuren completed its planned A$50 million share buyback at average price of A$12.27 per share, whilst still retaining cash and short-term investments of A$300 million at 30 June 2025, up from A$222 million at 31 December 2024. Basic earnings per share increased from 6.3 cents in H1 2024 to 11.9 cents in H1 2025.

Neuren's financial strength has enabled it to pursue development of its second drug NNZ-2591 to treat multiple neurological conditions. During the half-year the primary endpoints for a single pivotal Phase 3 trial of NNZ-2591 in Phelan-McDermid syndrome (PMS) were agreed with the US Food and Drug Administration (FDA) at a Type C meeting. This followed an End of Phase 2 Type B meeting at which alignment was reached on other key elements of the trial design. Neuren recently announced initiation of the first investigational site in the US for the trial, with other sites in the US at various stages of the initiation process. The trial will be the first ever Phase 3 trial in PMS, a serious neurodevelopmental disorder with no approved treatments. The trial program is fully funded from Neuren's existing cash reserves.

During H1 2025, Neuren's program for NNZ-2591 in Pitt Hopkins syndrome (PTHS) received Fast Track designation from the FDA. In addition, a patent covering the use of NNZ-2591 to treat PTHS was allowed by the US Patent and Trademark Office, with an expected expiry date after issue of April 2040. Related patent applications are pending in other territories.

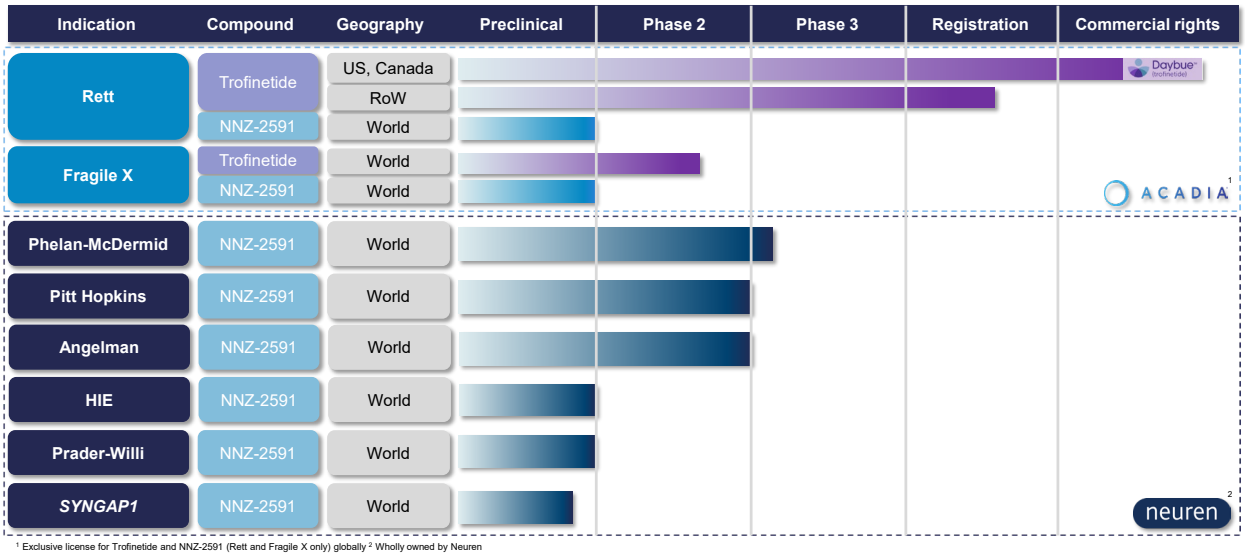
Neuren initiated development in H1 2025 for NNZ-2591 in Hypoxic Ischemic Encephalopathy (HIE), a devastating type of brain injury caused when a baby's brain does not receive enough oxygen or blood flow before or shortly after birth. Many thousands of babies and children experience HIE every year. It is one of the leading causes of neonatal death and neurodevelopmental disability worldwide. Based on its therapeutic properties and data from preclinical models, Neuren believes that NNZ-2591 can potentially provide a highly differentiated form of treatment continuing beyond acute treatment in the neonatal intensive care unit to target both the acute effects and chronic impairments resulting from HIE.

Neuren also recently announced the addition of *SYNGAP1* related disorder (SRD) into its neurodevelopmental disorders pipeline for NNZ-2591, following positive results in a pre-clinical model. The incidence of the genetic cause of SRD has been reported as 1 per 16,000 individuals and there are currently no approved treatments.

H1 Financial summary:

	H1 2025 A$m	H1 2024 A$m
DAYBUE royalty income	**28.3**	**24.3**
Interest income	6.3	5.9
Foreign exchange gain/(loss)	5.1	-
Gain/(loss) on financial derivatives	(2.6)	1.9
R&D costs	(14.9)	(17.9)
Corporate and admin costs	(2.5)	(2.4)
Profit before tax	**19.7**	**11.8**
Income tax expense	(4.7)	(3.8)
Profit after tax	**15.0**	**8.0**

Current product pipeline:



[1] Exclusive license for Trofinetide and NNZ-2591 (Rett and Fragile X only) globally [2] Wholly owned by Neuren

About Neuren

Neuren is developing new drug therapies to treat multiple serious neurological disorders that emerge in early childhood and have no or limited approved treatment options. Recognising the urgent unmet need, programs have been granted "orphan drug" designation in the United States. Orphan drug designation provides incentives to encourage development of therapies for rare and serious diseases.

DAYBUE™ (trofinetide) is approved by the US Food and Drug Administration (FDA) and Health Canada for the treatment of Rett syndrome. Neuren has granted an exclusive worldwide licence to Acadia Pharmaceuticals Inc. for the development and commercialisation of trofinetide.

Neuren's second drug candidate, NNZ-2591, is in development for multiple neurodevelopmental disorders, with positive results achieved in Phase 2 clinical trials in Phelan-McDermid syndrome, Pitt Hopkins syndrome and Angelman syndrome.

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ASX Listing Rules information

This announcement was authorized to be given to the ASX by the CEO & Managing Director of Neuren Pharmaceuticals Limited, Suite 201, 697 Burke Road, Camberwell, VIC 3124

Forward-looking Statements

This announcement contains forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Neuren to be materially different from the statements in this announcement.