

Neuren (NEU) – ASX Announcement

3 November 2023

DAYBUE™ net sales US\$66.9 million in Q3 2023

Melbourne, Australia: Neuren Pharmaceuticals (ASX: NEU) today reported highlights from the Q3 2023 earnings announcement and conference call of its partner Acadia Pharmaceuticals (Nasdaq: ACAD). Acadia announced Q3 net sales of DAYBUE™ (trofinetide) in the United States of US\$66.9 million and provided guidance for net sales in Q4 2023 of between US\$80 million and US\$87.5 million.

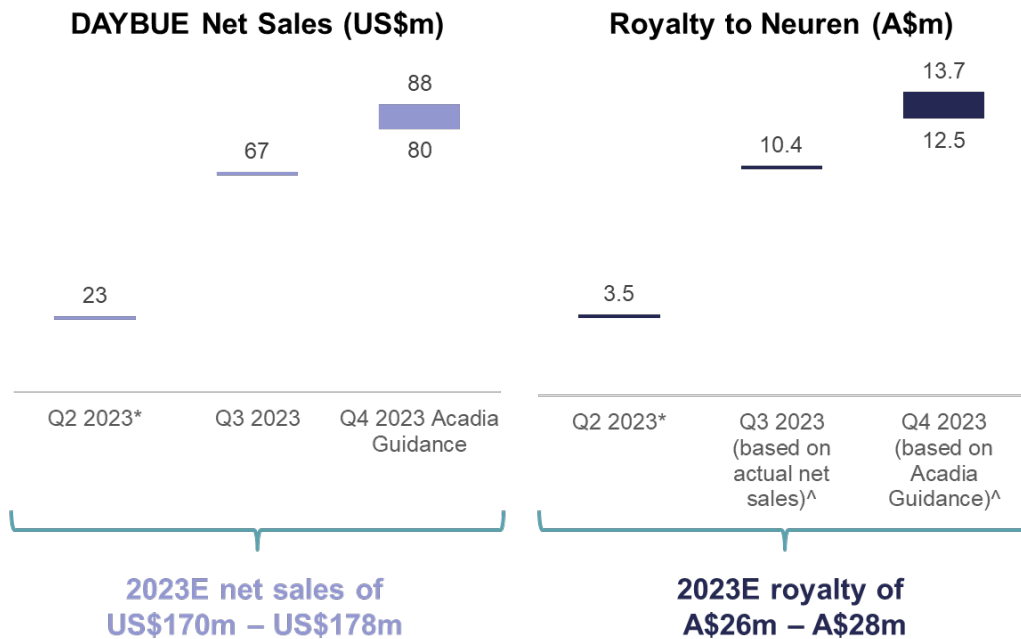
Anticipated royalties to Neuren (assuming Acadia guidance for Q4 is met and exchange rate of 0.64) are:

- A\$10.4 million for Q3 2023
- A\$12.5 to 13.7 million for Q4 2023
- A\$26 to 28 million for the full year 2023.

The Q3 earnings conference call and presentation can be accessed in the Investors section of the Acadia website www.acadia.com. Key highlights for DAYBUE were as follows:

- DAYBUE (trofinetide) net sales in Q3 2023 of US\$66.9 million, up from US\$23.2 million in Q2
- Guidance provided for net sales of between US\$80 million and US\$87.5 million in Q4 2024
- 800 patients on DAYBUE as at 30 September 2023 – surge in initial demand has exceeded pre-launch expectations
- 81% of patients remain on treatment at 4 months, measured by confirmed discontinuations – clinical efficacy, medical education and GI management measures have produced significant benefits
- 80% of lives now covered by formal reimbursement plans - faster access to reimbursement has enabled early conversion of prescription demand to new patient starts
- 75%-80% compliance to labeled dose at 3 months
- Physicians and caregivers continued reporting benefits

Neuren CEO Jon Pilcher commented: “The launch of DAYBUE has been exceptional, with all metrics exceeding expectations and we are delighted to see the positive impact in the Rett community. The first full quarter of sales has achieved an annual run-rate of more than US\$250 million. For Neuren, in addition to very significant royalty revenues, this brings into focus the potential sales milestone payments.”



* Since launch to 30 Jun 2023

^ Based on 10% of DAYBUE net sales and AUDUSD of 0.6433 for Q3 and 0.6400 for Q4

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.

DAYBUE™ (trofinetide) is approved by the US Food and Drug Administration (FDA) for the treatment of Rett syndrome in adult and pediatric patients two years of age and older. Neuren has granted an exclusive worldwide licence to Acadia Pharmaceuticals Inc. for the development and commercialisation of trofinetide.

Neuren is conducting Phase 2 trials of its second drug candidate, NNZ-2591, for each of Phelan-McDermid syndrome, Angelman syndrome, Pitt Hopkins syndrome and Prader-Willi syndrome.

Recognising the urgent unmet need, all 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.

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ASX Listing Rules information

This announcement was authorized to be given to the ASX by the board of directors 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.

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