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Neuren Pharmaceuticals (NEU)

It Keeps Getting Better

Recommendation
Buy (Hold)
Price
$22.20
Target (12 months)
$27.00 (previously $17.50)

GICS Sector

Pharmaceuticals & Biotechnology

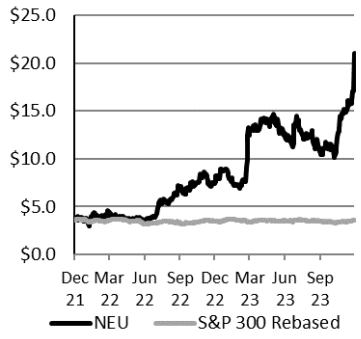
Expected Return	
Capital growth	**21.6%**
Dividend yield	**0.0%**
Total expected return	**21.6%**

Company Data & Ratios	
Enterprise value	**$2,586m**
Market cap	**$2,810m**
Issued capital	**126.6m**
Free float	**97%**
Avg. daily val. (52wk)	**$8.4m**
12 month price range	**$6.72 - $22.20**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	14.18	12.06	7.49
Absolute (%)	48.10	74.13	180.37
Rel market (%)	42.13	71.10	177.51

Absolute Price



SOURCE: IRESS

Very Encouraging Phase 2 PMS Results

NEU released impressive efficacy and safety results today from the first of four single-arm Phase 2 trials evaluating NNZ-2591 (n=18). Results in patients with Phelan-McDermid syndrome (PMS) showed statistically significant and clinically meaningful improvements in efficacy outcomes, as measured by clinicians and caregivers, and a well-tolerated safety profile. In particular:

1) **Clinician** overall assessment of improvement (**CGI-I**) mean score of 2.4. We had flagged ~3.0-3.5 would be a positive outcome, hence, this 2.4 is a great result (lower = better). Additionally, 16/18 children had an improvement from baseline, with 10/18 deemed "very much improved" or "much improved".

2) **Caregiver** overall assessment of improvement (**CIC**) mean score of 2.7. Similarly, 15/18 children had any degree of improvement from baseline, with 7/18 deemed "very much improved" or "much improved".

NNZ-2591 was generally well tolerated by the 18 subjects, with only one severe TEAE unrelated to the study drug and low rates of discontinuation. Diarrhea, a common side effect of NEU's first drug trofinetide, has not presented as an issue for NNZ-2591. Looking ahead, we expect NEU will look to commence a larger placebo-controlled Phase 3 PMS trial to confirm the initial results seen in this single-arm study. NEU have more than enough cash at hand (A$230m as at 30th Sep 2023) to do so.

Investment View: Upgrade to BUY, $27.00 PT

We have far greater confidence in NNZ-2591 following the Phase 2 results and therefore materially increase our Probability of Success in PMS and the other three indications which are similarly characterised disorders. We increase our PT to $27.00 following the increased value attributed to NNZ-2591. This represents >15% upside to the current price hence we upgrade to a BUY. Additional catalysts are expected to continue driving interest over the next 12 months, specifically (1) DAYBUE quarterly updates in the US, (2) DAYBUE submissions in Canada & Europe, (3) additional NNZ-2591 Phase 2 results, and (4) NNZ-2591 Phase 3 preparations.

Earnings Forecast

December Year End	2022	2023e	2024e	2025e
Revenue (A$m)	14.6	232.5	204.7	269.2
EBITDA (A$m)	-0.2	204.0	170.2	228.1
NPAT (reported) (A$m)	0.2	188.3	121.1	161.6
NPAT (adjusted) (A$m)	0.2	188.3	121.1	161.6
Diluted EPS (cps)	0.1	146.0	93.9	125.4
EPS growth (%)	nm	102218%	-36%	33%
PE (x)	15553.2	15.2	23.6	17.7
EV/EBITDA (x)	nm	12.7	15.2	11.3
FCF yield (%)	0.0%	6.4%	4.3%	5.6%
Dividend (cps)	0.0	0.0	0.0	0.0
Franking (%)	0.0%	100.0%	100.0%	100.0%
Dividend yield (%)	0.0%	0.0%	0.0%	0.0%
ROE (%)	0.4%	81.9%	34.5%	31.5%

SOURCE: BELL POTTER SECURITIES ESTIMATES

NNZ-2591 Phase 2 Results

Positive results in Phelan-McDermid Syndrome (PMS) Ph2 Trial

Neuren released impressive efficacy and safety results today from the first of four Phase 2 trials with their second drug candidate, NNZ-2591. The trial was conducted in 18 children with Phelan-McDermid Syndrome (PMS). Results showed statistically significant and clinically meaningful improvements in efficacy outcomes, and a well-tolerated safety profile.

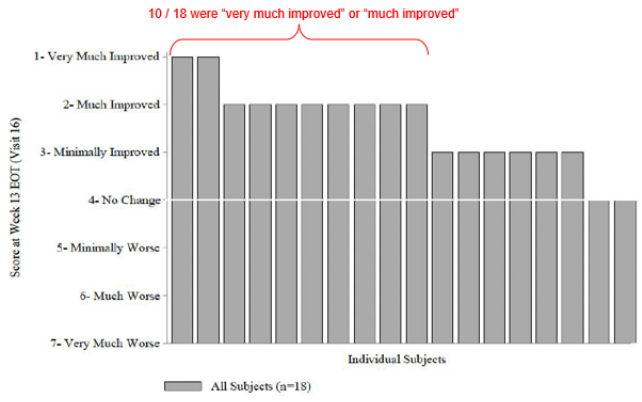
Broad efficacy improvements from baseline

There were 14 exploratory efficacy endpoints included in the single-arm trial. Endpoints included various clinician and caregiver assessments of symptomatic improvement from a baseline measurement. For 10 of the 14 efficacy endpoints, statistically significant improvements from baseline to week 13 of treatment were achieved, based on a Wilcoxon signed rank test $p<0.05$. This is a statistical test often used in single arm trial designs.

Two key efficacy endpoints showed impressive results:

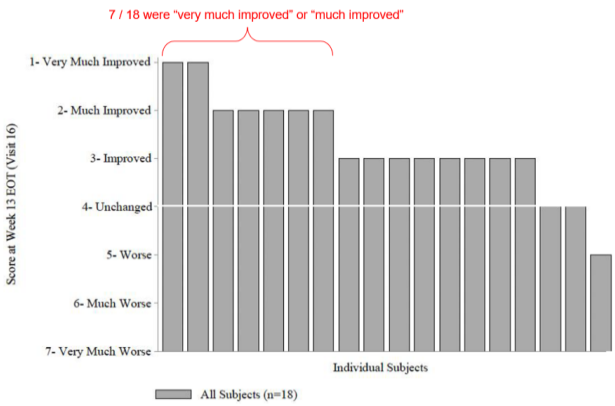
1) Clinical Global Impression of Improvement (**CGI-I**) (Figure 1):
    a. Reminder this is a **clinician assessed** 7-point rating system where 4 = no change in overall illness, 3 = "minimally improved", 2 = "much improved", and 1 = "very much improved". This is the same endpoint also suggested by the FDA to be used as a co-primary endpoint in the trofinetide Phase 3 trial.
    b. Mean CGI-I score of 2.4. We previously flagged a score of ~3.0 to 3.5 would be a positive outcome, hence, the 2.4 mean CGI-I score is a great result (lower = better).
    c. 16/18 children showed improvement from baseline.
    d. 10/18 children were "very much improved" or "much improved".
2) Caregiver Overall Impression of Change (**CIC**) (Figure 2):
    a. This is a similar 7-point measurement to CGI-I but provided by caregivers, not clinicians.
    b. Mean CIC score of 2.7.
    c. 15/18 children showed improvement from baseline.
    d. 7/18 were "very much improved" or "much improved".

Figure 1 – Clinician CGI-I Outcome at Week 13



SOURCE: COMPANY DATA

Figure 2 – Caregiver CIC Outcome at Week 13



SOURCE: COMPANY DATA

A study investigator stated that on both of the above CGI-I and CIC measurements, "improvements typically considered clinically meaningful were achieved".

When analysing the individual domain results, for both clinician and caregiver assessments, the largest improvements were seen in (1) communication, (2) cognitive/learning abilities and (3) social interactions. These domains are similar in nature to the traits most commonly identified by caregivers as their Top 3 Concerns: communication (n=13), behaviour (n=10), social interaction (n=7) and self-care (n=7).

Overall, these are very encouraging efficacy results that demonstrate clinically significant improvements for these patients. Confirmation of these outcomes in a future placebo-controlled Phase 3 trial will now be the key to ultimately gaining regulatory approval.

Safety and tolerability

NNZ-2591 was generally well tolerated by the 18 children with PMS. There was only 1 serious Treatment Emergent Adverse Events (TEAE) – gastroenteritis – and it was deemed not related to study drug. There were 3 discontinuations: 2 for COVID-19 and 1 due to seizures. Note the investigator deemed the seizure discontinuation was not treatment-related and instead related to the background condition.

Pleasingly, and unlike trofinetide, there appears to be no significant increase in rate of diarrhea. Only 2 of the 18 subjects (11%) had diarrhea reported as a TEAE (compared to ~80% for the trofinetide Phase 3 trial).

The most common TEAE was psychomotor hyperactivity, present in 4 of 18 subjects (22%). This occurs when people struggle to stay still or calm and use movement (such as fidgeting or pacing) to release tension/anxiety. Management mentioned 2 of the 4 subjects with this TEAE had a history prior to treatment and 2 had the TEAE resolve during the study. No subjects discontinued due to psychomotor hyperactivity.

In conclusion, NNZ-2591 demonstrated a relatively benign safety profile in these 18 patients. The low-risk toxicity profile is very appealing for orphan indications like PMS where regulators and clinicians are desperate to try treatments due to the lack of any approved therapies. In other words, a low risk profile means there is 'not much to lose' by trying the medication.

Figure 3 - TEAEs in 2 or More Subjects

Event	NNZ-2591 (N=18) n (%)	Event	NNZ-2591 (N=18) n (%)
Constipation	2 (11.1)	Somnolence	3 (16.7)
Diarrhea	2 (11.1)	Pyrexia	3 (16.7)
Nausea	2 (11.1)	Fatigue	2 (11.1)
Vomiting	2 (11.1)	Aggression	2 (11.1)
COVID-19	3 (16.7)	Insomnia	2 (11.1)
Nasopharyngitis	2 (11.1)	Decreased Appetite	3 (16.7)
Otitis Media	2 (11.1)	Rhinorrhea	2 (11.1)
Psychomotor Hyperactivity	4 (22.2)		

SOURCE: COMPANY DATA

Next steps for NNZ-2591

We expect these encouraging results will mean Neuren will progress NNZ-2591 into a potentially pivotal Phase 3 clinical trial for PMS. The first step will be to engage the FDA in an End of Phase 2 (EOP2) meeting to discuss these results and plans for a Phase 3 trial. There is further data analysis (including PK data) still to be conducted before submitting the meeting request to the FDA, hence, we tentatively expect the EOP2 meeting may be held around mid-CY24.

Upcoming catalysts over the next ~12 months

Beyond Phelan-McDermid syndrome (PMS), NEU are also conducting three additional Phase 2 trials for NNZ-2591 that should have topline results read out over the next ~12 months:

- **Pitt-Hopkins syndrome**: Recruitment completed 5th December 2023. Topline results expected 2Q CY24. US sites only.
- **Prader-Willi syndrome**: US sites only. Recruitment started June 2023.
- **Angelman syndrome**: Australian sites only. Recruitment started July 2022.

Moving to DAYBUE (trofinetide), there will continue to be ongoing updates from ACADIA regarding the US commercial uptake. The next could be at the JPM Conference (8-11th Jan 2024) or at the latest during their next quarterly result in ~end-Feb 2024. Additional updates are also expected regarding ACADIA's plans for ex-US territories. Lastly, Neuren is also eligible to receive one third of the Priority Review Voucher (~US$33m) owned by ACADIA, which we forecast to occur in CY24.

Investment Thesis: Upgrade to BUY, Price Target $27.00

The very encouraging results from the first clinical trial with NNZ-2591 in patients marks a material de-risking event for Neuren's second drug candidate. We have far greater confidence following these Phase 2 results and therefore increase our Probability of Success (PoS) for NNZ-2591 in PMS and the other 3 indications which are also neurodevelopmental disorders characterised by impaired neuronal function.

Phelan-McDermid syndrome (PMS) is a very commercially attractive orphan indication with estimated prevalence of ~23k US patients, very few drug candidates in the clinic, of which NNZ-2591 is the most advanced, and no currently approved treatments. We estimate NNZ-2591 could come to market as early as end-CY27/early CY28, assuming a total of ~4 years to run the Phase 3 trial, submit the NDA, and receive regulatory approval.

There will be further catalysts for Neuren over the next 12 months that will continue to drive interest; specifically, DAYBUE quarterly updates in the US, Acadia's plans for DAYBUE in Canada and Europe, additional NNZ-2591 Phase 2 results, and NNZ-2591 Phase 3 preparations.

We increase our PT to $27.00 following the increased valuation attributed to NNZ-2591. Our PT is >15% upside to the current price hence we upgrade to a BUY recommendation.

Neuren Pharmaceuticals

Neuren Pharmaceuticals (ASX:NEU) is a drug development company targeting disorders of the Central Nervous System (CNS). The lead asset is DAYBUE™ (trofinetide) which first out-licensed to Acadia (NASDAQ:ACAD) for North America in 2018. The FDA approved trofinetide for the treatment of Rett syndrome in adult & paediatric patients (>2years) in March 2023 and Acadia announced the US launch in April 2023 (triggering a US$40m milestone). In July 2023, Neuren expanded the Acadia agreement for all remaining global territories, receiving US$100m upfront. Neuren will receive tiered double-digit royalties and annual sales-based milestones from Acadia's sales of DAYBUE™.

Neuren's second asset is NNZ-2591 which is under development targeting multiple rare diseases and neurological indications. Specifically, there are four currently Phase 2 studies underway in Angelman, Phelan-McDermid, Pitt-Hopkins and Prader-Willi Syndrome. Progress along this clinical development pathway and subsequent commercialisation represent key value drivers for Neuren.

KEY RISKS

We see the following key stock specific risks to our investment thesis on Neuren:

Regulatory risk: Following FDA approval in March 2023, regulatory risk related to trofinetide has decreased. However, emergence of any potential new safety information that changes the risk-benefit profile of trofinetide may result in re-evaluation of regulatory approvals. Whilst it remains highly likely that regulatory approvals in other jurisdictions will follow, the inability to secure these will impact our forecasts.

Clinical trial risks: NNZ-2591 has been granted Orphan Drug designation and IND approval across all four targeted indications (Angelman, Phelan-McDermid, Pitt-Hopkins, Prader-Willi). Phase 2 trials are underway in each indication. Positive Phase 1 safety results were reported in healthy adult volunteers and in a single-arm Phase 2 trial in PMS patients. We recognise that delays to the proposed timelines may impact our forecasts and valuation of NNZ-2591. Clinical risks may include enrolment delays, patient dropout during trials and potential study design modifications.

Competitor risks: There are no other approved therapies for Rett Syndrome beyond trofinetide. Competing therapies include Anavex 2-73 (blarcamesine) which has also been granted orphan drug status and fast track designation by the FDA. Primary and secondary endpoints were met in the AVATAR (Phase 3) trial in adult patients whilst top line results from the paediatric study (ages 5 to 17) EXCELLENCE (Phase 2/3) are expected in CY24. Subsequent regulatory approval in key jurisdictions may impact the commercialisation strategy for trofinetide and present a downside risk to our current forecasts.

Reliance on Acadia for further development of trofinetide: Acadia has been primarily focused on the development of trofinetide for Rett Syndrome. Whilst there is the potential to explore additional indications such as Fragile X, the timing and choice of these indications will likely impact our forecasts.

Neuren Pharmaceuticals

as at 18 December 2023

Recommendation	Buy
Price	$22.20
Target (12 months)	$27.00

Table 1 - Financial summary

Profit & Loss (A$m)	2021	2022	2023e	2024e	2025e
Year Ending 30 December					
Total revenue	**0.0**	**14.6**	**232.5**	**204.7**	**269.2**
Growth (%)		*nm*	*1498%*	*-12%*	*31%*
COGS	0.0	0.0	0.0	0.0	0.0
Gross Profit	**0.0**	**14.6**	**232.5**	**204.7**	**269.2**
Other income	3.6	2.1	0.0	0.0	0.0
Operating expenses	-11.4	-16.8	-28.5	-34.5	-41.0
EBITDA	**-7.8**	**-0.2**	**204.0**	**170.2**	**228.1**
Depreciation & amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	**-7.8**	**-0.2**	**204.0**	**170.2**	**228.1**
EBIT margin	*nm*	*-1%*	*88%*	*83%*	*85%*
Net Interest (expense)/benefit	0.0	0.4	2.8	2.8	2.8
Profit before tax	**-7.8**	**0.2**	**206.8**	**173.0**	**230.9**
Tax expense	0.0	0.0	-18.5	-51.9	-69.3
NPAT (pre abnormals)	**-7.8**	**0.2**	**188.3**	**121.1**	**161.6**
Other comprehensive income/(loss)	0.0	0.0	0.0	0.0	0.0
Total comprehensive income/(loss)	**-7.8**	**0.2**	**188.3**	**121.1**	**161.6**

Valuation Ratios (A$m)	2021	2022	2023e	2024e	2025e
Year Ending 30 December					
Diluted EPS (cents)	-6.6	0.1	146.0	93.9	125.4
EPS growth (%)	*nm*	*nm*	*102218%*	*-36%*	*33%*
PE(x)	**nm**	**15,553.2**	**15.2**	**23.6**	**17.7**
EV/EBITDA (x)	**nm**	**nm**	**12.7**	**15.2**	**11.3**
EV/Revenue (x)	nm	177.7	11.1	12.6	9.6
NTA/share (cents)	31.1	33.5	182.4	275.8	402.2
Price/NTA (x)	71.5	66.2	12.2	8.0	5.5
Book value of equity/share (cents)	30.4	32.2	178.2	272.1	397.5
Price/Book value per share (x)	72.9	68.8	12.5	8.2	5.6
Dividend per share (cents)	0.0	0.0	0.0	0.0	0.0
Dividend payout ratio (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Dividend yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	0.0%	0.0%	100.0%	100.0%	100.0%

Cash Flow (A$m)	2021	2022	2023e	2024e	2025e
Year Ending 30 December					
EBITDA	-7.8	-0.2	204.0	170.2	228.1
Change in working capital	5.1	-2.0	4.9	-0.8	1.9
Gross operating cash flow	**-12.9**	**1.8**	**199.1**	**171.1**	**226.2**
Income taxed paid	0.0	0.0	-18.5	-51.9	-69.3
Net interest income/(payment)	0.1	0.2	2.8	2.8	2.8
Receipts from R&DTI & GST	2.5	1.4	0.0	0.0	0.0
Net operating cash flow	**-10.0**	**3.6**	**183.4**	**121.9**	**159.7**
Payments for PPE	0.0	0.0	0.0	0.0	0.0
Net investing cash flow	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Proceeds from issuance of shares	23.3	0.0	0.0	0.0	0.0
Payment of share issue expense	-1.1	0.0	0.0	0.0	0.0
Net financing cash flow	**22.2**	**0.0**	**0.0**	**0.0**	**0.0**
Net change in cash	**12.2**	**3.6**	**183.4**	**121.9**	**159.7**
Cash at start of period	24.2	36.8	40.2	223.6	345.5
Exchange rate impact	**0.4**	**-0.2**	**0.0**	**0.0**	**0.0**
Cash at end of period	**36.8**	**40.2**	**223.6**	**345.5**	**505.2**

Performance Ratios	2021	2022	2023e	2024e	2025e
Year Ending 30 December					
EBITDA margin	na	-1%	88%	83%	85%
EBIT margin	na	-1%	88%	83%	85%
EBT margin	na	1%	89%	85%	86%
NPAT margin	na	1%	81%	59%	60%
Effective tax rate	0%	0%	9%	30%	30%

Leverage Ratios	2021	2022	2023e	2024e	2025e
Net debt/(cash)	-36.8	-40.2	-223.6	-345.5	-505.2
Net debt/equity (x)	nm	nm	nm	nm	nm
Net debt/assets (x)	nm	nm	nm	nm	nm
Net debt/EBITDA (x)	nm	nm	nm	nm	nm

Balance Sheet (A$m)	2021	2022	2023e	2024e	2025e
Year Ending 30 December					
Cash and cash equivalents	36.8	40.2	223.6	345.5	505.2
Receivables	3.3	3.1	11.6	10.2	13.5
Other current assets	0.0	0.0	0.0	0.0	0.0
PPE	0.0	0.0	0.0	0.0	0.0
Total assets	**40.1**	**43.3**	**235.2**	**355.7**	**518.7**
Payables	0.8	1.0	4.7	4.1	5.4
Derivative liabilities	0.0	0.7	0.7	0.7	0.7
Non-current liabilities	0.0	0.0	0.0	0.0	0.0
Total Liabilities	**0.8**	**1.7**	**5.4**	**4.8**	**6.1**
Net Assets	**39.3**	**41.6**	**229.9**	**351.0**	**512.6**
Issued capital	167.6	167.7	167.7	167.7	167.7
Share option reserve	1.2	3.2	3.2	3.2	3.2
Currency translation reserve	-10.7	-10.7	-10.7	-10.7	-10.7
Retained earnings/(accumulated losses)	-118.9	-118.7	69.6	190.7	352.3
Total equity	**39.3**	**41.6**	**229.9**	**351.0**	**512.6**

Revenue Analysis (A$m)	2021	2022	2023e	2024e	2025e
DAYBUE (trofinetide)	0.0	14.6	232.5	204.7	223.0
NNZ-2591	0.0	0.0	0.0	0.0	46.2
Total revenue	0.0	14.6	232.5	204.7	269.2
Growth (%)	*nm*	*nm*	*1498%*	*-12%*	*31%*

Interim Results	1H23	2H23e	1H24e	2H24e
Revenue	62.9	169.6	85.4	119.3
EBITDA	48.9	155.1	85.4	84.8
NPAT (pre abnormals)	47.8	140.5	59.8	61.3

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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