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Speculative

Key risks are on Page 7 &  
Biotechnology Risk Warning on Page 9  
Speculative securities may not be  
suitable for Retail clients

## Neuren (NEU)

### Trofinetide Phase 3 success, Next step FDA approval

**Recommendation**  
**Buy** (unchanged)  
**Price**  
**\$3.20**  
**Valuation**  
**\$5.60** (previously \$3.10)  
**Risk**  
**Speculative**

**GICS Sector**  
**Pharmaceuticals & Biotechnology**

**Expected Return**

Capital growth	<b>75.0%</b>
Dividend yield	<b>0.0%</b>
Total expected return	<b>75.0%</b>

**Company Data & Ratios**

Enterprise value	<b>\$369.5m</b>
Market cap	<b>\$403.1m</b>
Issued capital	<b>125.97m</b>
Free float	<b>93%</b>
Avg. daily val. (52wk)	<b>\$378,267</b>
12 month price range	<b>\$1.20- \$3.56</b>

**Price Performance**

	(1m)	(3m)	(12m)
Price (A\$)	1.80	2.26	1.17
Absolute (%)	81.06	43.81	177.78
Rel market (%)	82.35	46.70	166.49



SOURCE: IRESS

BELL POTTER SECURITIES LIMITED  
ABN 25 006 390 7721  
AFSL 243480

### Clean and robust Phase 3 results – transformative for NEU

Acadia/NEU have reported positive results from their Phase 3 Lavender trial in Rett Syndrome with trofinetide. The trial met its co-primary efficacy end points (RSBQ and CGI-I) and a key secondary endpoint on ability to communicate with high statistical significance. Cohen’s analysis suggests that the effect size was medium for each of the endpoints. Results were consistent across age and severity of disease, which should support a broader label. Results trended in favour of trofinetide for each of the 8 RSBQ subscales, which highlights its disease modifying effect. Drug was safe with most adverse events being mild-to-moderate. SAEs were low and >95% patients rolled-over to the Lilac extension study. However, there seems to be a transient tolerability issue with the drug with high rates of diarrhea and vomiting in the trofinetide group. Diarrhea while not serious led to higher discontinuation rates in trofinetide group. A management plan has been implemented and experts do not view this as a worsening of quality of life in a patient population where constipation is a significant issue. **There is no approved treatment and we are confident that the Phase 3 results are supportive of trofinetide becoming the first FDA approved treatment for Rett.** We believe this single pivotal trial with strong p values along with supportive evidence from phase 2 and other open label trials will be sufficient for NDA filing. FDA may ask for an ADCOM panel to review a diarrhea management plan. ACAD plans to submit NDA by mid-CY22, following a pre-NDA meeting with the FDA in 1Q22. NEU stands to earn US\$83m in milestones from ACAD over FY22/23, plus double digit royalties on sales (BPe 10-15%) and US\$350m in commercial milestones. We also expect the results to provide impetus to NEU’s Ex-US deal negotiations for trofinetide.

### Investment view: Valuation lifted to \$5.60, Retain Buy (spec)

Earning changes in the short term were driven by shifting timing of approval and launch milestones for trofinetide from ACAD to FY23 (from FY22) and an increase in R&D costs related to NNZ-2591. As a result of raising our probability of success on trofinetide to 85% and NNZ-2591 to 25%, including Prader Willi syndrome as 4<sup>th</sup> indication for NNZ-2591, reducing WACC to 15% and rolling forward our DCF model, our valuation for NEU has lifted materially to \$5.60/sh (was \$3.10/sh).

### Earnings Forecast

Year end 31st December	2019A	2020A	2021E	2022E	2023E
Revenue (A\$m)	0.5	0.7	3.8	32.9	100.3
EBITDA (A\$m)	-11.1	-8.8	-11.2	7.9	84.7
NPAT (reported) (A\$m)	-10.8	-9.2	-11.0	8.0	73.8
NPAT (adjusted) (A\$m)	-10.8	-9.2	-11.0	8.0	73.8
EPS (reported) (cps)	-10.8	-8.6	-9.3	6.2	57.2
EPS (adjusted) (cps)	-10.8	-8.6	-9.3	6.2	57.2
EPS growth (%)	N/A	N/A	N/A	NM	827.4%
PER (x)	N/A	N/A	N/A	51.9	5.6
EV/EBITDA (x)	-33.4	-42.0	-33.0	46.9	4.4
Dividend (cps)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
ROE (%)	-78.1%	-38.0%	-30.4%	15.8%	59.4%

NOTE: FY22/FY23 REVENUE INCLUDES MILESTONES FROM ACADIA AND UPFRONT FROM EX-US PARTNERING DEAL FOR TROFINETIDE.  
SOURCE: BELL POTTER SECURITIES ESTIMATES

DISCLAIMER: THIS REPORT MUST BE READ WITH THE DISCLAIMER ON PAGE 9 THAT FORMS PART OF IT.  
DISCLOSURE: BELL POTTER SECURITIES ACTED AS LEAD MANAGER TO NEU'S \$23M CAPITAL RAISING IN SEP'21 AND RECEIVED FEES FOR THAT SERVICE.

# Strong Phase 3 results supportive of FDA approval

Neuren (NEU) and its partner Acadia (ACAD) have announced positive Top-line results from their Phase 3 Lavender trial in Rett Syndrome with trofinetide, which we believe is strongly supportive of the drug becoming the first FDA approved treatment for Rett.

Rett Syndrome is a debilitating disease with no FDA approved treatments. It's a rare neurodevelopmental disorder affecting primarily girls. A typical child with Rett syndrome cannot speak, use her hands, walk, eat, sleep well or breathe easily and requires around the clock care from parents/caregivers. Constipation is a significant issue for most families in this patient population.

## Key highlights

### BASELINE CHARACTERISTICS WELL BALANCED BETWEEN TROFINETIDE AND PLACEBO GROUPS

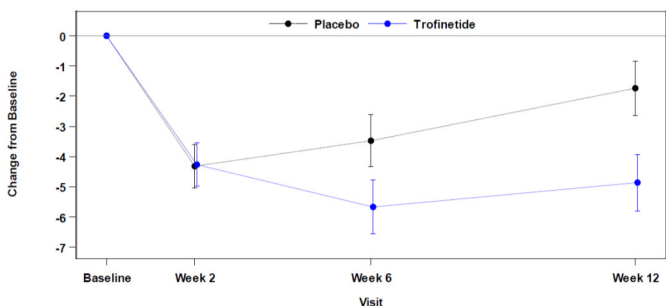
- The trial was a randomized, double-blind, placebo controlled trial which recruited 187 young females (age 5-20 years) with Rett Syndrome. Patients were randomised 1:1 to receive either Trofinetide (200mg/kg dose optimised for weight bands) or placebo over 12 weeks.
- **Baseline characteristics between trofinetide and placebo arms were well balanced.** Average age of patients enrolled was 11 years. The trial primarily enrolled patients presenting with moderate to severe rett syndrome.

### EFFICACY ENDPOINTS ACHIEVED WITH HIGH STATISTICAL SIGNIFICANCE

- **Trofinetide met co-primary efficacy endpoints demonstrating statistically significant improvement over placebo** in the Rett Syndrome Behaviour Questionnaire (RSBQ) and the Clinical Global Impression of Improvement (CGI-I). The RSBQ is a caregiver assessment of the core symptoms of Rett syndrome and the CGI-I is a global physician assessment of worsening or improving of Rett syndrome.
- On RSBQ, the change from baseline to Week 12 was -5.1 for trofinetide vs. -1.7 for placebo (p=0.0175, Cohen's effect size 0.37). This scale consists of subscores across 8 domains and looks at the severity and frequency of core symptoms of Rett. We understand that small changes on this scale can have a meaningful impact on quality of life and functioning of patients. **Therefore we view this as clinically meaningful improvement as well.**
- **We are also encouraged to see that the placebo effect dissipated quite early in the trial (within 2 weeks)** and there was continued and significant separation between drug and placebo at week 6 which further extended at Week 12.
- Results trended in favour of trofinetide for each of the 8 subscales for RSBQ, without overall effect being driven by any 1-2 subscales, **which highlights its disease modifying effect and its broad applicability irrespective of subtypes of Rett.**
- On CGI-I, the score at Week 12 was 3.5 for trofinetide vs. 3.8 for placebo (p=0.0030, Cohen's effect size 0.47).
- **Encouragingly the results were consistent across age groups and severity of disease, which should help trofinetide to get a broader label** (i.e. not restricted to the 5-20 years age enrolled in the trial). We note that ACAD is also running a safety trial in 2-5 year old patients and intends to have the safety data from that included in its planned NDA filing which should further support a broader label.

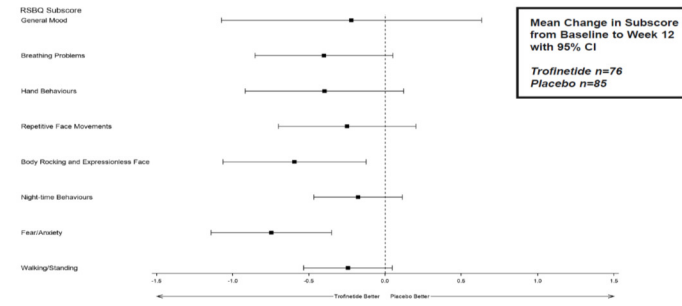
- We also understand that there was significant correlation between the co-primary endpoints (one being a caregiver assessment and the other a physician assessment), which validate each other and further highlight the robustness of these results.

**Figure 1 - RSBQ Change from baseline by Visit**



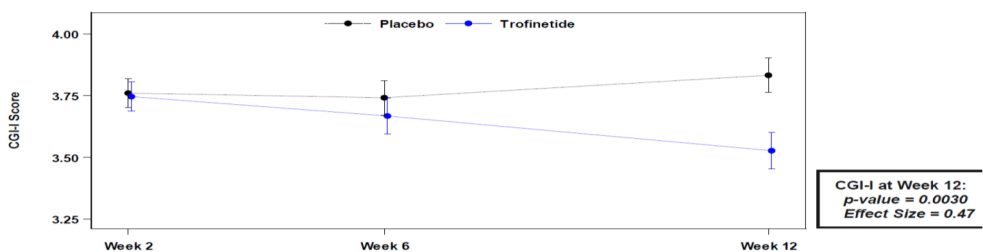
SOURCE: ACADIA RESULTS PRESENTATION

**Figure 2 - Consistent trend on individual RSBQ scores in favour of trofinetide - Disease Modifying Therapy**



SOURCE: ACADIA RESULTS PRESENTATION

**Figure 3 – CGI-I score at Week 12**



SOURCE: COMPANY DATA

- On key secondary efficacy endpoint of CSBS-DP-IT-Social (Communication and Symbolic Behavior Scales Developmental Profile Infant-Toddler Checklist–Social composite score), which is a caregiver evaluation of a patients ability to communicate, the change from baseline to Week 12 was -0.1 for trofinetide vs. -1.1 for placebo (p=0.0064, Cohen’s effect size 0.43).

**DRUG IS SAFE WITH MILD-MODERATE ADVERSE EVENTS BUT HIGHER DISCONTINUATION IN TROFINETIDE ARM**

- Drug was generally safe with most treatment emergent adverse events (TEAEs) being mild-to-moderate. Serious Adverse events (SAEs) were low and consistent with placebo arm at 3.2%. More than 95% of the participants in the study elected to roll-over to the open label Lilac extension study.

**Figure 4 - Low SAEs, higher discontinuation rate with trofinetide**

	Placebo (N=94) n (%)	Trofinetide (N=93) n (%)
Any Treatment-Emergent Adverse Event (TEAE)	51 (54.3)	86 (92.5)
Any Serious TEAE	3 (3.2)	3 (3.2)
Any TEAE Leading to Drug Withdrawn	2 (2.1)	16 (17.2)
Any Fatal TEAE	--	--

SOURCE: COMPANY DATA

**Figure 5 - Diarrhea and Vomiting most common and mostly mild-moderate**

Preferred Term	Placebo (N=94) n (%)			Trofinetide (N=93) n (%)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Diarrhea	15 (16.0)	3 (3.2)	--	39 (41.9)	34 (36.6)	2 (2.2)
Vomiting	8 (8.5)	1 (1.1)	--	18 (19.4)	6 (6.5)	1 (1.1)
Seizure	3 (3.2)	2 (2.1)	--	3 (3.2)	5 (5.4)	--
Pyrexia	2 (2.1)	2 (2.1)	--	7 (7.5)	1 (1.1)	--
Decreased appetite	1 (1.1)	1 (1.1)	--	2 (2.2)	3 (3.2)	--
Irritability	--	--	--	3 (3.2)	2 (2.2)	1 (1.1)

SOURCE: COMPANY DATA

- However, there seems to be a transient tolerability issue with the drug with high rates of diarrhea and vomiting in the trofinetide group. The rate of discontinuations were higher in trofinetide group (17.2% vs. 2.1% in placebo). Diarrhea was the primary driver of

discontinuations in the trofinetide group. 12% of the discontinuation was due to diarrhea and 3% was due to closure of sites during COVID. For the most part diarrhea was mild-moderate and did not cause dehydration or require hospitalisation.

- Diarrhea occurred early in the trial for most patients but there were some cases that occurred late. There was also variability in the duration of diarrhea. Given the high rate of GI side effects, there is a risk that this potentially 'unblinded' the trial and therefore potentially skewed results in favour of trofinetide. However, we note that Acadia is confident that it was not the case having analysed the data in several ways including and excluding diarrhea and in each case trofinetide performed better than placebo.
- A management plan has been implemented for diarrhea late in the trial and implemented more broadly in the open label LILAC trial. It includes getting patients to discontinue using their anti-constipation medications, change in diet and adding more fibre to a person's diet. ACAD management said implementation of this is easier in the open label trial as everyone is getting treatment drug, however in Lavender trial was difficult as parents knew their child could potentially be randomised to placebo in which case there was fear of worsening constipation. They said this plan seems to be having an effect and they are seeing fewer discontinuations in the open label LILAC study.
- Experts do not view the high incidence of diarrhea as a worsening of quality of life in a patient population where constipation is a significant issue. It is also manageable for the family given the patient population is essentially in diapers to start with. It is also seen as ameliorating the risk of hospitalisations due to constipation.

### **Next step NDA filing and FDA approval for trofinetide for Rett**

Acadia plans to submit NDA by mid-CY22, following a pre-NDA meeting with the FDA in 1Q22. With priority review (since Trofinetide has orphan drug designation from FDA) we could see the drug getting approved and launched in early CY23. NDA submission will include the Lavender trial results, supportive Phase 2 data from the trial run by Neuren earlier and safety data from multiple ongoing open-label extension studies.

**There is no approved treatment for this debilitating disease and we are confident that the Phase 3 results are supportive of trofinetide becoming the first FDA approved treatment for Rett.** If approved, Acadia is likely to be awarded a Priority Review Voucher (PRV) due to Trofinetide having been granted Rare Paediatric Disease designation by the FDA.

**We view this as a transformative event for NEU.** Over the next two years (FY22/FY23), NEU stands to earn US\$50m in milestones from Acadia on filing, approval and launch in US for Rett and US\$33m as its share of market value of the PRV. We expect the payments to be skewed more towards FY23. It will also earn double digit royalties on sales (BPe 10-15%) following product launch and US\$350m in commercial milestones on sales thresholds being met. We also expect the results to provide impetus to NEU's Ex-US deal negotiations for trofinetide. An EX-US partnership agreement for the drug could be as valuable as the deal with Acadia but with higher upfront payment. We expect an EX-US deal to materialize in CY22 which will further bolster NEU's balance sheet.

Importantly this provides NEU with a very strong balance sheet to accelerate Phase 2 development of its second (currently unpartnered) drug candidate NNZ-2591 which is targeting 4 rare neurodevelopmental disorders. NEU's strengthened balance sheet will also allow it to explore utility of NNZ-2591 in other indications beyond the 4 already disclosed.

NEU is likely to have multiple strategic alternatives following completion of proof of concept Phase 2 trials for NNZ-2591 which could include partnering, Phase 3 development or sale of business. We believe with an approved product and with Phase 2 data in hand for NNZ-2591 by CY23 NEU could also look attractive as a takeover target.

# Earnings and Valuation Changes

We have revisited our assumptions for NEU based on the positive Phase 3 results reported for Trofinetide and also updated our model for the 1H21 results and recent capital raising, which have impacted earnings and valuation.

## Key changes to our modelling assumptions

- We have increased the probability of success assigned to Trofinetide for Rett Syndrome for the US market to 85% (was 60%) following successful Phase 3. We have also removed the risk adjustment for our estimated milestone to be triggered on NDA filing for Trofinetide. Based on the successful Phase 3, we believe the NDA filing will happen by mid-CY22 as flagged by Acadia.
- Based on the mid-CY22 filing time for the NDA, we now expect launch of Trofinetide for Rett in the US in early CY23. Accordingly we have moved related milestones and royalty revenues from FY22 to FY23.
- We have also reduced the probability of success assigned to trofinetide for second indication of Fragile X Syndrome in US to 10% (was 25%). Acadia management seem to be focused entirely on the upcoming pre-NDA meeting and filing of NDA for Rett. When asked about additional indications they did not mention Fragile X but did say trofinetide could be applicable for other indications but that is not their focus now. Our read through on the fact that Fragile X was not mentioned but Traumatic Brain Injury was in terms of earlier trials with trofinetide, that in priority order Fragile X is unlikely to be second indication of development.
- We have updated our model for NEU's recent cap raise via placement and SPP. NEU raised gross \$23.1m (net \$22m) via issue of 11.4m shares @\$2.05/sh.
- We now include Prader Willi syndrome (PWS) indication for NNZ-2591 in our model following NEU raising capital to move this into a Phase 2 trial in CY22. We now expect combined peak sales for NNZ-2591 across 4 orphan neurodevelopmental indications in US/EU markets to be US\$1.8bn.
- We have also increased the probability of success assigned to NNZ-2591 to 25% (was 18%) following completion of Phase 1 trial and given that Phase 2 trials in 4 indications are expected to start in CY22.
- We have increased the R&D rebate for FY21 based on the overseas finding approved for NNZ-2591 earlier this year.
- We have increased our R&D forecasts for FY21-FY23 to account for the cost of a Phase 2 trial for NNZ-2591 in PWS and costs related to foundational activities (including manufacturing) in preparation for Phase 3 in parallel.
- We have increased our G&A expense for FY21 onwards by ~\$0.9m to account for increased share based payment expense.
- We have reduced the WACC used in our DCF to 15% (was 17%) due to lower Bell Potter assumptions around equity risk and risk free rate and overall de-risking of NEU both financially and clinically following the positive Phase 3 Rett trial results.
- We have reduced our interest rate forecasts which has resulted in lowering our forward interest income forecasts.

**We value NEU at  
A\$5.60/sh**

The net result is a 16% increase in our Net loss forecast for FY21 and large decrease in our FY22 NPAT forecast. These were driven primarily by shifting timing of approval and launch milestones for trofinetide from ACAD to FY23 (from FY22) and an increase in our R&D costs related to NNZ-2591 Prader Willi trial and foundational work in preparation for

Phase 3. The short term earning changes and dilutive impact of recent capital raising were more than offset by longer term impact of improved probability of success assigned to trofinetide for Rett and to NNZ-2591 for 4 indications, inclusion of Prader Willi Syndrome as 4<sup>th</sup> indication for NNZ-2591 in our model, reducing WACC used in DCF to 15% and rolling forward our DCF. This has resulted in a material increase in our valuation of NEU (rounded off) to \$5.60/sh (was \$3.10/sh). **We retain our Buy, Speculative recommendation.**

**Figure 6 - Key changes to our last published FY21-22 forecasts**

	FY2021E			FY2022E		
	Old	New	Change (%)	Old	New	Change (%)
Revenues	1.0	3.8	282%	59.4	32.9	-45%
Interest Income	0.2	0.1	-69%	0.4	0.1	-77%
R&D	8.6	12.0	40%	7.6	21.9	188%
G&A	2.1	3.0	43%	2.2	3.1	40%
EBITDA	-9.7	-11.2	15%	49.6	7.9	-84%
EBIT	-9.7	-11.2	15%	49.6	7.9	-84%
NPAT (adjusted)	-9.5	-11.0	16%	35.0	8.0	-77%
Adjusted Diluted EPS	-8.3	-9.3	12%	29.8	6.2	-79%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Our DCF valuation model is based on a WACC of 15% and a terminal growth rate of 1%.

**Table 1 - Summary of Valuation**

Revised Forecasts	Base case
Enterprise value from DCF (AUDm)	683.6
Add: Last Reported cash (AUDm)	33.6
Add: Cash raised from SPP (AUDm)	3.1
Less: Debt (AUDm)	0.0
Equity value (AUDm)	720.3
Total diluted shares (million)	129.0
<b>Value per share (AUD)</b>	<b>\$5.58</b>

SOURCE: BELL POTTER SECURITIES ESTIMATES

**Table 2 - NEU -Probability-Weighted Sum-of parts Valuation Summary**

Asset	Stage	First Fiscal Year of sales (Est.)	Peak Market share	Peak Sales (US\$m)	Probability of success	Probability adjusted NPV (A\$m)	Value per share (A\$)	% Mix
Trofinetide (oral)- Rett Syndrome (US and EU)	Phase 3	2023	50% (US), 30% (EU)	\$786	85% (US), 70% (EU)	\$489	\$3.79	67.9%
Trofinetide (oral)- Fragile X Syndrome (US only)	1 Phase 2 complete	2026	25.0%	\$681	10.0%	\$29	\$0.23	4.1%
NNZ-2591 - Angelman, Pitt Hopkins, Phelan-McDermid Syndrome, Prader Willi Syndrome (US and EU)	Phase 2 in preparation	2026	Various	\$1,830	25.0%	\$186	\$1.44	25.8%
Other Pipeline/Non-allocated	NA	NA	NA	NA	NA	(\$20)	-\$0.16	-2.8%
Proforma cash (incl. SPP)	NA	NA	NA	NA	NA	\$36.7	\$0.28	5.1%
<b>Equity Value</b>						<b>\$720.3</b>	<b>\$5.58</b>	<b>100%</b>

GLOBAL PEAK SALES ARE PRE-RISK ADJUSTMENT AND ROYALTIES. SOURCE: BELL POTTER SECURITIES ESTIMATES

## Risk of confirmatory study for Rett?

We have assessed the risk around FDA requiring a confirmatory study for trofinetide for Rett and in our view we believe that to be highly unlikely due to the following factors:

- For orphan drugs one Phase 3 trial is sufficient to satisfy approval requirements provided the trial is robustly positive. The trial met both its co-primary endpoints with strong p values suggesting high statistical significance. ACAD will also be submitting Phase 2 data and additional safety data from open label trials as supportive evidence. This is a small molecule drug so we don't expect a higher bar for approval.
- The Cohen effect size for CGI-I was 0.47 and for RSBQ was 0.37, which can be viewed as medium effect size. Given the debilitating nature of the disease a seemingly small change has a much larger and meaningful impact on functioning and quality of life of patients.
- Drug is essentially safe with low SAE's but suffers from transient tolerability issue for which a management plan is being implemented. More than 95% of patients elected to roll over into open label study including some who had discontinued treatment.
- There is no approved FDA treatment for this rare disease.



## Neuren Pharmaceuticals (NEU)

### COMPANY DESCRIPTION

Neuren Pharmaceuticals (ASX: NEU), registered in Auckland, NZ and with offices in the US and Australia, is a clinical stage drug development company focused on drugs to treat disorders of the Central Nervous System (CNS). The company's lead candidate is trofinetide. NEU has reported promising Top-line results from its Rett Phase 3 Lavender trial, partnered with CNS specialist Acadia for the North American market. Neuren is also preparing to initiate Phase 2 trials with its second drug NNZ-2591, which is targeting 4 neurodevelopmental disorders including Phelan-McDermid Syndrome.

### INVESTMENT STRATEGY

Neuren is an attractive orphan drug play targeting rare neurodevelopmental disorder Rett Syndrome with its lead drug Trofinetide and 4 other orphan childhood disorders with its second drug NNZ-2591. Promising results from Phase 3 Lavender trial provide a clear path to NDA submission and subsequent approval for trofinetide in Rett, de-risking the company. NEU is in-line to receive ~US\$83m in milestones on filing, approval and launch of trofinetide plus double digit royalties on sales. ACAD estimates peak US sales for Rett of at least US\$500m. Phase 3 success also provide impetus to Ex-US licensing discussions for trofinetide. NEU is now progressing NNZ-2591 which has blockbuster potential (BPe peak sales US\$1.8bn across 4 disorders). Its progress in the clinic and monetisation following proof of concept Phase 2 trials represent key value drivers over FY22-23.

### KEY RISKS

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

- Regulatory risk:** Based on the successful Phase 3 trial for trofinetide in Rett, Acadia plans to submit the NDA around mid-CY22 following a pre-NDA meeting with the FDA in 1QCY22. With a 6 month priority review, we expect approval and launch in early CY23. While we believe there is low risk of the drug not receiving approval (85% likelihood of approval), should the FDA require additional REMS to manage the diarrhea risk beyond what Acadia is already implementing, it may delay the approval process, which would have an impact on our current forecasts.
- Reliance on Acadia for further development of trofinetide:** Acadia is currently singularly focused on the upcoming NDA filing for trofinetide for Rett. At this time they have not planned for development of trofinetide for additional indications. We include Fragile X as the second indication in our forecast but assign it a low probability of success (10%). While we believe ACAD will develop trofinetide for a second indication, we believe from ACAD comments that Fragile X may not be the next one in the priority order. The timing and choice of second indication would likely impact our forecasts.
- Clinical risk:** FDA has placed a clinical hold on NEU's IND for NNZ-2591 pending certain changes to the Phase 2 trial protocol to enhance the safety monitoring in first trials of the drug in a paediatric population. This has delayed the start of the Phase 2 trials. We believe NEU will be able to come to an agreement and implement the changes to the protocol and initiate trials in 1HCY22. Further delays to this timeline if any is likely to impact our current forecasts. Changes requested by the FDA could also be onerous enough to increase the cost of these trials beyond current budgets.
- Funding risk:** We estimate a proforma cash position for NEU of \$36.7m following recently completed placement and SPP. The company is in a strong cash position, with further cash injection from milestone payments from Acadia expected over CY22/CY23. However given the skew of these payments to CY23 and dependent on timing of a deal for Ex-US markets for trofinetide, if NEU wants to pursue additional indications for NNZ-2591 beyond the 4 already disclosed, it may need to raise further capital which is likely to be dilutive to current shareholders.

**NEU has proforma cash of ~\$37m following recent financing**

Table 3 - Financial summary

Neuren Pharmaceuticals (NEU)						Share price (A\$)	\$3.200				
As at 8 December 2021						Market cap (A\$m)	403.1				
<b>Profit and Loss</b>											
<b>Y/e December 31 (A\$m)</b>	<b>2019A</b>	<b>2020A</b>	<b>2021E</b>	<b>2022E</b>	<b>2023E</b>						
Revenue*	0.5	0.7	3.8	32.9	100.3						
<b>EBITDA</b>	<b>-11.1</b>	<b>-8.8</b>	<b>-11.2</b>	<b>7.9</b>	<b>84.7</b>						
Depreciation & Amortisation	0.0	0.0	0.0	0.0	0.0						
<b>EBIT</b>	<b>-11.1</b>	<b>-8.8</b>	<b>-11.2</b>	<b>7.9</b>	<b>84.7</b>						
Net interest & Other Income/(Expense)	0.3	-0.4	0.2	0.1	0.2						
Pre-tax profit	-10.8	-9.2	-11.0	8.0	84.8						
Tax	0.0	0.0	0.0	0.0	11.1						
NPAT (adjusted) before allocation to Minority Interests	-10.8	-9.2	-11.0	8.0	73.8						
Less minority interests	0.0	0.0	0.0	0.0	0.0						
<b>NPAT (adjusted)</b>	<b>-10.8</b>	<b>-9.2</b>	<b>-11.0</b>	<b>8.0</b>	<b>73.8</b>						
One off items	0.0	0.0	0.0	0.0	0.0						
<b>NPAT (reported)</b>	<b>-10.8</b>	<b>-9.2</b>	<b>-11.0</b>	<b>8.0</b>	<b>73.8</b>						
<b>Cashflow</b>											
<b>Y/e December 31 (A\$m)</b>	<b>2019A</b>	<b>2020A</b>	<b>2021E</b>	<b>2022E</b>	<b>2023E</b>						
Reported NPAT plus minority interests	-10.8	-9.2	-11.0	8.0	73.8						
Non-cash items	0.1	1.1	0.7	0.6	0.2						
Working capital	-1.0	0.0	-0.7	2.7	0.0						
Other operating cash flow	0.0	0.0	0.0	0.0	0.0						
<b>Operating cashflow</b>	<b>-11.7</b>	<b>-8.1</b>	<b>-11.0</b>	<b>11.3</b>	<b>74.0</b>						
Capex	0.0	0.0	0.0	0.0	0.0						
Investments	0.0	0.0	0.0	0.0	0.0						
Other investing cash flow	0.0	0.0	0.0	0.0	0.0						
<b>Investing cashflow</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>						
Change in borrowings	0.0	0.0	0.0	0.0	0.0						
Equity issued	1.9	19.1	22.0	5.5	0.0						
Dividends paid	0.0	0.0	0.0	0.0	0.0						
Other financing cash flow	0.0	0.0	0.0	0.0	0.0						
<b>Financing cashflow</b>	<b>1.9</b>	<b>19.1</b>	<b>22.0</b>	<b>5.5</b>	<b>0.0</b>						
<b>Net change in cash</b>	<b>-9.9</b>	<b>11.1</b>	<b>11.0</b>	<b>16.8</b>	<b>74.0</b>						
<b>Cash at end of period*</b>	<b>13.8</b>	<b>24.2</b>	<b>35.6</b>	<b>52.3</b>	<b>126.3</b>						
* Includes effect of exchange rate fluctuations on cash balance											
<b>Free cash flow</b>	<b>-11.7</b>	<b>-8.1</b>	<b>-11.0</b>	<b>11.2</b>	<b>74.0</b>						
<b>Balance sheet</b>											
<b>Y/e December 31 (A\$m)</b>	<b>2019A</b>	<b>2020A</b>	<b>2021E</b>	<b>2022E</b>	<b>2023E</b>						
Cash	13.8	24.2	35.6	52.3	126.3						
Current receivables	0.1	0.0	0.0	0.0	0.0						
Inventories	0.0	0.0	0.0	0.0	0.0						
Other current assets	0.5	0.7	2.0	0.0	0.0						
<b>Current assets</b>	<b>14.4</b>	<b>24.9</b>	<b>37.6</b>	<b>52.3</b>	<b>126.3</b>						
PPE	0.0	0.0	0.0	0.0	0.0						
Non-current receivables	0.0	0.0	0.0	0.0	0.0						
Intangible assets	0.0	0.0	0.0	0.0	0.0						
Other non-current assets	0.0	0.0	0.0	0.0	0.0						
<b>Non-current assets</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>						
<b>Total assets</b>	<b>14.4</b>	<b>25.0</b>	<b>37.6</b>	<b>52.4</b>	<b>126.3</b>						
Payables	0.6	0.8	1.3	2.0	2.0						
Debt	0.0	0.0	0.0	0.0	0.0						
Provisions	0.0	0.0	0.0	0.0	0.0						
Other liabilities	0.0	0.0	0.0	0.0	0.0						
<b>Total liabilities</b>	<b>0.6</b>	<b>0.8</b>	<b>1.3</b>	<b>2.0</b>	<b>2.0</b>						
Shareholders' equity	13.8	24.2	36.2	50.3	124.3						
Minorities	0.0	0.0	0.0	0.0	0.0						
<b>Total shareholders funds</b>	<b>13.8</b>	<b>24.2</b>	<b>36.2</b>	<b>50.3</b>	<b>124.3</b>						
<b>Total funds employed</b>	<b>14.4</b>	<b>25.0</b>	<b>37.6</b>	<b>52.4</b>	<b>126.3</b>						
<b>W/A Diluted shares on issue</b>	<b>100.2</b>	<b>107.1</b>	<b>118.1</b>	<b>129.0</b>	<b>129.0</b>						
<b>Valuation data</b>											
<b>Y/e December 31</b>	<b>2019A</b>	<b>2020A</b>	<b>2021E</b>	<b>2022E</b>	<b>2023E</b>						
Adjusted Net profit (A\$m)	-10.8	-9.2	-11.0	8.0	73.8						
EPS (c)	-10.8	-8.6	-9.3	6.2	57.2						
EPS growth (%)	N/A	N/A	N/A	N/A	827.4%						
P/E ratio (x)	N/A	N/A	N/A	51.9	5.6						
CFPS (c)	-11.7	-7.5	-9.3	8.7	57.4						
Price/CF (x)	-27.4	-42.4	-34.3	36.6	NM						
DPS (c)	0.0	0.0	0.0	0.0	0.0						
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%						
Franking (%)	N/A	N/A	N/A	N/A	N/A						
EV/EBITDA	-33.4	-42.0	-33.0	46.9	4.4						
EV/EBIT	-33.4	-41.9	-32.9	47.0	4.4						
<b>Share price now (A\$)</b> \$3.200											
<b>Valuation (A\$):</b> \$5.600											
<i>Premium (discount) to price</i> 75.0%											
<b>Recommendation:</b> Buy											
<b>Risk Rating</b> Speculative											
<b>Profitability ratios</b>											
<b>Y/e December 31</b>	<b>2019A</b>	<b>2020A</b>	<b>2021E</b>	<b>2022E</b>	<b>2023E</b>						
EBITDA/revenue (%)	N/A	N/A	N/A	24.0%	84.4%						
<b>EBIT/revenue (%)</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>23.9%</b>	<b>84.4%</b>						
Return on assets (%)	-75.1%	-36.8%	-29.3%	15.2%	58.4%						
Return on equity (%)	-78.1%	-38.0%	-30.4%	15.8%	59.4%						
Return on funds empl'd (%)	-78.1%	-38.0%	-30.4%	15.8%	59.4%						
Dividend cover (x)	N/A	N/A	N/A	N/A	N/A						
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	13.0%						
<b>Liquidity and leverage ratios</b>											
<b>Y/e December 31</b>	<b>2019A</b>	<b>2020A</b>	<b>2021E</b>	<b>2022E</b>	<b>2023E</b>						
Net cash (debt) (A\$m)	13.8	24.2	35.6	52.3	126.3						
<b>Net debt/equity (%)</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>						
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A						
Current ratio (x)	25.8	33.1	28.0	25.6	61.9						
<b>Interims</b>											
<b>Y/e December 31 (A\$m)</b>	<b>2H19A</b>	<b>1H20A</b>	<b>2H20A</b>	<b>1H21A</b>	<b>2H21E</b>						
Revenue	0.5	0.0	0.7	0.0	3.8						
<b>EBITDA</b>	<b>-3.2</b>	<b>-5.3</b>	<b>-3.5</b>	<b>-8.2</b>	<b>-3.0</b>						
Depreciation & Amortisation	0.0	0.0	0.0	0.0	0.0						
<b>EBIT</b>	<b>-3.2</b>	<b>-5.3</b>	<b>-3.5</b>	<b>-8.2</b>	<b>-3.0</b>						
Net interest & Other Expense	0.2	0.6	-0.9	0.2	0.0						
Pre-tax profit	-2.9	-4.8	-4.4	-8.0	-3.1						
Tax	0.0	0.0	0.0	0.0	0.0						
Adjusted Net Profit	-2.9	-4.8	-4.4	-8.0	-3.1						
Less minority interests	0.0	0.0	0.0	0.0	0.0						
<b>Net profit to shareholders</b>	<b>-2.9</b>	<b>-4.8</b>	<b>-4.4</b>	<b>-8.0</b>	<b>-3.1</b>						

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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