First NNZ-2591 trial underway

NEU has announced that the Phase 2 trial of NNZ-2591 in Angelman Syndrome is open for enrolment with the first patient expected to start 'imminently'. Phase 2 trials in the Pitt Hopkins and Phelan McDermid are planned to commence shortly, with the Prader Willi to follow. In December 2021, NEU announced strongly positive Phase 3 trials of its drug, trofinetide, in Rett Syndrome. In MST's view, the similarities of the two drugs' mechanisms of action (MOA) and the targeted conditions provide support for NNZ-2591's potential. NNZ-2591 accounts for ~28% of MST's NEU valuation.

NEU's portfolio offers commercial advantages

From a revenue perspective, there are a number of considerations.

- NEU's targeted syndromes are seriously debilitating, life-long conditions, presenting a strong long-term clinical need.
- There are no approved treatments.
- Both trofinetide and NNZ-2591 have been awarded orphan drug designation by the FDA and European Medical Agency (EMA) regulatory bodies, bringing advantages including extended patent life.
- As rare diseases, pricing is attractive - the average annual cost of an orphan drug is ~US$150K.
- Trofinetide which targets Rett Syndrome, a similar condition, was designated FDA Fast Track Approval.

Strong cash position

The four Phase 2 trials are funded. In addition, licensing revenues of ~A$111m from NEU's North American partner Acadia Pharmaceuticals (NASDAQ: ACAD) are expected over CY22/23 on FDA approval of trofinetide in Rett Syndrome and other milestones. NEU plans to license the rights for ex-NAM Rett markets over CY22/23. In MST's view, the strong Phase 3 trial results will support NEU's negotiations.

Financials, Valuation, Risks, Sensitivities

Cash of $34.1m at Q1FY22 is expected to be sufficient to fund NNZ-2591 Phase 2 trials to CY23 readout. In MST's view, NEU has leveraged its trofinetide trials' experience to optimise success in the NNZ-2591 trials. MST has adjusted its risk-weighted DCF valuation to reflect a higher probability of approval of 30% (prev-20%), resulting in a valuation of $6.84ps (prev A$6.21). This valuation is subject to the upside/downside risks and sensitivities of drug development as noted in the following valuation summary on page 6.

For further NEU Research Reports please visit: www.mstaccess.com.au
rosemary.cummins@mstaccess.com.au

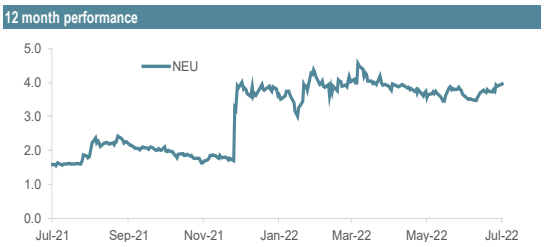
Neuren Pharmaceuticals is an ASX listed biotechnology company developing drugs for debilitating neurodevelopmental disorders. Trofinetide and NNZ-2591 are targeting six disorders for which there are no approved therapies. Positive Phase III trial results in Rett Syndrome were reported in Q4CY21. The FDA decision for approval is expected in early CY23. Trofinetide is also targeting Fragile X syndrome. NEU is to commence four Phase 2 trials of NNZ-2591 over H2CY22. The results are planned for CY23.
Board and management are well credentialled with in-depth experience in drug development and commercialisation.

Company data	
Stock	ASX: NEU
Primary Exchange	ASX
Price	A$4.00
Market cap	A$505m
Valuation (per share)	A$6.84 (prev $6.21)
Net cash (30.03.22)	A$34.1m
Shares on issue	126m
Options/Rights	3m

Potential Milestones

- H2CY22 – Start of other NNZ-2591 Phase 2 trials
- H2CY22- New Drug Application (NDA) for approval of trofinetide in Rett Syndrome
- CY22/23 – ex-NAM Rett licensing deals
- Q1CY23 - FDA approval trofinetide in Rett Syndrome
- CY23 - Phase 2 NNZ-2591 trials results

Share Price Performance (12 months)



Financial Summary

Exhibit 1 – MST Financial Summary

Neuren Pharmaceuticals Limited — **NEU-AU**

Year end 31 December

MARKET DATA

Share Price	**A$**	**4.00**
52 week high / low	A$	4.68 - 1.52
Valuation (12 month forward)	**A$**	**6.84**
Market capitalisation	**A$m**	**504**
Shares on issue	m	126
Options	m	3
Other equity	m	-
Potential shares on issue (diluted)		129

12 month performance

INVESTMENT FUNDAMENTALS		FY20	FY21	FY22E	FY23E	FY24E
EPS Reported (undiluted)	¢	(8.6)	(6.6)	53.3	6.5	39.8
EPS Underlying (undiluted)	**¢**	**(8.6)**	**(6.6)**	**53.3**	**6.5**	**39.8**
Underlying EPS growth	%	n/m	n/m	n/m	n/m	n/m
P/E Reported (undiluted)	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
P/E at Valuation	x	n/m	n/m	n/m	n/m	n/m
Dividend	**¢**	**-**	**-**	**-**	**-**	**-**
Payout ratio	%	0%	0%	0%	0%	0%
Yield	**%**	**-**	**-**	**-**	**-**	**-**

KEY RATIOS (A$)		FY20	FY21	FY22E	FY23E	FY24E
Forecast year end shares	m	118	129	129	129	129
Market cap (Y/E / Spot)	**$m**	**470.4**	**515.9**	**515.9**	**515.9**	**515.9**
Net debt /(cash)	$m	(24.2)	(36.8)	(105.6)	(114.0)	(165.3)
Enterprise value	**$m**	**446.2**	**479.1**	**410.3**	**401.8**	**350.5**
EV/Sales	x	546.2	133.3	2.5	8.2	3.0
EV/EBITDA	**x**	**(47.8)**	**(61.1)**	**4.0**	**33.8**	**4.7**
EV/EBIT	x	(47.8)	(61.1)	4.2	40.6	5.0
Net debt / Enterprise Value	x	(0.1)	(0.1)	(0.3)	(0.3)	(0.5)
Gearing (net debt / EBITDA)	**x**	**2.6**	**4.7**	**(1.0)**	**(9.6)**	**(2.2)**
Operating cash flow per share	$	(0.1)	(0.1)	0.6	0.1	0.4
Price to operating cash flow	**x**	**(58.2)**	**(51.7)**	**6.9**	**49.6**	**9.2**
Free cash flow	**$m**	**(8.1)**	**(10.0)**	**68.8**	**8.4**	**51.3**
Free cash flow per share	$	(0.07)	(0.08)	0.53	0.07	0.40
Price to free cash flow	**x**	**(58.2)**	**(51.7)**	**7.5**	**61.1**	**10.1**
Free cash flow yield	**%**	**-1.7%**	**-1.9%**	**13.3%**	**1.6%**	**9.9%**
Book value / share	$	0.21	0.30	0.82	0.88	1.28
Price to book (NAV)	**x**	**19.4**	**13.1**	**4.9**	**4.5**	**3.1**
NTA / share	$	0.21	0.30	0.82	0.88	1.28
Price to NTA	**x**	**19.4**	**13.1**	**4.9**	**4.5**	**3.1**
EBITDA margin	%	n/m	n/m	64%	24%	65%
ROE (Average Equity)	%	n/m	n/m	n/m	n/m	n/m
ROA (EBIT)	%	n/m	n/m	n/m	n/m	n/m
Interest cover (EBIT / net interest)	x	n/m	n/m	90.1	4.6	27.9

PROFIT AND LOSS (A$)		FY20	FY21	FY22E	FY23E	FY24E
Total Revenue & Other Income	$m	0.8	3.6	162.6	49.2	115.1
COGS	$m	-	-	(33.3)	(10.1)	(26.2)
Gross margin	**$m**	**0.8**	**3.6**	**129.2**	**39.0**	**88.9**
Corporate costs	$m	(10.2)	(11.4)	(25.5)	(27.2)	(13.5)
EBITDA	**$m**	**(9.3)**	**(7.8)**	**103.7**	**11.9**	**75.4**
Depreciation & amortisation	$m	-	-	(6.5)	(2.0)	(4.6)
EBIT	$m	(9.3)	(7.8)	97.2	9.9	70.8
Net interest	$m	0.1	0.0	1.1	2.2	2.5
Pretax Profit	$m	(9.2)	(7.8)	98.3	12.1	73.3
Tax expense	$m	-	-	(29.5)	(3.6)	(22.0)
Minorities	$m	-	-	-	-	-
Underlying NPAT	**$m**	**(9.2)**	**(7.8)**	**68.8**	**8.4**	**51.3**

BALANCE SHEET (A$)		FY20	FY21	FY22E	FY23E	FY24E
Cash	$m	24.2	36.8	105.6	114.0	165.3
Receivables	$m	0.8	3.3	6.7	2.0	4.7
Inventory	$m	-	-	-	-	-
PPE	$m	0.0	0.0	0.0	0.0	0.0
Intangibles	$m	-	-	-	-	-
Other	$m	-	-	-	-	-
Total Assets	**$m**	**25.0**	**40.0**	**112.3**	**116.0**	**170.0**
Payables	$m	0.8	0.8	6.7	2.0	4.7
Borrowings	$m	-	-	-	-	-
Leases	$m	-	-	-	-	-
Provisions	$m	-	-	-	-	-
Other	$m	-	-	-	-	-
Total Liabilities	**$m**	**0.8**	**0.8**	**6.7**	**2.0**	**4.7**
Shareholder's Equity	**$m**	**24.2**	**39.2**	**105.6**	**114.0**	**165.3**

CASH FLOW (A$)		FY20	FY21	FY22E	FY23E	FY24E
Receipts from customers	$m	-	-	133.3	40.5	104.9
Payments to suppliers and employees	$m	(1.4)	(2.7)	(39.0)	(13.9)	(31.3)
R&D	$m	(7.8)	(9.8)	(19.9)	(23.4)	(8.4)
Govt Grants, Rebates & Milestones	$m	0.9	2.5	29.2	8.6	10.2
Interest	$m	0.2	0.1	1.1	2.2	2.5
Tax	$m	-	-	(29.5)	(3.6)	(22.0)
Operating cash flow	**$m**	**(8.1)**	**(10.0)**	**75.3**	**10.4**	**55.9**
Capex	$m	(0.0)	(0.0)	(6.5)	(2.0)	(4.6)
Acquisitions	$m	-	-	-	-	-
Other	$m	-	-	-	-	-
Investing cash flow	**$m**	**(0.0)**	**(0.0)**	**(6.5)**	**(2.0)**	**(4.6)**
Borrowings	$m	-	-	-	-	-
Equity	$m	19.1	22.2	-	-	-
Dividend	$m	-	-	-	-	-
Financing cash flow	**$m**	**19.1**	**22.2**	**-**	**-**	**-**
Change in Cash / FX	$m	11.1	12.2	68.8	8.4	51.3
Year end cash	**$m**	**24.2**	**36.8**	**105.6**	**114.0**	**165.3**

Source: Company Reports, MST Assumptions

Trofinetide support for NNZ-2591

NNZ-2591 and trofinetide

NEU has announced that the Phase 2 trial in Angelman Syndrome of its second drug, NNZ-2591, has commenced. It is the first of four planned Phase 2 trials of NNZ-2591. Industry standards report a ~20% probability of approval for Phase 2 trials. In December 2021, NEU's US partner, Acadia Pharmaceuticals (NASDAQ: ACAD) announced strongly positive Phase 3 trials of NEU's trofinetide in Rett Syndrome. MST has compared the development of trofinetide to NNZ-2591's program to date. In our view, the success of trofinetide lends support to NNZ-2591.

- Method of Action (MOA) - Both drugs have similar MOAs and are targeting genetic neurodevelopmental syndromes that share underlying pathological features. NNZ-2591 is a novel synthetic analog or replica of a key neural peptide, cyclic glycine-proline (cGP). Trofinetide is an analog of glycine-proline-glutamate (GPE), another key neural peptide. Both peptides are intimately involved in the regulation of the growth hormone, Insulin Growth Factor 1 (IGF-1). IGF-1 plays an important role in foetal development and growth during childhood and adolescence. IGF-1 also has a neural protective role, regulating nerve transmission and the development and maintenance of the synapses. All NEU's targeted syndromes arise from genetic mutations that result in significant dysfunction of the nervous system. In MST's view, given the relationship between GPE, cGP and IGF-1, the success of trofinetide gives confidence in NNZ-2591's approach.

- Drug characteristics - NEU has reported that the pharmacokinetic characteristics of NNZ-2591 are superior to trofinetide and therefore potentially offers a more effective therapy.

- NNZ-2591 clinical trial program advantage – In MST's view, review shows that NEU management has leveraged its experiences from the trofinetide clinical trial program to plan NNZ-2591's trial program. NEU conducted two Phase 2 trials of trofinetide in Rett Syndrome and one in Fragile X Syndrome.

Exhibit 2 – NNZ-2591 Phase 2 Trials Program - leveraging the trofinetide experience

Trofinetide	Number of patients	Age	Dose	Trial duration	Results
Rett Syndrome Phase 2.1	53	16-60	50 &70mg/kg	4 weeks	Trend to efficacy.
Phase 2.2	82	5-15	50,100, 200mg/kg	6 weeks	200mg/kg - Statistically significant improvement in RSBQ[1] ($p \leq 0.042$), CGI-I Rett Syndrome.
Phase 3	187	5-15	200mg/kg	12 weeks	Met co-primary efficacy endpoints statistically significant improvement RSBQ[1] ($p=0.0175$) & CGI-I[2] ($p=0.0030$).
Fragile X	72	12-45	35 or 70 mg/kg	4 weeks	Consistent signal of efficacy at the higher dose.

[1] RSBQ- Rett Syndrome Behaviour Questionnaire
[2] CGI-I- Clinical Global Impression-Improvement

Source: Company Reports, MST Assumptions

Trofinetide in Rett Syndrome

The first trofinetide Phase 2 trial of 53 16 to 45-year-old women studied two doses over a four-week duration. The trial demonstrated safety and a trend to efficacy, particularly at the higher dose of 70mg/kg twice daily.

A second trial was undertaken with 82 girls, aged 5-15 years. The higher dose of 200 mg/kg twice daily and a longer six-week trial demonstrated a statistically significant improvement ($p \leq 0.042$) over placebo in three endpoints - Rett Syndrome Behaviour Questionnaire (RSBQ), Clinical Global Impression-Improvement (CGI-I) and RTT-Clinician Domain Specific Concerns-Visual Analog Scale (RTT-DSC-VAS). From a safety perspective, trofinetide was well tolerated at all doses (50, 100, and 200 mg/kg BID). The improvement increased through to the time that treatment ceased, suggesting further benefit may have been achieved with a longer treatment duration.

Fragile X

NEU has also undertaken a four-week Phase 2 trial of trofinetide in Fragile X Syndrome. The study included 72 adolescent and adult males and was a double-blind, placebo-controlled, parallel-group study of the safety and tolerability of two doses of orally administered trofinetide. This study showed clinical improvement in many of the core symptoms. The results were not statistically significant.

Phase 3 trial

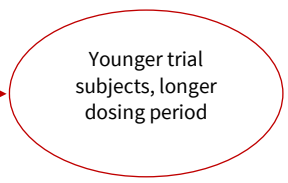
The Phase 3 trial was undertaken by NEU's US-based licensing partner, Acadia Pharmaceuticals (NASDAQ: ACAD). It comprised a 12-week, double-blind, randomized, placebo-controlled study. It included 187 females, aged 5-20 years. The trial met the co-primary efficacy endpoints demonstrating statistically significant improvement over placebo in the Rett Syndrome Behaviour Questionnaire (RSBQ) (p=0.0175) and the Clinical Global Impression of Improvement (CGI-I) (p=0.0030).

In summary, the trofinetide trials have shown that higher dosing and longer treatment periods of 12 weeks within the younger age cohort resulted in a strongly statistically significant improvement.

NEU program for NNZ-2591

Exhibit 3 – NEU Phase 2 Trials Summary

Neurodevelopmental Syndrome	Genetic Mutation	Clinical Trial	Patient Cohort	Trial Endpoints
Angelmann	UBE3A	Phase 2	up to 20 3-17 yr olds in a 13-week trial	Safety, tolerability, pharmacokinetics and efficacy
Pitt-Hopkins	TCF4	Phase 2	up to 20 3-17 yr olds in a 13-week trial	Safety, tolerability, pharmacokinetics and efficacy
Phelan-MeDermid	Shank3	Phase 2	up to 20 3-12 yr olds in a 13-week trial	Safety, tolerability, pharmacokinetics and efficacy
Prader-Willi	15q11-q13	Phase 2	To be announced	Safety, tolerability, pharmacokinetics and efficacy



Source: Company Reports, MST Assumptions

In MST's view, management has leveraged its learnings from trofinetide's clinical trial program to optimise NNZ-2591's clinical program.

- Younger cohort – In keeping with trofinetide which demonstrated a greater effect in the 5-15 year olds trial cohort, NNZ-2591 Phase 2 trials will include 3-17 year olds (3-12 years in Phelan McDermid). A younger cohort limits the heterogeneity of the syndrome presentations thereby increasing the opportunity to

demonstrate a clinical effect across the group. Subsequent trials are expected to examine NNZ-2591 in adult populations.

- Longer trial – In keeping with the Phase 3 trofinetide Rett Syndrome trial, the NNZ-2591 Phase 2 trial will treat the participants for 13 weeks.
- Selection of the dose is well supported – The single-dose level selected for the trial has been informed by a clear dose-ranging study. The Phase 2 trial will include only one dose allowing for a smaller cohort of 20 patients.

Proof to date

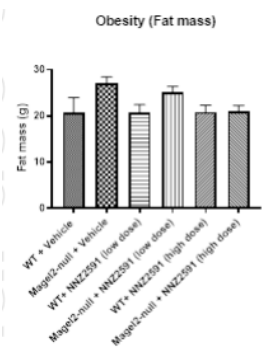
NNZ-2591 is also supported by:

Safety

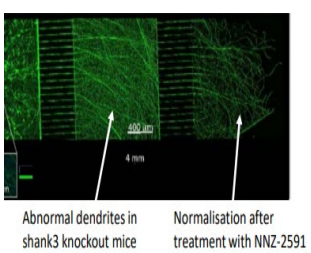
NEU conducted a seven-day Phase 1 trial of NNZ-2591 in healthy volunteers with twice-daily dosing at a range of levels. The dosing data have been incorporated into the Phase 2 trials. There were no significant adverse events (SAE), with drowsiness the most common adverse effect reported. The pharmacokinetics of NNZ-2591 were favourable as measured by the biochemical effects in the brain and confirmed the optimum dose. In summary, the Phase 1 trial in healthy individuals showed NNZ-2591 was well tolerated and safe.

Potential Efficacy

Preclinical studies in mouse models of all four syndromes have demonstrated a strong effect of NNZ-2591 across a broad range of syndrome-related symptoms, including behaviour, learning and memory, sociability, anxiety, motor function and seizure reduction/elimination. In Prader-Willi, where excessive eating is a feature, NNZ-2591 normalised the fat mass, as well as insulin and IGF-1 levels. In a Phelan-McDermid model, NNZ-2591 showed restoration of the nerve cells' dendrites, important in the transmission of the neural signals from nerve cell to nerve cell.



Preclinical Studies of NNZ-2591 in Prader-Willi Syndrome, show the disease model mice (Magel2) with a high dose of NNZ-2591 reduces the fat mass to the level of the control mice (WT).



In a Phelan-McDermid model, NNZ-2591 demonstrated normalisation of the dendrites.

Potential Milestones

H2CY22 - Commence Phase 2 trials Pitt-Hopkins, Phelan-McDermid and Prader-Willi syndromes

H2CY22 - Submission of New Drug Application (NDA) for approval of trofinetide in Rett syndrome

CY22/23 - Commercial partnerships for trofinetide in ex-North America regions

Q1CY23 - FDA approval trofinetide in Rett Syndrome

CY23 - Phase 2 NNZ-2591 trials results, licensing deals

Valuation, Key Risks and Sensitivities

In view of the supporting data and commencement of the Phase 2 trial program of NNZ-2591 after FDA query, we have adjusted the probability of approval of NNZ-2591 in the nominated syndromes from 20% to 30%. Our valuation of $6.84 per share (previously $6.21) is based on a 12-month forward risk-adjusted DCF. MST's valuation is subject to the usual upside/downside risks and sensitivities of drug development, including clinical trial patient recruitment, timing and costs, regulatory approval and market entry, pricing, market penetration and sales royalties/licensing payments.

Key assumptions include that trofinetide's ex-NAM rights are licensed on/prior to FDA approval and NNZ-2591 is licensed on a positive Phase 2 data in CY23. The COVID pandemic has resulted in clinical trial delays with the abandonment of some trials. We note that trofinetide's Phase 3 trial in Rett syndrome did not experience any delay despite significant COVID outbreaks during the trial. In our view, enrolment in NNZ-2591's clinical trial program will be enhanced by the widespread news of success of the Rett Syndrome Phase 3 trials amongst the patient and medical communities.

Approval by the FDA in Rett Syndrome is a key valuation driver. Requirements regarding data to support European Medicines Agency approval and other jurisdictions are yet to be established. The failure of NEU to secure licensing agreements of trofinetide in Rett Syndrome in the ex-NAM markets, may see an extension of the forecast timelines, additional costs and changes to the revenue forecasts. Other risk arises from the lack of clinical efficacy data of NNZ-2591 in patients. To date there are only preclinical data to support the efficacy of NNZ-2591. The ACAD agreement includes the rights for use of trofinetide in Fragile X. ACAD is yet to confirm further development plans for the additional indication. All bring upside/downside risk to MST forecasts.

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