NEUREN PHARMACEUTICALS LIMITED

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Opportunity only knocks once

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Q3 Update - all on track

- Enrolment continues in the US Phase 3 trials of trofinetide in Rett syndrome. Acadia Pharmaceuticals (ACAD), which has licensed the rights to the North American (NAM) markets from NEU, expects to announce the results in H2CY21.
- NEU has commenced discussions with the European regulatory bodies and potential Asian market partners regarding the ex-NAM rights.
- NNZ-2591 is targeting Phelan-McDermid, Angelman and Pitt Hopkins syndromes. Results of a Phase 1 safety trial are expected in January 2021.
- NEU plans to submit an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) in H1CY21 to start Phase 2 trials.
- NEU has submitted Orphan Designation applications to the European Medicines Agency (EMA) for the 3 NNZ-2591 syndromes with a decision due in January 2021.

Timing of trials presents opportunity

With its maturing drug development program, NEU is approaching potentially significant increments in value. The timing of the two drugs' trials presents further opportunity. In our view, positive results in both drugs increase the likelihood of an acquisition of NEU. The similar patient characteristics in combination with the inter-relationship of the two drugs lend weight to success in trofinetide supporting success in NNZ-2591. ACAD is an obvious potential suitor as a 'one' drug company with a limited pipeline. NEU's portfolio is also likely to be of interest to other specialty pharma companies in neurological conditions or rare diseases.

Valuation creates 'once-off' opportunity

NEU's current market value of $122m is difficult to reconcile. In MST's view, the potential upcoming milestones are yet to be reflected in its share price. Positive results in trofinetide's Phase 3 and NNZ-2591's Phase 2 trials are expected to lead to significant licensing payments.

Across a number of key valuation methodologies, NEU appears undervalued. MST's risk adjusted DCF presents a $398m valuation. In MST's view, NEU is a likely acquisition target. Review of corporate activity in rare diseases and comparison to ASX listed companies, PAR.AX ($629m) and OPT.AX ($756m), also support a re-rating. MST's valuation is subject to the usual sensitivities and upside and downside risks of new drug development including safety, clinical trial timing, regulatory approval and commercial uptake. Additional funding may be required if licensing agreements are not secured.

neuren pharmaceuticals

Neuren Pharmaceuticals is an ASX listed biotechnology company developing two drugs, trofinetide and NNZ-2591. NNZ-2591 Phase 1 results are planned for January 2021 with trofinetide's Phase 3 trial results in Rett Syndrome to follow in late CY21.

Trofinetide and NNZ-2591 are targeting five disorders for which there are no approved therapies. If successful, market uptake is expected to be strong. Their mechanism of action offers potential to address a much wider range of neural diseases and trauma related injury.

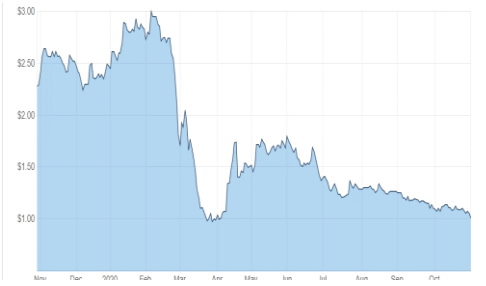
Board and management are well credentialled with in-depth experience in drug development and commercialisation.

Company data	
Net cash (30/9/20)	A$26.5m
Shares on issue	114.6m
Options and Rights Outstanding	3m
Code ASX	NEU.AX
Primary exchange	ASX

Next steps

- Phase 1 results NNZ-2591 end CY20
- Phase 3 results trofinetide in Rett Syndrome in late CY21
- Phase 2 results NNZ-2591 in CY22

12 month performance Price: $1.01



Investment Thesis

Investment Case

With its maturing drug development program, NEU is approaching potential significant increments in value. The similar patient characteristics, in combination with the inter-relationship of the two drugs, lend weight to success in trofinetide supporting success in NNZ-2591. The timing of the next milestones in trofinetide and NNZ-2591 presents further opportunity. In our view, positive results in both drugs increase the likelihood of an acquisition of Neuren.

Both trofinetide and NNZ-2591 offer suitors several advantages. From a market competitive position, there are no approved treatments for the targeted conditions. From a regulatory perspective, trofinetide and NNZ-2591 are targeting rare conditions. The key global regulatory bodies offer incentives that include market exclusivity extensions and expedited review of drugs that are developed for small patient populations. Trofinetide has US and EU Orphan Drug status in Rett Syndrome and NNZ-2591 has US Orphan Drug status for all three conditions and an application has been submitted to the EMA. A decision is expected in January 2021.

NEU's assets are likely to be of interest to a number of companies. ACAD is an obvious suitor. Its only approved drug has had a checkered history. Trofinetide is the key asset in its development pipeline. Companies targeting neurological diseases, genetic based disorders or other developmental conditions are also potential acquirors.

NEU's market capitalisation of $122m is difficult to reconcile. Review of relevant transactions and ASX comparable companies shows a steep discount. With two drugs in clinical trial development, expected newsflow is likely to see the discount reverse as investors better understand the value of its assets.

Short Term Milestones - NNZ-2591 to Phase 2 trials in CY21

- Results Phase 1 clinical trial of NNZ-2591 healthy adult volunteers
- Complete non-clinical program for IND application
- EU Orphan Drug decision for NNZ-2591
- Type C Meeting with FDA to discuss IND submission
- Submit IND application to FDA
- Drug supply for trial completed and released
- IND approval from FDA
- Commence Phase 2 trials

Significant Value Milestones

Over next two years plus, a number of value-creating milestones are expected to be reached. The potential near term catalysts include:

- Jan 21 Results Phase 1 clinical trial of NNZ-2591 healthy adult volunteers
- CY 21 Start Phase 2 trials NNZ-2591 in the three syndromes
- CY21 Results of Phase 3 clinical trial of trofinetide in Rett Syndrome
- CY22 FDA New Drug Application (NDA) approval of trofinetide in Rett Syndrome
- CY22 Results Phase 2 clinical trials NNZ-2591
- CY22 Milestone payments from NEU's NAM partner, ACAD Pharmaceuticals
- CY22 Licensing agreements for ex NAM rights for trofinetide and for NNZ-2591

Q3 Update

Trofinetide Phase 3 trial in Rett Syndrome

NEU's Q3 summary reported that enrolment in US trial was continuing with results expected in H2CY21. On the assumption of positive Phase 3 results, NEU is preparing for registration of trofinetide in ex-NAM markets. Its licensing agreement with ACAD only covers the rights in North America. NEU can use Acadia's trial and other supporting data to seek registration in rest of world markets.

NEU has met with 4 national regulatory agencies in Europe to discuss trofinetide approval pathway. EMA approval commonly requires a trial to be conducted in the EU. Given the small treatment population and unmet clinical need, the regulatory agencies may accept the ACAD trial results or only require additional data to support the results in the EU patient population. NEU has also commenced discussions with potential Asian market partners.

NNZ-2591's Phase 1 safety trial

NNZ-2591 is targeting three neurodevelopmental syndromes, Phelan-McDermid, Angelman and Pitt Hopkins. NEU has reported that it has completed the first stage of Phase 1 clinical trial. It plans to have a Type C meeting with FDA to discuss the IND application for Phase 2 trials in all three conditions. On confirmation of safety in the Phase 1 trial which us expected in January 2021, NEU plans to submit the IND application. NEU has submitted Orphan drug applications to the EMA for the three conditions. A decision is expected in January 2021.

Funding

NEU had a cash balance of $26.5m as of 30 September 2020. With ACAD funding the Phase 3 Rett Syndrome trials, NEU believes it has funding to the release of the Phase 2 data for NNZ-2591.

Timing of trofinetide and NNZ-2591 trials presents attractive options

NEU's second neurodevelopment drug, NNZ-2591, is coming into the limelight as trofinetide continues in its pivotal Phase 3 trial. As discussed, the results of a Phase 1 trial to confirm safety in healthy adults are expected in January 2021. Phase 2 trials are planned for CY21/22 with the data expected over CY22. The data will give some insight to NNZ-2591's efficacy.

The results of trofinetide's Phase 3 trial are expected in H2CY21. MST valuation has assumed licensing models for both drugs. However, the timing of the results creates interest. Positive results in both trials are likely to add to commercialisation opportunities for NEU. As an Orphan Drug, trofinetide should qualify for Priority Review by the FDA, which is a 6-month review. Positive results are expected to see approval over CY22. The results of the Phase 2 trials in NNZ-2591 are also expected over CY22.

The results of Rett Syndrome trial may influence the sentiment towards NNZ-2591. The two drugs share a similar Method of Action (MOA). Both trofinetide and NNZ-2591 are synthetic analogues or replicas of two molecules, glycine-proline-glutamate (GPE) and cyclic glycine proline (cGP) respectively. Both molecules play a role in the action of IGF-1, a growth factor which is critical for both normal development of the brain and its response to any injury and disease. Trofinetide and NNZ-2591 have been shown to reduce neuroinflammation and support neural transmission and synaptic function. Given the commonality of the two drugs' MOAs and disease targets, positive trial results in trofinetide in Rett Syndrome are likely to build expectations of efficacy in NNZ-2591 and potential interest in acquisition of both drugs.

NEU assets

1. ACAD Licensing Milestones/Royalties Rett Syndrome North American Markets (NAM)

NEU licensed the NAM rights of trofinetide to ACAD in 2018. NEU had completed a Phase 2b trial in Rett Syndrome and a Phase 2a in Fragile X. ACAD is undertaking a Phase 3 trial in Rett Syndrome with results planned for H2CY21. Acadia's plans for the development of Fragile X have not been disclosed. Given the common neuropathology, MST model assumes that on positive results of trofinetide in Rett syndrome, confirmatory Phase 2 and Phase 3 trials in Fragile X will be undertaken.

In total, NEU's agreement with ACAD includes milestone payments of US$455m. MST assumes that US$105m are based on approval with some US$350m contingent on sales performance. Sales royalty estimates range from 10% to 12%.

2. ex NAM Licensing Milestones /Royalties Rett and Fragile X Syndromes

NEU retains the rights for trofinetide in ex-NAM markets. NEU has the rights to use all the technical, clinical, and regulatory data developed by ACAD to seek approval and commercialise the drug in countries outside North America for both Rett Syndrome and Fragile X. On positive Phase 3 trials in the US, the MST model assumes NEU will seek a licensing deal that includes both Rett syndrome and Fragile X for rest of world markets. While the licensing partner may be required to submit additional data or conduct bridging studies in other jurisdictions such as EU and Japan, positive Phase 3 trials and FDA approval would effectively de-risk trofinetide for Rett syndrome and potentially 'front -end' any licensing arrangements.

3. NNZ-2591

NEU's second drug in development, NNZ-2591, is targeting Phelan McDermid syndrome (PMS), Angelman syndrome (AS) and Pitt Hopkins syndrome (PH). Phase 1 trial results are expected in January CY21 with commencement of Phase 2 trials to follow in CY21. MST valuation assumes NEU will license the drug on positive Phase 2 results under similar licensing terms to trofinetide.

Trofinetide and NNZ-2591 offer potential suitors a number of attractions

Trofinetide offers a number of attractions. From a competitive position, there are no approved treatments for any of the conditions that NEU is targeting. There is upside from a regulatory perspective as well. Trofinetide and NNZ-2591 are targeting rare conditions. The key global regulatory bodies including FDA, EMA and Japanese Pharmaceuticals and Medical Devices Agency offer incentives to encourage drug companies to develop drugs for small patient populations.

Trofinetide has been granted Orphan drug status for Rett Syndrome in the US and EU. NNZ-2591 has received FDA Orphan drug status for all three conditions and more recently Neuren announced that it had applied to the EMA for Orphan status in Europe. Orphan drug status confers market exclusivity for 7 years in US with 6-month extension in paediatric diseases and for 10 years in EU with a 2-year paediatric extension.

Trofinetide has also been granted Rare Paediatric Disease designation, which means that on marketing approval ACAD will qualify to receive a Priority Review Voucher from the FDA. It can be used for an expedited review of another drug application within 6 months, in comparison to the usual 10 months. Priority Review Vouchers are 'tradeable' with recent sale values of ~US$100m. Under the licence agreement, Neuren will receive one third of the value of any Priority Review Voucher. Trofinetide also has Fast Track designation from the FDA.

In addition, rare disease drugs usually carry a pricing premium. In the US, in 2018 the mean orphan drug cost per patient in the US was almost 4.5 times greater than non-orphan drug cost.

Possible Acquisition Scenarios for NEU

NEU is also likely to be attractive to specialty pharma companies with focus in neurology, genetic based disorders, or other rare diseases. In MST's view, ACAD is an obvious potential suitor.

Acadia Pharmaceuticals (ACAD)

Given the similarities of the two regulatory processes, FDA approval is likely to be repeated in EU, acknowledging the possible requirement for data in EU patients. ACAD knows the drug, clinical trials processes, patient groups and likely regulatory requirements. It has also stated it plans to acquire or in-license drugs.

It is also hungry. In 2016 FDA approved its drug, NUPLAZID (pimavanserin) approved for hallucinations and delusions associated with Parkinson's disease psychosis. In 2018, the U.S. Food and Drug Administration (FDA) completed a review of all post-marketing reports of deaths and serious adverse events reported with the use of Nuplazid (pimavanserin). The FDA did not identify any new or unexpected safety findings with NUPLAZID.

In July 2020, ACAD announced that its Phase 3 trial of pimavanserin in major depressive disorder (MDD) had failed. It has submitted for FDA approval of the drug in Dementia-Related Psychosis (DRP) commonly associated with Alzheimer and Parkinsonian diseases. It is also trialling NUPLAZID in negative symptoms associated with Schizophrenia patients.

In September 2020, Acadia Pharmaceuticals acquired clinical-stage biotechnology company CerSci Therapeutics. It is an early clinical stage company developing neurological drugs. Review of ACAD's pipeline indicates trofinetide is likely to be viewed as an important part of this effectively 'one' drug company.

ACAD' s pipeline

Exhibit 1 - ACAD's R&D pipeline

COMPOUND/PROGRAM	INDICATION	PHASE 1	PHASE 2	PHASE 3	REGISTRATION	MARKETED
NUPLAZID® (pimavanserin)	Parkinson's Disease Psychosis					
Pimavanserin	Dementia Related Psychosis					
Pimavanserin	Negative Symptoms of Schizophrenia					
Trofinetide	**Rett Syndrome**					
ACP-044	Pain Management					
M1 PAM	CNS Disorders					

Source: Acadia Pharmaceuticals

Risks, Sensitivities & Valuation

The valuation of NEU has been derived from a risk adjusted DCF. The investment case is based on the use of trofinetide and NNZ-2591 in the nominated indications. No value has been ascribed to other potential clinical indications. The valuation is subject to the usual sensitivities and risks of new drug development.

Risk presents through confirmation of safety, clinical trial timing, regulatory approval, milestone payments and sales royalties from both ACAD and expected new licensing partners. The failure to secure new partners may see NEU assume the regulatory filings and marketing/distribution role which would impact MST forecasts. The Phase 3 trofinetide trial has only been conducted in the US. There is risk that the European Medicines Agency and other regulatory bodies may require European / local clinical trial data, adding cost and delay to market entry. The expected commercial performance is based on a number of assumptions. The assumptions present upside and downside risk.

MST's risk adjusted DCF valuation of NEU at A$398m. The implied A$3.38 per share compares to its current price of $1.01. From a number of standpoints, NEU's potential near term and significant milestones appear not to be reflected in its current share price.

- Trofinetide is in its final stage of clinical trial in Rett Syndrome. Positive trial results expected in late CY21 and if positive, likely to lead to FDA approval and market entry in CY22.
- Trofinetide has been licensed for the North American markets in Rett Syndrome and Fragile X syndromes. Under the agreement, the costs of these trials, and on positive results, registration and market entry processes are assumed by its partner, ACAD. The agreement carries potential milestone payment totalling US $455m and double-digit royalties.
- Through its licensing process, trofinetide has undergone independent review.
- NEU holds the Ex NAM rights to trofinetide and has access to ACAD's clinical and regulatory data to support approval in other jurisdictions.
- On positive Phase 2 results in expected in CY22, NNZ-2591' is likely to be licensed and transition to Phase 3. Industry data supports a higher probability of ~60% in Phase 3 trials, against the MST current probability weighting of 19%.

While direct comparisons cannot be made, some insight can be gained from comparison of NEU to two other later stage ASX development companies.

Exhibit 2 - MST Comparison of NEU.AX, PAR.AX & OPT.AX

NEU versus Comparable ASX Companies				
Based on MST Estimates , ASX releases		**NEU**	**PAR**	**OPT**
Market Capitalisation*		$122m	$629m	$756m
Stage of development in leading indication **		Phase 3 trial in progress	Planning Phase 3 trials	Planning Phase 3 trial
Potential Total Patient population**		√	√√	√√
Regulatory Approval for Phase 3 Trials **				
	FDA	Trial commenced	Meeting planned	Planning meetings held
	EMA	Trial commenced	√	
Competitive market opportunity**		√√***	√	√√
Pricing opportunity**		√√	√	√√
Potential Total Market Size (all indications)*		√	√√	√√

* All Indications
** Lead indication
***No approved therapy
√ - √√ lowest - highest relative value

Source: MST assumptions, Company reports

NEU's current valuation appears to represent a steep discount to its peers. Comparison of NEU's valuation to corporate transactions of rare /orphan drugs also provides further evidence of significant upside to its current valuation.

Exhibit 3 - Rare Disease Transactions

Relevant Rare Disease and Orphan Drug Company Transactions						
Date	Acquirer	Target	Target location	Description of target	Phase / stage of lead product	Transaction US$ (m)
Apr-20	UCB SA	RA Pharmaceuticals Inc.	USA	Focuses on treatment of rare muscle diseases. Lead candidate, zilucoplan, developed for treatment of generalized myasthenia gravis.	Phase III	$2,100
Jan-20	Alexion Pharmaceuticals Inc.	Achillon Pharmaceuticals Inc.	USA	Focuses on the development of oral small molecule Factor D inhibitors to treat people with complement alternative pathway-mediated rare diseases, such as paroxysmal nocturnal hemoglobinuria (PNH) and C3 glomerulopathy (C3G).	Phase II	$930+
Nov-19	Swedish Orphan Biovitrum AB	Dova Pharmaceuticals Inc.	USA	Focuses on acquiring, developing, and commercializing drug candidates for rare diseases. Founded in 2016 to commercialise Doptelet® (avatrombopag) for the treatment of thrombocytopenia.	Market	$915
Jul-19	Pfizer Inc.	Therachon Holding AG	Switzerland	Focuses on rare gastrointestinal and musculoskeletal disorders and conditions, including both achondroplasia and short bowel syndrome. Lead product TA-46 developed for treatment of achondroplasia.	Phase I	$810
Apr-19	Ipsen SA	Clementia Pharmaceuticals Inc.	Canada	Develops treatments for people with ultra-rare bone disorders and other diseases with high medical need. Company preparing for a 2019 NDA submission to the FDA to seek approval of its lead product candidate, Palovarotene, for the prevention of heterotopic ossification.	Phase III	$1,310
Jun-18	Alexion Pharmaceuticals Inc.	Wilson Therapeutics AB	Sweden	Develops novel therapies for patients with rare copper-mediated disorders. Lead candidate, WTX101, developed for Wilson disease.	Phase III	$855
Mar-18	H. Lundbeck A/S	Prexton Therapeutics BV	Netherlands	Private CNS company developing, foliglurax, a first-in-class treatment for Parkinson's disease in July 2017.	Phase II	EUR905m+*
Feb-18	Mallinckrodt Plc	Sucampo Pharmaceuticals Inc.	USA	A company with branded constipation and ophthalmic drugs and a pipeline of candidates targeted rare diseases.	Market	$1,200
Jan-15	BioMarin Pharmaceutical Inc.	ProSena Therapeutics BV	Netherlands	Engaged in the discovery, development and commercialization of RNA-modulating therapeutics for the treatment of genetic disorders. Lead product for treatment of Duchenne Muscular Dystrophy.	Phase II	$840
Jun-14	H. Lundbeck A/S	Chelsea Therapeutics International Ltd	USA	Acquires and develops innovative products for the treatment of a variety of human diseases, including central nervous system disorders. Lead product, Northera for symptomatic neurogenic orthostatic hypotension, approved in 2014.	Approved	$658

*Euro

Source: MST review

Neuren boasts two drugs in clinical trials. Trofinetide, its more advanced drug candidate, has positive Phase 2 trial data in both Rett and Fragile X syndromes and effectively one year from Phase 3 trial read out in Rett syndrome. In our view, NEU presents significant upside risk, with positive trial outcomes over CY21/CY22 likely to trigger a re-rating of the company.

Exhibit 4 - MST Forecast Financial Summary

STATEMENT OF COMPREHENSIVE INCOME	2018A	2019A	2020E	2021E	2022E	2023E
Revenue						
Revenue from License	13,544			36,250	79,750	72,500
Australian R&D tax incentive	446	495	500	1,000	500	500
Gross Profit	13,098	300	500	37,250	80,250	73,000
Expenses						
R&D	-6,101	-9,858	-7,000	-15,000	-1,500	-1,500
Administration	-2,074	-1,713	-2,000	-2,000	-2,000	-2,000
Other	-3,921	-261				
Amortisation of intangibles	-72	-72	-72	-72	-72	-72
Depreciation	-6	-6	-6	-6	-6	-6
Operating profit (loss)	1,002	-12,686	-8,578	20,172	76,672	69,422
Interest received	218	389	192		558	1,805
Interest Paid						
Net Interest Received	218	389	192		558	1,805
Profit (loss) before income tax	3,073	-10,816	-8,386	20,172	77,230	71,227
Income tax expense						
Total comprehensive profit (loss) attributable	3,073	-10,816	-8,386	20,172	77,230	71,227
Marginal tax rate						
Profit after tax	3,073	-10,816	-8,386	20,172	77,230	71,227

STATEMENT OF FINANCIAL POSITION	2018A	2019A	2020E	2021E	2022E	2023E
Current Assets						
Trade and other receivables	942	522	522	522	522	522
Cash and cash equivalents	23,576	13,844	25,488	45,660	122,890	194,117
Other	2,121					
Total current assets	26,639	14,396	26,010	46,182	123,412	194,639
Non-Current Assets						
Property, plant and equipment	2	10	10	10	10	10
Intangible Assets	1					
Total non-current assets	3	10	10	10	10	10
Total Assets	26,639	14,406	26,020	46,192	123,422	194,649
Current Liabilities						
Trade and other payables	1,973	559	559	559	559	559
Total current liabilities	1,973	559	559	559	559	559
Non-Current Liabilities						
Total Liabilities	1,973	559	559	559	559	559
Net Assets	24,669	12,519	25,461	45,633	122,863	194,090
Minority Interst						
Net assets attributable	24,669	13,847	25,461	45,633	122,863	194,090
Equity	126,426	126,426	146,426	146,426	146,426	146,426
Other Reserves	-8,497	-8,503	-8,503	-8,503	-8,503	-8,503
Accumulated Deficit	-93,260	-104,076	-112,462	-92,290	-15,060	56,167
Total Equity	24,669	13,847	25,461	45,633	122,863	194,090

STATEMENT OF CASH FLOWS	2018A	2019A	2020E	2021E	2022E	2023E
License Agreement Receipts	13,544			36,250	79,750	72,500
Tax paid						
Australian R&D Tax Incentive Receipts	446	450	500	1,000	500	500
Interest Received	165	413	192		558	1,805
GST Refunded	95	102				
Payments for Employees and Directors	-1,909	-1,742	-2,000	-2,000	-2,000	-2,000
R&D and Other Payments	-6,118	-10,942	-7,048	-15,078	-1,578	-1,578
Net Cash Flow from Operating Activities	6408	-11719	-8,356	20,172	77,230	71,227
Net Cash Flow from Investing Activities		-12				
Cash Flows from Financing Activities						
Proceeds from Issue of Shares	11,730	1,860	20,000			
Payments of Shares Issue Expenses	-16					
Net Cash Provided from Financing Acitivites	11,714	1,860	20,000			
Net Increase/Decrease in cash	18,122	-9,871	11,644	20,172	77,230	71,227
Cash equivalents at beginning of year	4,706	23,576	13,844	25,488	45,660	122,890
Cash & equivalents at end of year	23,576	13,844	25,488	45,660	122,890	194,117

Source: Company reports, MST assumptions

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