NEUREN PHARMACEUTICALS LIMITED

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All the ducks in a row

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Rett Syndrome Phase 3 Trial on Track √

US partner reconfirms planned Phase 3 results in H2CY21

Acadia Pharmaceuticals (NASDAQ:ACAD) has confirmed H2CY21 as the expected release date for the topline results for the Phase 3 clinical trial in Rett Syndrome. Acadia has licensed the North American rights for trofinetide from Neuren Pharmaceuticals. The Phase 3 trial which was suspended due to the impact of COVID, recommenced in June.

Positive results in the Phase 3 trial with subsequent FDA approval and market entry are expected to trigger milestone payments of ~U$55m (MST estimate) over CY22. Sales royalties of 10% (MST estimate) of net sales would commence on market entry.

NNZ–2591 on track √

Funding for the planned Phase 2 trial of NNZ-2591 in three neurodevelopmental conditions has also been confirmed. Post a capital raising in June of net ~$19m, NEU has a cash reserve of ~$28m. The funding will allow NEU to undertake its Phase 2 trials, assuming a successful Phase 1 trial. The Phase 2 trial is planned to start in CY21. Positive results in CY22 would open the opportunity to license NNZ-2591 with possible upfront payments.

Valuation

MST's risk adjusted DCF valuation of NEU at A$398m is unchanged. The change in the implied valuation of A$3.32 (down from A$3.88), reflects the increased shares on issue post the capital raise. This compares to a share price of ~$1.31. In MST's view, the upcoming milestones for both drugs have not yet been recognised in the share price.

Trofinetide is in the final stage of clinical trial, which has a probability of approval of ~60%. Positive trial results would see a 60% increase in value in CY21. Similarly, on positive Phase II results in CY22, NNZ-2591's transition to Phase III would result in a probability of ~60%, against 19% currently.

Our valuation forecasts carry the usual risks and sensitivities of new drug development. Our forecasts are based on licensing models. NEU is yet to negotiate agreements of trofinetide in ex North American markets and the global rights for NNZ-2591.

Comparison of NEU to ASX listed biotechs, Opthea (OPT) ~A$658m and Paradigm (PAR) ~A$672m shows a significant discount. Both OPT and PAR are yet to commence Phase III trials.

We believe NEU presents significant upside risk, with positive trial outcomes over CY21/CY22 likely to trigger a re-rating of the company.

Neuren Pharmaceuticals is an ASX listed biotechnology company developing two drugs, trofinetide and NNZ-2591. Trofinetide's Phase III trial results in Rett Syndrome expected over CY21.

Trofinetide and NNZ-2591 are targeting five disorders. Their mechanism of action offers the potential to address a much wider range of neural diseases and trauma related injury.

Acadia Pharmaceuticals has licensed the North American (NAM) rights to trofinetide.

NNZ-2591 is in Phase I clinical trial.

Board and management are well credentialled with expertise in drug development and commercialisation.

Company data	
Net cash (30/6/20)	A$9.2m
Shares on issue	120.0m
Options and Rights Outstanding	
Code ASX	NEU.AX
Primary exchange	ASX

Next steps

- Phase III results trofinetide in Rett Syndrome in CY21
- Phase II results NNZ-2591 in CY22

Price: $1.31 (one year)

Investment Thesis

Investment Case

With confirmation of the timing of Rett Syndrome Phase 3 trial results and funding for Phase 2 trials for NNZ-2591, NEU is on track to meet potential significant value drivers over CY21 and CY22.

Neuren Pharmaceuticals (NEU) is targeting five neurodevelopmental disorders. Trofinetide is in Phase III clinical trial for Rett Syndrome and has completed a Phase II trial in Fragile X. The NAM rights are licensed to Acadia Pharmaceuticals (NASDAQ: ACAD). NEU retains the rights for ex-NAM markets. Neuren's NNZ-2591, targeting Phelan McDermid Syndrome (PMS), Angelman (AS) and Pitt Hopkins (PH), has commenced Phase I clinical trial. Currently, there are no approved treatments for any of the five conditions. Neuren's drug candidates are optimised versions of two neural acting peptides, which play a key role in the body's nervous system.

Significant Value Points

Over next two years plus, a number of value-creating milestones are expected to be reached.

The potential near term catalysts include:

- CY20 Results Phase I clinical trials of NNZ-2591 healthy adult volunteers
- CY 21 Start Phase II trials NNZ-2591 in the three syndromes
- CY21 Results Phase II clinical trials NNZ-2591
- CY21 Results of Phase III clinical trial of trofinetide in Rett Syndrome
- CY22 FDA New Drug Application (NDA) approval of trofinetide in Rett Syndrome
- CY22 Milestone payments from NEU's NAM partner, Acadia Pharmaceuticals
- CY22 Licensing agreements for ex NAM rights for trofinetide and for NNZ-2591

Risks, Sensitivities & Valuation

The valuation of Neuren 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. The expected commercial performance is based on a number of assumptions. The assumptions present upside and downside risk.

Risk presents through confirmation of safety, clinical trial timing, regulatory approval, milestone payments and sales royalties from both Acadia and expected new licensing partners. Failure to secure new partners, may see Neuren assume the regulatory filings and marketing/distribution role, which would impact MST forecasts. The Phase III trofinetide trials have 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.

MST's risk adjusted DCF valuation of NEU at A$398m implies a valuation of A$3.32. In MST's view, the upcoming milestones for both drugs are not yet reflected in NEU's share price. Trofinetide is in the final stage of clinical trial, carrying a probability of approval at 60%. Positive trial results would see a 60% increase in value. Similarly, on positive Phase II results in CY22, NNZ-2591's transition to Phase III would result in a probability of 60%, against 19% currently.

Comparison of NEU's valuation to listed ASX biotechs, Opthea (OPT) ~A$658m and Paradigm (PAR) ~A$672m that are yet to commence Phase III trials, shows a significant discount. In our view, NEU presents significant upside risk, with positive trial outcomes over CY21/CY22 likely to trigger a re-rating of the company.

Figure 1 – Neuren Pharmaceuticals Financial Summary

NEUREN PHARMACEUTICALS						
Year ending 31 December 2019	A$000					
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	-5,000	-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	-6,578	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	-6,386	20,172	77,230	71,227
Income tax expense						
Total comprehensive profit (loss) attributable	3,073	-10,816	-6,386	20,172	77,230	71,227
Marginal tax rate						
Profit after tax	3,073	-10,816	-6,386	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	27,488	47,660	124,890	196,117
Other	2,121					
Total current assets	26,639	14,396	28,010	48,182	125,412	196,639
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	28,020	48,192	125,422	196,649
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	27,461	47,633	124,863	196,090
Minority Interst						
Net assets attributable	24,669	13,847	27,461	47,633	124,863	196,090
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	-110,462	-90,290	-13,060	58,167
Total Equity	24,669	13,847	27,461	47,633	124,863	196,090

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	-5,048	-15,078	-1,578	-1,578
Net Cash Flow from Operating Activities	6408	-11719	-6,356	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	13,644	20,172	77,230	71,227
Cash equivalents at beginning of year	4,706	23,576	13,844	27,488	47,660	124,890
Cash & equivalents at end of year	23,576	13,844	27,488	47,660	124,890	196,117

Source: Company Reports, MST Estimates

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