BELL POTTER

24 August 2022

Speculative

See key risks on Pages 3 & 4 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

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Neuren (NEU)

Strong cash position and IND approvals

Recommendation
Hold (unchanged)
Price
$5.48
Valuation
$6.85 (previously $7.00)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

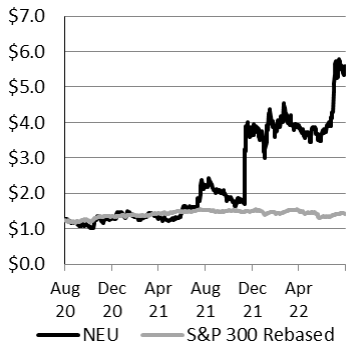
Expected Return	
Capital growth	**16.7%**
Dividend yield	**0.0%**
Total expected return	**16.7%**

Company Data & Ratios	
Enterprise value	**$659.2m**
Market cap	**$690.3m**
Issued capital	**126.0m**
Free float	**97%**
Avg. daily val. (52wk)	**$0.68m**
12 month price range	**$1.62-$5.99**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	4.29	3.74	2.20
Absolute (%)	28.21	47.06	150.00
Rel market (%)	25.20	48.06	156.40

Absolute Price



SOURCE: IRESS

H1FY22 Update

Neuren had a cash balance of $31.1m as at 30 June 2022, having spent $5.8m in operating activities throughout the period, of which, $4.6m was spent on R&D activities. This R&D spend was down compared to the pcp (from $7.0m in H1FY21 – when the company was in the midst of running a number of clinical trials and drug manufacturing was underway). We are anticipating this spend to increase in the next half year as three (and possibly four) Phase 2 clinical trials commence and progress.

In March this year, NEU received investigational new drug (IND) approvals from the FDA for NNZ-2591 in the treatment of Angelman, Phelan-McDermid and Pitt Hopkins syndromes – the green light for Phase 2 trials in these indications. These P2 trials are progressing and top line results are likely to be available in H1FY23. A fourth indication, Prader-Willi syndrome, is also in the pipeline for this drug.

The overall loss after tax for H1FY22 was $7.0m, compared with $8.0m for the half-year ended 30 June 2021.

Income is negligible at this early stage for NEU, with a total income of $283,000 for H1FY22 from interest and foreign exchange gains. This is not unusual for a clinical trial stage company.

A date for the meeting of the FDA's Advisory Committee to discuss the submitted NDA for NEU's trofinetide in the treatment of Rett syndrome is yet to be announced. We have reduced our risk rating for an FDA approval from 75% to 70%, to more closely reflect the modest clinical effects reported in the Phase 3 trial of trofinetide in girls with Rett syndrome.

Investment view: Valuation $6.85, retain Hold (Spec.)

Our valuation has been reduced to $6.85 (previously $7.00). Anticipated Phase 2 and 3 clinical trials for NEU's second therapeutic asset, NNZ-2591, in at least 3, and possibly 4, neurological indications, are likely to require a greater R&D spend than we previously attributed over the next 3 years. The risk rating reduction for an FDA approval for trofinetide has also had a material impact on our valuation.

Table 1 - Earnings Forecast

December Year End	FY21	FY22e	FY23e	FY24e
Revenues ($m)	3.6	16.9	85.1	79.5
EBIT ($m)	-7.8	-3.7	66.2	56.5
NPAT - ($m)	-7.8	-3.7	48.0	41.0
EPS - (cps)	-6.2	-2.9	38.1	32.5
EPS growth (%)	nm	nm	-1406%	-15%
PER (x)	nm	nm	14.4	16.8
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	(84.5)	(179.4)	10.0	11.7
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield (%)	0%	0%	0%	0%
ROE (%)	-20%	-11%	58%	33%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Valuation Amendments

Anticipated future R&D spend increased

Earlier this month (1 Aug 2022), we introduced conservative putative revenues from sales of NNZ-2591 from FY26 onwards into our model, which affected our valuation. We now consider the cash spend required over the next 3 financial years if NEU is going to successfully run the 4 proposed Phase 2 trials for NNZ-2591 and follow these up with the even more expensive Phase 3 clinical trials.

We have therefore increased the R&D spend from approximately $10m per annum for FY22, FY23 and FY24 to ~$17m for FY22, $16m for FY23 and $20m for FY24.

At this stage, revenues from the sales of NNZ-2591 for any indication other than Angelman syndrome are beyond the time scope of our current DCF.

Risk rating for an FDA approval of trofinetide

We have also reduced our risk rating for an FDA approval from 75% to 70%, which we feel more closely reflects the modest clinical benefit of trofinetide in patients with Rett syndrome (we have previously detailed these considerations in a note dated 14 Feb 2022). These changes, along with changes to our earnings forecasts, are summarised in Table 2 below.

Table 2 - Summary of earnings and R&D spend changes

	2022			2023			2024		
	New	**Old**	**% change**	**New**	**Old**	**% change**	**New**	**Old**	**% change**
Revenues	16.9	16.9	0%	85.1	85.3	0%	79.5	80.0	-1%
R&D - clinical trial costs	-17.6	-9.7	82%	-17.0	-10	70%	-19.0	-10.0	90%
EBIT	-3.7	4.2	-187%	66.2	72.3	-9%	56.5	67.0	-16%
NPAT	-3.7	3.0	-223%	48	52.4	-8%	41.0	48.6	-16%
EPS	-2.9	2.4	-221%	38.1	41.6	-8%	32.5	38.5	-16%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Valuation

The valuation of $6.85 is derived from a discounted cash flow model. We have kept the WACC at 11.5% given NEU has a large pharmaceutical partner in the US. We assume a terminal growth rate of 3%.

The model includes recent and potential milestone payments of up to A$118m over FY22 and FY23; and double-digit percentage royalties on net sales from Acadia, NEU's US pharmaceutical partner. These are risk rated in our model as described above.

The model also includes potential future revenues from NNZ-2591 for use in Angelman syndrome. While future revenues for NEU from NNZ-2591 are likely to materialise in the form of non-dilutive upfront and milestone payments from a putative pharmaceutical partner, rather than from the direct launch and sale of NNZ-2591 by NEU, our model includes risk-weighted potential future revenues of NNZ-2591 commencing in FY26 as this can be directly extrapolated (unlike a possible partnership deal).

NEUREN PHARMACEUTICALS

Neuren Pharmaceuticals (ASX: NEU), registered in Auckland, NZ, 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 top line results from its Rett Phase 3 Lavender trial, in partnership 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 Angelman Syndrome (the most progressed of the trials).

NEU is in-line to receive ~US$118m in milestones on filing, approval and launch of trofinetide plus double digit royalties on sales. Acadia estimates peak US sales of trofinetide for Rett of at least US$500m. Phase 3 results also provide impetus to Ex-US licensing discussions for trofinetide. NEU is now progressing NNZ-2591, which may be highly lucrative (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 has now submitted the NDA (July 2022) following a pre-NDA meeting with the FDA. With a 6 month priority review, we expect approval and launch in early CY23. While we believe there is a good chance of the drug receiving approval (70% likelihood of approval), should the FDA require additional risk evaluation and mitigation strategies (REMS) to manage the diarrhoea 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 focused solely on the upcoming NDA filing for trofinetide for Rett. They have not yet planned for the development of trofinetide for additional indications. We have therefore removed Fragile X as the second indication in our current forecast. While we believe it is still possible Acadia may develop trofinetide for a second indication, their comments suggest that Fragile X may not be the next priority. The timing and choice of a second indication would likely impact our forecasts.

Funding risk: The company is in a strong cash position, with $31.1m as at 30 March 2022. This follows a recently completed placement and SPP. Further cash injections from milestone payments from Acadia are expected over CY22/CY23. Assuming trofinetide is approved and the milestone income is received, we believe NEU will be fully funded for the development of NNZ-2591. It is unlikely the Board will consider a dividend.

Clinical risks:

- NNZ-2591 has been given Orphan Drug designation by the FDA for all 4 disorders. IND approval has been granted for investigating the drug for the treatment of patients with 3 of the 4 target indications. While some of these studies have commenced, we have no data from these trials yet. Any delays to the proposed timeline for all of these P2 studies are likely to impact our current forecasts.

- It is possible that the FDA could request a confirmatory study for trofinetide in Rett syndrome. Drug is essentially safe and tolerability issues are being proactively managed in the open label LILAC™ study.
- No other treatment exists for Rett Syndrome, although other companies are investigating novel pharmacothrapeutics for the disase. These include Anavex 2-73 (blarcamesine), an experimental treatment that Anavex Life Sciences is developing to treat Rett syndrome. This drug has also been grant orphan drug status and fast track designation by the FDA. Anavex Life Sciences notes that primary and all secondary efficacy and safety endpoints for their recent phase 3 trial, were met for the treatment of adult patients with Rett syndrome, with consistent improvements in RSBQ AUC ($p = 0.037$), ADAMS ($p = 0.010$) and CGI-I ($p = 0.037$) response. This trial also showed positive biomarker data unlike the trofinetide P3 trial. This poses the risk that the FDA will consider one of these drugs as superior to the other – although technically this is not supposed to occur (ie, each drug is supposed to be considered in isolation of other proposals).
- Patient uptake and ongoing use of trofinetide (if approved) is not clear given the modest effects seen in the Phase 3 trial. We have conservative assumptions built into our model around revenue from commercial milestones and royalties that are dependent on ongoing patient usage.

Neuren
as at 24 August 2022

Recommendation	Hold, Speculative
Price	$5.48
Valuation	$6.85

Table 3- Financial summary

A$m	FY20	FY21	FY22e	FY23e	FY24e
Year Ending 31 December					
Total Revenues	**0.7**	**3.6**	**16.9**	**85.1**	**79.5**
Revenue grow th	0.0%	0.0%	364.5%	404.1%	-6.6%
COGS	0.0	0.0	0.0	0.0	0.0
Gross profit	0.7	3.6	16.9	85.1	79.5
GP Margin	na	na	100.0%	100.0%	100.0%
R&D - clinical trial costs	-7.8	-9.5	-17.6	-16.0	-20.0
Corporate and admin	-1.8	-1.9	-2.0	-2.0	-2.0
Other expenses	-0.5	0.0	-1.0	-1.0	-1.0
Total Expenses	-10.1	-11.4	-20.6	-19.0	-23.0
EBIT	-9.4	-7.8	-3.7	66.2	56.5
Add back D&A	0.0	0.0	0.0	0.0	0.0
EBITDA	-9.4	-7.8	-3.7	66.2	56.5
Interest expense	0.1	0.0	0.0	0.0	0.0
Other items	0.0	0.0	0.0	0.0	0.0
Pre tax profit	(9.2)	(7.8)	(3.7)	66.2	56.5
Tax expense	0.0	0.0	0.0	-18.2	-15.5
NPAT- reported	**(9.2)**	**(7.8)**	**(3.7)**	**48.0**	**41.0**
Add back					
Non recurring items net of tax	-	-	-	-	-
Reported normalised	(9.2)	(7.8)	(3.7)	48.0	41.0

Cashflow (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Gross cashflow	-8.2	-7.0	-6.9	52.5	57.6
Net interest	0.2	0.0	0.0	0.0	0.0
Income tax paid	0.0	0.0	0.0	-18.2	-15.5
Operating cash flow	-8.1	-7.0	-6.9	34.3	42.1
Maintenance capex	0.0	0.0	0.0	0.0	0.0
Capitalised R&D	0.0	0.0	0.0	0.0	0.0
Free cash flow	-8.1	-7.0	-6.9	34.3	42.1
Purchase of other intangibles	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	19.1	22.1	0.0	0.0	0.0
Movement in borrow ings	0.0	0.0	0.0	0.0	0.0
Redemption of preference shares	0.0	0.0	0.0	0.0	0.0
Dvidends paid (common stock)	0.0	0.0	0.0	0.0	0.0
Change in cash held	11.1	15.1	-6.9	34.3	42.1
Cash at beginning of period	13.8	24.2	39.3	32.4	66.7
FX adjustment	-0.7	0.0	0.0	0.0	0.0
Cash at year end	**24.2**	**39.3**	**32.4**	**66.7**	**108.8**

Balance Sheet (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Cash	24.2	36.8	32.4	66.7	108.8
Receivables	0.8	3.3	3.4	17.0	15.9
Other current assets	-	-	-	-	-
Inventory	-	-	-	-	-
Property, Plant and Equipment	0.0	0.0	0.0	0.0	0.0
Intangibles	0.0	0.0	0.0	0.0	0.0
Right of use assets	-	-	-	-	-
Other non current assets	-	-	-	-	-
Total assets	25.0	40.1	35.8	83.8	124.7
Trade payables	0.8	0.8	1.0	1.0	1.0
Other liabilities	-	-	-	-	-
Debt	-	-	-	-	-
Lease liabilities	-	-	-	-	-
Total Liabilities	0.8	0.8	1.0	1.0	1.0
Net Assets	24.2	39.3	34.8	82.8	123.7
Share capital	145.6	167.7	167.7	167.7	167.7
Other equity	-	-	-	-	-
Retained earnings	(111.1)	(118.9)	(122.6)	(74.6)	(33.7)
Reserves	(10.3)	(9.4)	(10.3)	(10.3)	(10.3)
Shareholders Equity	24.2	39.3	34.8	82.8	123.7
Net debt	(24.2)	(36.8)	(32.4)	(66.7)	(108.8)

Valuation Ratios (A$m)	FY20	FY21	FY22e	FY23e	FY24e
Reported EPS (cps)	-8.6	-6.2	-2.9	38.1	32.5
Normalised EPS (cps)	-8.6	-6.2	-2.9	38.1	32.5
EPS grow th (%)	0%	nm	nm	-1406%	-15%
PE(x)	**nm**	**nm**	**nm**	**14.4**	**16.8**
EV/EBIT (x)	nm	-84.5	-179.4	10.0	11.7
P/NTA (x)	26.6	17.5	19.8	8.3	5.6
Book Value Per Share (cps)	20.6	31.2	27.6	65.7	98.2
Price/Book (x)	26.6	17.5	19.8	8.3	5.6
DPS (cps)	-	-	-	-	-
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%	0.0%	0.0%	0.0%
FCF yield %	nm	nm	nm	nm	nm
Net debt/Equity	0.0%	0.0%	0.0%	0.0%	0.0%
Net debt/Assets	0.0%	0.0%	0.0%	0.0%	0.0%
Gearing	net cash	net cash	net cash	net cash	net cash
Net debt/EBITDA (x)	2.6	4.7	8.8	net cash	net cash
Interest cover (x)	na	na	na	na	na

	FY20	FY21	FY22e	FY23e	FY24e
Revenues Analysis					
Royalties	-	-	-	1.6	7.1
Milestone income	-	-	13.9	80.6	69.4
Other income	0.7	3.6	3.0	3.0	3.0
	0.7	3.6	16.9	85.1	79.5

Interim Results	1H21	2H21	1H22e	2H22e
Revenues	0.0	0.4	0.3	13.9
EBIT	-7.7	-3.3	-7.1	-3.4
NPAT	-7.7	-3.3	-7.1	-3.4

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

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