



## CLINUVEL PHARMACEUTICALS LTD

HOLD

## Minimal concerns over FDA delay

Pharmaceuticals, Biotechnology &amp; Life Sciences / Biotechnology

4 June 2019

## COMPANY UPDATE

Ticker	CUV
Stock Price	\$31.00
Target Price	\$26.43
Forecast Capital Return	(14.7%)
Forecast Dividend Yield	0.1%
Estimated Total Return - 12 Mth Forward	(14.7%)

## Company market data

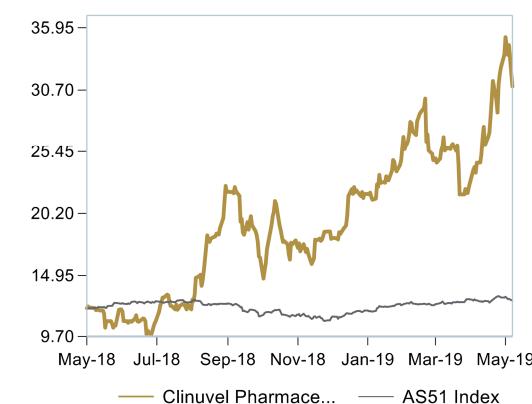
Market Cap.	\$1,516.7m
Free Float (%)	75.2
Enterprise Value	\$1,454.2m
52 Week Range	\$9.82 - \$35.16
Shares Out.	48.9m
Avg. Daily Value	\$1.2m

Estimates changes	2018a	2019e	2020e	2021e
Core NPAT - old	13.2	12.8	11.5	15.1
Core NPAT - new	13.2	12.8	11.5	15.1
% Change	0.0	0.0	0.0	0.0
Core EPS dil. (¢) - old	26.7	26.5	23.5	31.0
Core EPS dil. (¢) - new	26.7	26.5	23.5	31.0
% Change	0.0	0.0	0.0	0.0
DPS (¢) - old	2.0	2.0	2.0	3.0
DPS (¢) - new	2.0	2.0	2.0	3.0
% Change	0.0	0.0	0.0	0.0

All figures are in AUD unless otherwise specified.

## Share price performance

Clinuvel Pharmaceuticals Ltd vs. ASX51 (rebased index)



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## EVENT

**FDA extends PDUFA date to 6 October 2019**, from the original PDUFA date of 8 July 2019. The FDA will also communicate requirements around product labelling and post-market authorization commitments on the 6<sup>th</sup> of September. The FDA has stated that it requires more time to complete a full review of the NDA.

Clearly any delay around FDA approval is disappointing, given it will push back first sales in the US by at least 3 months. However, we are not concerned that this delay is a sign of anything sinister. Rather we regard this as likely only a timing issue.

## IMPACT

- No clarity around specifically which areas of the NDA the FDA wants to review further**, however there has been nothing in the review process that would suggest that the delay is anything sinister. Rather the company believes it is likely due to lack of resources on the FDA's end meaning they require a further 3 months to fully review its application.
- No signs that CUV's submission or responses have been insufficient**, as if that were the case the FDA would have asked CUV to withdraw its application. There have been no indications of this.
- PDUFA date extension appears similar to CUV's initial NDA filing** in June last year. Traditionally once an NDA is submitted to the FDA, there is a 60 day validation period, after which the FDA will advise a PDUFA date where either FDA approval is granted or the application is rejected. However after CUV submitted its NDA in June 2018, the FDA requested additional data in September and then didn't provide a PDUFA date until January 2019. While clearly a delay on the PDUFA date is not a good outcome - as it delays the timing around first sales in the US, it is equally not a sign that SCENESSE will not be approved. Rather we view it largely as a timing issue.

## INVESTMENT VIEW

Our EPS estimates and valuation remain unchanged. We continue to see CUV as owning a high quality pharmaceutical that addresses a severe unmet need in a niche market. As a result, we still believe there is a high probability that CUV will achieve FDA approval in CY19. However at current levels, we continue to believe much of the upside is reflected in the price and so we retain our HOLD recommendation.

Y/E Dec 31	2018a	2019e	2020e	2021e
EBITDA	12.7	16.2	16.1	21.4
EV/EBITDA	114.3x	89.9x	90.6x	68.1x
Core NPAT	13.2	12.8	11.5	15.1
Core EPS (Diluted) (¢)	26.7	26.5	23.5	31.0
P/E	116.2x	117.0x	132.2x	99.9x
EPS growth	86.0%	(0.7%)	(11.4%)	32.2%
DPS (¢)	2.0	2.0	2.0	3.0
Yield	0.1%	0.1%	0.1%	0.1%
DPS growth	-	0.0%	0.0%	49.8%
Dividend Payout Ratio	7.5%	7.6%	8.5%	9.7%

All figures are in AUD.

**Clinuvel Pharmaceuticals Ltd (CUV)** Market Cap: \$1,517m Last Price: \$31.00 Target Price: \$26.43 Hold

Y/E Dec 31

Profit and Loss (\$m)	2017a	2018a	2019e	2020e	2021e
<b>Revenue</b>	<b>16.7</b>	<b>25.5</b>	<b>30.6</b>	<b>36.7</b>	<b>48.1</b>
<i>Growth</i>	169.2%	52.4%	20.2%	19.9%	30.9%
<b>EBITDA</b>	<b>6.9</b>	<b>12.7</b>	<b>16.2</b>	<b>16.1</b>	<b>21.4</b>
<i>Growth</i>	(306.9%)	84.3%	27.2%	(0.8%)	33.0%
Dep'n & Amort	(0.1)	0.0	(0.1)	(0.2)	(0.3)
<b>EBIT</b>	<b>6.8</b>	<b>12.7</b>	<b>16.1</b>	<b>15.9</b>	<b>21.0</b>
<i>Growth</i>	(303.7%)	85.1%	27.1%	(1.5%)	32.6%
Net Interest Expense	0.3	0.3	0.4	0.5	0.6
<b>Profit Before Tax</b>	<b>7.1</b>	<b>12.9</b>	<b>16.5</b>	<b>16.4</b>	<b>21.6</b>
Tax	0.0	0.3	(3.7)	(4.9)	(6.5)
<i>Tax Rate (%)</i>	0.0%	(2.2%)	22.6%	30.0%	30.0%
Minorities	0.0	0.0	0.0	0.0	0.0
<b>NPAT (Underlying)</b>	<b>7.1</b>	<b>13.2</b>	<b>12.8</b>	<b>11.5</b>	<b>15.1</b>
<i>Growth</i>	(327.9%)	85.9%	(3.3%)	(10.4%)	32.2%
One-Off Items	0.0	0.0	0.0	0.0	0.0
<b>NPAT (Reported)</b>	<b>7.1</b>	<b>13.2</b>	<b>12.8</b>	<b>11.5</b>	<b>15.1</b>
<b>EPS (Underlying) (€)</b>	<b>14.3</b>	<b>26.7</b>	<b>26.5</b>	<b>23.5</b>	<b>31.0</b>
<i>Growth</i>	(320.3%)	86.0%	(0.7%)	(11.4%)	32.2%

Valuation Summary	
Current Mkt Capitalisation	1,516.7
Shares on Issue	48.9
Last Price	31.00
<b>12 Mth Target Price</b>	<b>26.43</b>
Total Estimated 12 Mth Return	(14.7%)
12 Mth Fwd Capital Return	(14.7%)
12 Mth Fwd Dividend Yield	0.1%

Valuation Ratios	2017a	2018a	2019e	2020e	2021e
<b>EPS (Underlying) (€)</b>	<b>14.3</b>	<b>26.7</b>	<b>26.5</b>	<b>23.5</b>	<b>31.0</b>
<i>Growth</i>	(320.3%)	86.0%	(0.7%)	(11.4%)	32.2%
<b>P/E (x)</b>	<b>216.2x</b>	<b>116.2x</b>	<b>117.0x</b>	<b>132.2x</b>	<b>99.9x</b>
Small Industrials (ex Fin's)	16.3x	14.6x	13.7x	0.0x	0.0x
Premium / (Discount)	1,226.6%	698.1%	756.0%	nm	nm
<b>EV/EBITDA (x)</b>	<b>210.7x</b>	<b>114.3x</b>	<b>89.9x</b>	<b>90.6x</b>	<b>68.1x</b>
Small Industrials (ex Fin's)	10.3x	9.3x	8.8x	0.0x	0.0x
Premium / (Discount)	1,944.8%	1,132.0%	924.4%	nm	nm
<b>DPS (€)</b>	<b>0.0</b>	<b>2.0</b>	<b>2.0</b>	<b>2.0</b>	<b>3.0</b>
<i>Growth</i>	-	-	0.0%	0.0%	49.8%
<b>Yield (%)</b>	<b>0.0%</b>	<b>0.1%</b>	<b>0.1%</b>	<b>0.1%</b>	<b>0.1%</b>
<b>Payout Ratio (%)</b>	<b>0.0%</b>	<b>7.5%</b>	<b>7.6%</b>	<b>8.5%</b>	<b>9.7%</b>
Franking (%)	100.0%	100.0%	100.0%	100.0%	100.0%
<b>NTA</b>	<b>25.4</b>	<b>39.2</b>	<b>51.6</b>	<b>61.3</b>	<b>75.1</b>
<b>NTA/Share (\$)</b>	<b>0.51</b>	<b>0.79</b>	<b>1.07</b>	<b>1.26</b>	<b>1.54</b>

Balance Sheet (\$m)	2017a	2018a	2019e	2020e	2021e
Cash	23.8	36.2	46.0	55.4	66.5
Inventory	1.2	0.6	1.0	1.2	1.5
Current Receivables	3.2	5.1	7.5	9.0	11.6
PPE	0.1	0.2	0.8	1.4	2.2
Intangibles	0.0	0.2	0.2	0.2	0.2
Other	0.2	0.6	0.9	0.9	0.9
<b>Total Assets</b>	<b>28.6</b>	<b>42.9</b>	<b>56.4</b>	<b>68.0</b>	<b>82.9</b>
Current Payables	2.3	2.5	3.4	5.1	5.7
ST Debt	0.0	0.0	0.0	0.0	0.0
LT Debt	0.0	0.0	0.0	0.0	0.0
Provisions	0.9	1.0	1.2	1.4	1.9
Other	0.0	0.0	0.0	0.0	0.0
<b>Total Liabilities</b>	<b>3.2</b>	<b>3.5</b>	<b>4.6</b>	<b>6.5</b>	<b>7.6</b>
<b>Net Assets</b>	<b>25.4</b>	<b>39.4</b>	<b>51.8</b>	<b>61.5</b>	<b>75.3</b>
Equity & Reserves	151.2	152.1	152.7	152.7	152.7
Retained Profits	(125.8)	(112.7)	(100.9)	(90.4)	(76.2)
<b>Shareholders' Equity</b>	<b>25.4</b>	<b>39.4</b>	<b>51.8</b>	<b>62.3</b>	<b>76.5</b>
Minorities	0.1	0.0	0.0	(0.8)	(1.2)
<b>Total Equity</b>	<b>25.4</b>	<b>39.4</b>	<b>51.8</b>	<b>61.5</b>	<b>75.3</b>

Performance Ratios	2017a	2018a	2019e	2020e	2021e
<b>ROA</b>	<b>29.2%</b>	<b>37.0%</b>	<b>25.8%</b>	<b>18.4%</b>	<b>20.1%</b>
<b>ROE</b>	<b>32.9%</b>	<b>40.8%</b>	<b>28.0%</b>	<b>20.1%</b>	<b>21.8%</b>
<b>ROIC</b>	<b>241.1%</b>	<b>527.7%</b>	<b>276.4%</b>	<b>186.3%</b>	<b>197.8%</b>
Net Debt (Cash) (\$m)	(23.8)	(36.2)	(46.0)	(55.4)	(66.5)
Net Debt/EBITDA (x)	(3.4x)	(2.8x)	(2.8x)	(3.5x)	(3.1x)
ND/(ND + Equity) (%)	(1,404.0%)	(1,125.0%)	(792.5%)	(905.8%)	(757.4%)
Interest Cover (x)	25.9x	47.9x	39.7x	32.5x	35.9x
Working Capital	1.6	2.6	4.6	4.2	6.1
Working Capital/Sales (%)	9.4%	10.2%	14.9%	11.6%	12.8%

Cashflow (\$m)	2017a	2018a	2019e	2020e	2021e
EBITDA	6.9	12.7	16.2	16.1	21.4
Net Interest	0.2	0.3	0.4	0.5	0.6
Tax	0.2	0.2	(3.7)	(4.9)	(6.5)
△ in Working Capital	2.1	(1.0)	(1.9)	0.1	(2.3)
Other	0.4	(0.5)	0.0	0.0	0.0
<b>Operating Cash Flow</b>	<b>9.9</b>	<b>11.7</b>	<b>10.9</b>	<b>11.7</b>	<b>13.1</b>
<i>Growth</i>	(296.9%)	17.9%	(6.5%)	7.3%	11.9%
Capex	(0.1)	(0.1)	(0.7)	(0.8)	(1.1)
Acquisitions	0.0	0.0	0.0	0.0	0.0
Divestments	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
<b>Investing Cash Flow</b>	<b>(0.1)</b>	<b>(0.1)</b>	<b>(0.7)</b>	<b>(0.8)</b>	<b>(1.1)</b>
Equity Raised	0.0	0.0	0.0	0.0	0.0
Dividends Paid	0.0	0.0	(1.0)	(1.0)	(1.0)
Net Borrowings	0.0	0.0	0.0	0.0	0.0
Other	0.1	0.0	0.0	0.0	0.0
<b>Financing Cash Flow</b>	<b>0.1</b>	<b>0.0</b>	<b>(1.0)</b>	<b>(1.0)</b>	<b>(1.0)</b>
FX / Non Cash Items	0.0	0.8	0.0	0.0	0.0
<b>Change in Cash</b>	<b>9.9</b>	<b>11.6</b>	<b>9.3</b>	<b>9.9</b>	<b>11.1</b>
<b>Free Cash Flow</b>	<b>9.8</b>	<b>11.6</b>	<b>10.2</b>	<b>10.9</b>	<b>12.0</b>

Cash Flow Metrics	2017a	2018a	2019e	2020e	2021e
<b>FCF/Share (\$)</b>	<b>0.21</b>	<b>0.24</b>	<b>0.21</b>	<b>0.22</b>	<b>0.25</b>
Price/FCPS (x)	150.0x	127.4x	146.4x	139.1x	125.9x
Free Cash Flow Yield (%)	0.7%	0.8%	0.7%	0.7%	0.8%
Gross Cash Conversion	139.4%	88.4%	85.5%	102.5%	86.7%
Capex/Sales (%)	0.4%	0.3%	2.3%	2.3%	2.3%
Capex/Depreciation (x)	1.3x	1.7x	9.6x	4.5x	3.5x

Margins	2017a	2018a	2019e	2020e	2021e
<b>EBITDA</b>	<b>41.3%</b>	<b>49.9%</b>	<b>52.8%</b>	<b>43.7%</b>	<b>44.4%</b>
<b>EBIT</b>	<b>41.0%</b>	<b>49.7%</b>	<b>52.6%</b>	<b>43.2%</b>	<b>43.8%</b>
<b>NPAT</b>	<b>42.5%</b>	<b>51.9%</b>	<b>41.7%</b>	<b>31.2%</b>	<b>31.5%</b>
<b>Valuation Methodology</b>					
WACC (%)					10.2%
Discounted Cash Flow Valuation					n/a
Sum-of-the-Parts Valuation					n/a
Average Valuation					26.43
<b>12 Mth Target Price</b>					<b>26.43</b>

Source: Company data, IRESS, Moelis Australia research estimates

4-Jun-19

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#### Distribution of Ratings as at 4 June 2019

SELL	HOLD	BUY
9.8%	36.1%	54.1%

## Rating and Price Target History: Clinuvel Pharmaceuticals Ltd (CUV) as of 3/06/2019



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