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Clinuvel gets US FDA ok

Company/ASX Code	Clinuvel Pharmaceuticals Limited/CUV
AGM date	Wednesday, 20 November 2019
Time and location	The Events Centre, Collins Square Melbourne
Registry	Computershare
Webcast	No
Poll or show of hands	Poll on all items
Monitor	Claudio Esposito
Pre AGM Meeting?	Yes, with CFO Darren Keamy and Investor Relations manager Malcolm Bull

Financial performance

Clinuvel Pharmaceuticals is a biopharmaceutical company that manufactures and distributes therapies for patients with serious rare skin pigmentation disorders, such as Porphyria. The company has only just finished developing and distributing its first and only flagship therapy over the last two years.

There are several different subtypes of porphyria but the one Clinuvel has had success with is called Erythropoietic Protoporphyria or EPP. The condition is a rare genetically inherited one where patients lack an important enzyme that prevents the accumulation of a substance within the tissues called Protoporphyrin IX or PPIX. In the presence of light from the sun, PPIX triggers a cascade of cell damage causing enormous pain and full body swelling affecting patients' lives in personal and professional settings.

Prior to Clinuvel, the condition could only be managed symptomatically by conventional means. The same technology is at early stage development in the application to the far more common skin pigmentation problem of blotchy white patches on the skin surface. The company listed in 2001 with the therapy being used to assist users in tanning process. After ongoing setbacks by the US Food and Drug Administration (FDA), in 2005 Clinuvel appointed a new CEO who changed the business model from an aesthetic lifestyle drug to the clinical therapeutic one used today. Called 'Scenesse', the therapy is administered by implant and helps the body produce its own melanin protecting the skin of affected patients from the sun's UV rays.

In 2014 the drug was approved by the European Commission for marketing authorisation and in the US this year in October. The company's revenues post EU authorisation started showing significant growth in 2017 generating $17m, 10 times more than the prior year. This year the revenues have grown to $32.5m (FY17 $26.2m) with a Net Profit after tax of $18.1m (FY18 $13.2m)

In early January 2018 the share price stood at around $8. By the second week of October this year, it had risen to $45 off the back of FDA approval in the US. For FY2019, revenues earned were $18m.The company declared a final dividend for the of 2.5c per share for second time in its history and with no debt and growing revenues from new regional authorisation, the company has shown remarkable resilience and financial discipline and appears poised for further success. ASA will be

monitoring Clinuvel for the first time this year as Clinuvel's market capitalisation had risen to $1.5b in line with the release of its therapy in the EU and now in the US.

Key events

After the end of the Financial year Clinuvel achieved a milestone in FDA approval in the USA. At this stage pricing and reimbursement details are still in negotiation but assuming a similar outcome to Europe, this may reignite sales considerably.

Key Board or senior management changes

This year, long serving Chair Stan McLiesh announced his retirement and will be stepping down after 17 years. Current non-executive director (NED) and chair of remuneration Willem Blijdorp will assume the role at the end of November this year.

ASA focus issues

During the Pre-AGM meeting, ASA discussed our focus issues and made some clarifications with management. Overall, we were comfortable with Clinuvel's governance policies but there were areas that were quite different from most typical companies within the S&P/ASX200 Index. We understand that companies that have only recently become profitable and have been going through a high growth phase may not have all the governance attributes we are accustomed to seeing.

Clinuvel's remuneration structure for example is not centred on financial metrics but rather clinical outcomes and accomplishments. Such outcomes are strong lead indicators for future revenue that will be later be replaced by the normal financial governing metrics. They have a strong policy supporting having a meaningful shareholding within the company, however director independence is not a major focal point for Clinuvel. Clinuvel has received $95m over the past 20 years by issuing capital seven times by private placement. This is not congruent with ASA guidelines, but the company argues that it is a comparatively low number of placements and could not be achieved as successfully relying on retail contribution particularly at the early stages of therapeutic development.

Summary

(As at FYE)	2019	2018	2017	2016	2015
NPAT ($m)	18.0	12.7	7.1	(2.9)	(10.7)
UPAT ($m)	18.1	13.2	7.1	(3.2)	(10.4)
Share price ($)	33.66	10.99	6.60	4.32	2.84
Dividend (cents)	2.5	2.0	-----	-----	-----
TSR (%)	234	67	53	52	40
Basic EPS (cents)	37.6	27.7	14.9	(7.0)	(24.0)
CEO total remuneration, actual ($m)	1.3	2.1	1.3	1.2	1.2

For the 2019 financial year, the CEO's total actual remuneration was **15 times** the Australian Full time Adult Average Weekly Total Earnings (based on May 2019 data from the Australian Bureau of Statistics).

Resolution 1	**Adoption of Remuneration Report**
ASA Vote	**For**

Key Management Personnel are paid a combination of cash and equity and the long-term equity value is determined using fair value. The calculation for fair value is based on the Binomial pricing model which discounts the value of shares granted to Key executives. This system is used as a way of compensating executives for the risk taken due to prolonged vesting periods and market volatility. The last rights that were issued was September 5th, 2017 and were priced at $4.20, which translates to 60% of its market value.

The structure of remuneration is consists of base salary, a short term incentive which is cash based and can be paid up to 100% of base pay and a long term incentive consisting of cash from Business Generation Incentives (BGIs), Performance Rights to encourage shareholding and discretionary payments to the CEO in instances where extraordinary performance has been achieved outside objectives set out in the short term and long term framework.

It has however been stated in the Notice of Meeting that Long term cash incentives will be phased out this year with Performance rights replacing cash based BGI's for all key executive management.

Non-executive remuneration structure consists of a $550,000 pool with only two NEDs who still have performance rights from previous years. The current chair fee stands at $110,000 and $65,000 for NEDs. Historically it was expected that NEDs would engage in executive activity given the small size of the company and management team so shareholders agreed to have NEDs

interests aligned in the same way. This year the board will seek to approve an increase to the current fee pool.

For the 2019 financial year 2019 (FY19) Philippe Wolgen's remuneration will consist of $893,660. He had 47% of his base salary paid as a cash short term incentive and no business generating Incentives or performance rights were paid. Mr Wolgen will be paid in Singaporean currency due to his place of residence outside Australia.

Resolution 2	**Re-election of Mrs Brenda Shanahan**
ASA Vote	**For**

Summary of ASA Position

Mrs Brenda Shanahan was elected to the board of Clinuvel in 2007 and shortly after assumed role of Chair for two and a half years. Her primary financial background is in asset management but she also has extensive experience in a hospital research senior advisory role. She is highly valued by the Clinuvel group but this financial year, Mrs Shanahan will be completing her 13th year as a NED. Under ASA guidelines, directors who have held a seat for more than 12 years are not considered independent, but the board is in a renewal phase and we are supporting Mrs Shanahan's corporate knowledge and skills in voting for her re-election.

Resolution 3	**Re-election of Mrs Susan Smith**
ASA Vote	**For**

Summary of ASA Position

Mrs Susan Smith was elected to the board in 2018. She has extensive experience managing hospitals at an executive level having been CEO of various hospitals in London and is well versed in advising boards on medical matters. Mrs Smith also has several advisory roles in specialised clinical practices in London. We see Mrs Smith as a good fit for Clinuvel.

Resolution 4	**Approval of grant of performance right to a related party: CEO Dr Philippe Wolgen**
ASA Vote	**For**

Summary of ASA Position

The board seeks approval by shareholders to issue Mr Wolgen with 1,513,750 Performance Rights under the terms of Clinuvel's executive remuneration plan for FY19. The Rights will also have a vesting period of a maximum of four years subject to meeting the conditions outlined in 'Schedule- A' in the Notice of Meeting. The board determined Mr Wolgen's Performance rights issue by setting a market capitalisation target of $7.5 billion ($146.72 per share) compared with its current value of $1.5 billion ($30.5 per share). It was then determined that if this achievement were to materialise that it would be worth 3.71% of the company's appreciated value. The company view this target as highly ambitious and unlikely given the nature of the business. The board sees this target as a way of keeping the CEO focused of future objectives and encourages him to see out the four year period.

Resolution 5	**Increase Non-Executive Director's Fee pool**
ASA Vote	**For**

Summary of ASA Position

The board seeks approval by shareholders to increase the Non-Executive directors' fee pool to $700,000. It currently stands at $550,000 and was approved in 2015. The fee increase will allow the company to add more directors and pay increases in the future.

The individual involved in the preparation of this voting intention has no a shareholding in this company.