ABN·AMRO

Wednesday 12 March 2008

Clinuvel Pharmaceuticals

CUV receives EU Orphan Drug status

CUV1647 has been granted two OMP designations in the EU. This sends a strong signal of the medical necessity of CUV's product. This news should be taken into account by US authorities when they make their OMP decision, most likely in 2010. Buy.

Key forecasts

	FY06A	FY07A	FY08F	FY09F	FY10F
EBITDA (A$m)	-10.3	-10.6	-15.4	-12.3	-3.22
Reported net profit (A$m)	-10.8	-9.18	-14.2	-12.2	-3.66
Normalised net profit (A$m)[1]	-10.8	-9.18	-13.5	-12.2	-3.66
Normalised EPS (c)[1]	-6.87	-3.70	-4.48	-4.05	-1.21
Normalised EPS growth (%)	-42.9	-46.2	21.3	-9.66	-70.1
Dividend per share (c)	0.00	0.00	0.00	0.00	0.00
Dividend yield (%)	0.00	0.00	0.00	0.00	0.00
Normalised PE (x)	n/m	n/m	n/m	n/m	n/m
EV/EBITDA (x)	n/m	n/m	n/m	n/m	n/m
Price/net oper. CF (x)	-4.54	-10.0	-8.13	-9.21	-47.4
ROIC (%)	-291.7	-148.4	-36.2	-30.1	-9.85

1. Pre-goodwill amortisation and exceptional items ***year to Jun, fully diluted***
Accounting Standard: IFRS
Source: Company data, ABN AMRO forecasts

OMP are designed to address unmet medical needs

Orphan Medicinal Products (OMP) are intended to prevent or treat conditions that are rare. The CUV EU OMP designation was granted for two diseases, namely: 1) Erythropoietic Porphyria (EPP) - absolute sun allergy; and 2) Congenital Erythropoietic Porphyria (CEP) - a congenital form of absolute sun allergy.

OMP status sends a signal of the medical necessity of CUV's product

The OMP designation has a number of benefits, including: 1) access to the EU's centralised approval procedures; 2) scientific advice during the product development phase, and 3) a 10-year marketing exclusivity in the EU. Subject to successful completion of the current Phase III EPP trial due in 2009, CUV will seek EMEA marketing authorisation for CUV1647 for EPP. This would be the final regulatory step before the start of sales in the EU.

EU decision should be taken into account by US for its OMP decision

We believe any EU decision on OMP is generally taken into account by US authorities when they make their OMP decisions. While the EU decision is a strong signal of the medical necessity of CUV's product, we believe CU1647's US decision is even more important as we believe the largest potential market for CUV1647 is the US. Should the CUV gain a positive US OMP decision (most likely for EPP), we continue to believe that, over time, there will be the development of a large off-label use of CUV1647 for: 1) Polymorphous light eruption (PMLE - market size up to 100m); and 2) Cosmesis - this is because one of the effects of treatment is the development of a suntan without the dangers of sun exposure. Due to the current focus of CUV on the on-label uses for CUV1647, we don't currently value its potential off-label use, but believe it could lead to material potential upside to our forecasts.

Buy maintained, price target A$1.00

We believe this news is significant, in that it highlights the change in strategy to make CUV1647 a medically necessary product. Given the near-term potential cash flow, we believe CUV warrants a premium compared to many other biotechs.

Important disclosures can be found in the Disclosures Appendix.
Priced at close of business 11 March 2008.

ABN AMRO Equities Australia Ltd, ABN 84 002 768 701, AFS Licence 240530
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Produced by: ABN AMRO Equities Australia Ltd

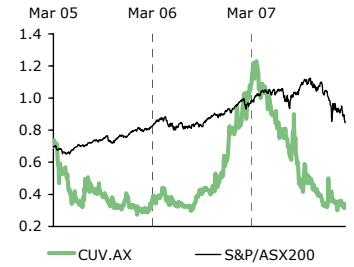
Buy

Absolute performance
n/a
Short term (0-60 days)

Pharmaceuticals & Biotechnology
Australia

Price
A$0.33
Target price
A$1.00
Market capitalisation
A$99.71m (US$92.20m)
Avg (12mth) daily turnover
A$0.36m (US$0.30m)
Reuters CUV.AX **Bloomberg** CUV AU

Price performance	(1M)	(3M)	(12M)
Price (A$)	0.3	0.4	1.0
Absolute %	10.0	-9.6	-68.0
Rel market %	18.6	17.6	-63.6
Rel sector %	11.6	-0.3	-63.0



Stock borrowing: Easy onshore, Hard offshore
Volatility (30-day): 65.6%
Volatility (6-month trend): ↓
52-week range: 1.40-0.30
S&P/ASX200: 5134.20
BBG AP Pharm & Biotech: 146.51

Source: ABN AMRO, Bloomberg

Analysts

Dr David Stanton

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CUV gains Orphan Drug status in the EU

CUV1647 has been granted two Orphan Medicinal Product (OMP) designations in the EU. This sends a strong signal of the medical necessity of CUV's product. This news should be taken into account by US authorities when they make their OMP decision, most likely in 2010.

US OMP designation

In the US, an orphan drug is any drug developed under the Orphan Drug Act (ODA) of January 1983, a federal law concerning rare diseases ('orphan diseases'), defined as diseases affecting fewer than 200,000 people in the US, or low prevalence, taken as prevalence of less than five per 10,000 in the community. Because medical research and the development of drugs to treat such diseases is financially disadvantageous, companies that do so are rewarded with tax reductions and marketing exclusivity on that drug for an extended time (seven years post-approval). The concept behind the ODA is that the longer period of exclusivity will encourage more companies to invest money in research. Should CUV1647 prove advantageous in the treatment of EPP, CUV will receive seven years of marketing exclusivity for its product to treat this disease.

Analysis of market segments

We believe there are a number of potential market segments for CUV1647 should it get to market. These include markets based on the treatment of sun allergy diseases by doctors and, subsequently, a market based on cosmetic therapy, as CUV1647 provides a sunless tan. Below we analyse each of these markets in turn. Using various scientific research studies, we have calculated the market size of the total on-label indications for CUV1647. By our estimates, the size for the four markets we have characterised is more than 100m in the EU and US alone. We believe the majority of the patients in these markets would require treatment once or twice a year.

Table 1 : Market size EU and US – on label use of CUV1647

Disease	Prevalence in population	Implied no. patients EU & US (000)
Polymorphous light eruption (PMLE)	1 in 7.8	116,691
Solar urticaria	3.1 in 100,000	24
Side effects of photodynamic therapy (PDT)	1 in 3,050	257
Erythropoietic protoporphyria (EPP)	1 in 350,000	2.2
	Total	**116,974**

Source: ABN AMRO estimates, PubMed

1. PMLE

We believe the PMLE market will be centred on doctors. This is due to the requirement for CUV1647 to be administered as a depot injection, which is generally performed by doctors.

Discussions with industry contacts suggest that PMLE is not a widely recognised disease at the GP level. At least initially we believe the diagnosis and subsequent depot injection will be performed at the specialist level. Should awareness of the product increase, we believe the diagnosis and treatment of PMLE could be made at the GP level.

However, for both patients and GPs to be made aware of PMLE as a clinical entity, we believe there needs to be an education campaign aimed at both potential patients

and GPs. This would have the effect of increasing the awareness of PMLE and other sun allergy diseases as clinical entity. Given the cost of a large marketing campaign, we believe CUV may ultimately co-ordinate a marketing campaign through a global partner, who may take a share of royalties.

2. Side-effects of photodynamic therapy (PDT)

Using various scientific research studies, we have estimated the potential market size for side-effects of photodynamic therapy (PDT). We have looked at the prevalence of the major uses of photodynamic therapy, namely in the treatment of non-small cell lung cancer, Barrett's oesophagus and oesophageal cancer. We have then analysed the literature to determine the use of PDT in these diseases. The literature suggests that the rate of sun-allergy-related side effects is in the order of 31%, so these patients would benefit from treatment with CUV1647. This is shown below. By our estimates, more than 250,000 people would benefit from the CUV1647 treatment to decrease the side-effects of PDT.

Table 2 : Potential market size for side effects of Photodynamic therapy (PDT)

	Prevalence in population	Implied no. patients EU & US (000)	Use of PDT	Prevalence of side effects	Potential number of patients (000)
Non-small cell lung cancer	1 in 2000	393	10%	31%	12
Barrett's oesophagus	1 in 100	7,850	10%	31%	243
Oesophageal cancer	1 in 10000	79	5%	31%	1
				Total	**257**

Source: ABN AMRO estimates, PubMed, UN data

3. Erythropoietic protoporphyria (EPP)

Erythropoietic protoporphyria is a rare genetic disorder due to a defect in red blood cell production. The resultant accumulated excess of its breakdown product, protoporphyrin, causes two principal manifestations: a skin sensitivity to light and liver disease. There is no registry for erythropoietic protoporphyria for the US, and therefore accurate data is lacking. However, internationally, an estimated one case in 200-750,000 people has been reported for some western European populations. By our estimates, c2,200 suffers in the US and EU would benefit from CUV1647 treatment for erythropoietic protoporphyria.

4. Cosmetic market – off-label use

Over the longer term, we believe there is a strong chance of an off-label cosmetic market being developed for CUV1647. This is because one of the effects of treatment is the development of a suntan without being in the sun. We believe this desirable among some sectors of the community, and is only increasing. For instance, there has been a 319% increase in the number of Yellow Pages 'solarium' listings in Australian capital cities in the past decade. This is shown below, and suggests to us that a product that promises a tan without the risk of skin cancer would be attractive to some members of the community.

Table 3 : Solarium/tanning centre Yellow Pages listings by Aust capital city

State	Number listed in 1996	Number listed in 2006	% increase since 1996
Melbourne	25	169	576%
Perth	5	55	1000%
Canberra	4	21	425%
Adelaide	12	39	225%
Brisbane	15	47	213%
Sydney	29	63	117%
Hobart	7	12	71%
Northern Territory	0	0	na
All capital cities	**97**	**406**	**319%**

Source: ABN AMRO, Victorian Cancer Council

By our estimates, if we assume one in 100 individuals would be willing to use CUV1647 instead of attending a tanning salon, the market size for the off-label tanning market that we have been able to characterise would be in the order of more than 7.8m in the EU and US alone.

Table 4 : Market size EU and US – off label use of CUV1647

Type of use of CUV1647	Reason for use	Prevalence in population	Implied no. patients EU & US (000)
Off-label use	Tanning	1 in 100	7,850

Source: ABN AMRO estimates

In addition, we believe the off-label use of CUV1647 is only likely to increase, as the link between tanning and skin cancer becomes more apparent and better publicised.

Buy recommendation maintained; price target A$1.00

We believe this news is significant, in that is highlights the change in strategy of management to make CUV1647 a medically necessary product. We use DCF valuation to derive our valuation and target price for CUV. Our valuation for CUV remains A$1.00 per share.

Upside risks include the faster-than-expected progression to production of CUV's photo-protective technology, while downside risks include any delay or failure to progress clinical trials. On an industry-wide basis, the chances of getting a product to market from the Phase III stage are in the order of 70%. CUV management will need to balance the use of funds to progress a number of projects through regulatory pathways against the increased cash flow that this would entail. Hence, we believe CUV is an investment opportunity for investors with a higher risk appetite.

CUV – financial summary

Year to 30 Jun (A$m)	AIFRS	AIFRS	AIFRS	AIFRS	AIFRS
Income statement	**2005A**	**2006A**	**2007F**	**2008F**	**2009F**
Divisional sales	0.0	0.0	0.0	0.0	0.0
Total revenue	0.1	0.8	0.3	0.4	0.5
EBITDA	-11.6	-10.3	-10.6	-15.4	-12.3
Associate income	0.0	0.0	0.0	0.0	0.0
Depreciation/Amortisation	-0.8	-0.9	-0.8	-0.9	-0.9
EBITA	-12.4	-11.2	-11.4	-16.3	-13.2
Goodwill Amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	-12.4	-11.2	-11.4	-16.3	-13.2
EBIT(incl associate profit)	-12.4	-11.2	-11.4	-16.3	-13.2
Net interest expense	0.5	0.4	2.2	2.8	0.9
Pre-tax profit	-12.0	-10.8	-9.2	-13.5	-12.2
Income tax expense	0.0	0.0	0.0	0.0	0.0
After-tax profit	-12.0	-10.8	-9.2	-13.5	-12.2
Minority interests	0.0	0.0	0.0	0.0	0.0
NPAT pre significant items	-12.0	-10.8	-9.2	-13.5	-12.2
Significant items	0.0	0.0	0.0	-0.7	0.0
Reported NPAT	-12.0	-10.8	-9.2	-14.2	-12.2
Cash flow statement	**2005A**	**2006A**	**2007F**	**2008F**	**2009F**
EBITDA	-11.6	-10.3	-10.6	-15.4	-12.3
Change in working capital	0.0	0.0	0.0	0.4	0.5
Net interest (pd)/rec	0.5	0.4	2.0	2.8	0.9
Taxes paid	0.5	0.5	0.4	0.0	0.0
Other oper cash items	1.4	-2.0	0.0	0.0	0.0
Cash flow from ops (1)	-9.2	-11.4	-8.2	-12.3	-10.8
Capex (2)	-0.2	0.0	-0.2	-0.1	-0.2
Disposals/(acquisitions)	-0.9	-2.3	-26.7	-0.3	-0.3
Other investing cash flow	0.0	0.0	0.4	0.0	0.0
Cash flow from invest (3)	-1.1	-2.4	-26.5	-0.4	-0.4
Incr/(decr) in equity	10.2	18.3	60.0	0.0	0.0
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	-0.5	-0.7	0.0	0.0	0.0
Cash flow from fin (5)	9.6	17.6	60.0	0.0	0.0
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0
Inc/(decr) cash (1+3+5+6)	-0.7	3.8	25.4	-12.7	-11.2
Equity FCF (1+2+4)	-9.4	-11.4	-8.4	-12.4	-11.0
Balance sheet	**2005A**	**2006A**	**2007F**	**2008F**	**2009F**
Cash & deposits	4.8	8.6	33.8	21.2	9.9
Trade debtors	0.1	0.2	0.2	0.3	0.3
Inventory	0.0	0.6	0.0	0.0	0.0
Investments	0.0	0.0	0.0	0.0	0.0
Goodwill	0.0	0.0	0.0	0.0	0.0
Other intangible assets	4.6	2.9	2.2	1.6	1.1
Fixed assets	0.2	0.2	0.3	0.4	0.5
Other assets	0.3	4.5	31.2	31.2	31.2
Total assets	10.1	17.1	67.8	54.7	43.1
Short-term borrowings	0.0	0.0	0.0	0.0	0.0
Trade payables	2.5	3.0	2.3	2.8	3.3
Long-term borrowings	0.0	0.0	0.0	0.0	0.0
Provisions	0.0	0.0	0.0	0.0	0.0
Other liabilities	0.1	0.1	0.1	0.1	0.1
Total liabilities	2.6	3.1	2.4	2.9	3.5
Preference shares					
Hybrid equity					
Share capital	35.1	52.7	112.8	112.8	112.8
Other reserves	1.5	1.2	1.6	1.6	1.6
Retained earnings	-29.2	-39.9	-49.1	-62.6	-74.8
Other equity	0.0	0.0	0.0	0.0	0.0
Total equity	7.5	14.0	65.4	51.8	39.6
Minority interest	0.0	0.0	0.0	0.0	0.0
Total shareholders' equity	7.5	14.0	65.4	51.8	39.6
Total liabilities & SE	10.1	17.1	67.8	54.7	43.1

Closing price (A$)	**0.33**	**Price target (A$)**	**1.00**
Valuation metrics			
Preferred methodology	DCF	Val'n (A$)	$ 1.06
DCF valuation inputs			
Rf	6.25%	10-year rate	6.25%
Rm-Rf	4.50%	Margin	2.0%
Beta	1.50	Kd	8.25%
CAPM (Rf+Beta(Rm-Rf))	13.0%	Ke	13.0%
E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A$m)	255.5
Equity (E/EV)	100.0%	Minority interest (A$m)	0.0
Debt (D/EV)	0.0%	Net debt (A$m)	-8.6
Interest rate	8.25%	Investments (A$m)	0.0
Tax rate (t)	30.0%	Equity market value (A$m)	264.1
WACC	13.0%	Diluted no. of shares (m)	248.2
		DCF valuation (A$)	**1.06**

Multiples	**2006A**	**2007F**	**2008F**	**2009F**
Enterprise value (A$m)	91.1	65.9	78.5	89.8
EV/Sales (x)				
EV/EBITDA (x)	-8.8	-6.2	-5.1	-7.3
EV/EBIT (x)	-8.1	-5.8	-4.8	-6.8
PE (normalised) (x)	-4.8	-8.9	-7.4	-8.1
PEG (normalised) (x)				

At target price	**2006A**	**2007F**	**2008F**	**2009F**
EV/EBITDA (x)	-28.5	-25.3	-18.2	-23.8
PE (normalised) (x)	-14.6	-27.1	-22.3	-24.7

Comparable company data (x)		**2007F**	**2008F**	**2009F**
Alchemia	EV/EBITDA	-4.1	-4.1	-33.0
Year to 30 Jun	EV/EBIT	-3.5	-3.6	-14.1
	PE	-3.9	-4.4	-20.2
	PEG	-1.1	-1.3	-5.8
Mesoblast	EV/EBITDA	-9.2	-9.6	-7.7
Year to 30 Jun	EV/EBIT	-9.2	-9.5	-7.6
	PE	-9.6	-8.5	-8.5
	PEG			

Per share data	**2006A**	**2007F**	**2008F**	**2009F**
No. shares	185.0	302.1	302.1	302.1
EPS (cps)	-6.9	-3.7	-4.7	-4.0
EPS (normalised) (c)	-6.9	-3.7	-4.5	-4.0
Dividend per share (c)	0.0	0.0	0.0	0.0
Dividend payout ratio (%)	0.0	0.0	0.0	0.0
Dividend yield (%)	0.0	0.0	0.0	0.0

Growth ratios	**2006A**	**2007F**	**2008F**	**2009F**
Sales growth	na	na	na	na
Operating cost growth	-11.3%	2.8%	45.7%	-20.5%
EBITDA growth	-11.3%	2.8%	45.7%	-20.5%
EBIT growth	-9.8%	1.8%	42.7%	-19.2%
Norm. NPAT growth	-10.0%	-14.8%	47.6%	-9.7%
Norm. EPS growth	-42.9%	-46.2%	21.3%	-9.7%

Operating performance	**2006A**	**2007F**	**2008F**	**2009F**
Asset turnover (%)	0.0	0.0	0.0	0.0
EBITDA margin (%)	na	na	na	na
EBIT margin (%)	na	na	na	na
Net profit margin (%)	na	na	na	na
Return on net assets (%)	-80.2	-17.5	-31.4	-33.2
Net debt (A$m)	-8.6	-33.8	-21.2	-9.9
Net debt/equity (%)	-61.5	-51.8	-40.8	-25.1
Net interest/EBIT cover (x)	25.1	5.1	5.9	14.1
ROIC (%)	-291.7	-148.4	-36.2	-30.1

Internal liquidity	**2006A**	**2007F**	**2008F**	**2009F**
Current ratio (x)	4.5	26.9	18.2	12.0
Receivables turnover (x)	na	0.0	0.0	0.0
Payables turnover (x)	na	4.0	6.1	4.0

Source: Company data, ABN AMRO estimates

DISCLOSURES APPENDIX

Recommendation structure

Absolute performance, short term (trading) recommendation: A Trading Buy recommendation implies upside of 5% or more and a Trading Sell indicates downside of 5% or more. The trading recommendation time horizon is 0-60 days. For Australian coverage, a Trading Buy recommendation implies upside of 5% or more from the suggested entry price range, and a Trading Sell recommendation implies downside of 5% or more from the suggested entry price range. The trading recommendation time horizon is 0-60 days.

Absolute performance, long term (fundamental) recommendation: The recommendation is based on implied upside/downside for the stock from the target price. A Buy/Sell implies upside/downside of 10% or more and a Hold less than 10%. For listed property trusts (LPT) or real estate investment trusts (REIT) the recommendation is based upon the target price plus the dividend yield, ie total return. This structure applies to research on Asian and European stocks published from 1 November 2005; on Australian stocks from 7 November 2006; on continental European small and mid cap stocks from 23 November 2006; and on Brazilian stocks from 18 June 2007.

Performance parameters and horizon: Given the volatility of share prices and our pre-disposition not to change recommendations frequently, these performance parameters should be interpreted flexibly. Performance in this context only reflects capital appreciation and the horizon is 12 months.

Sector relative to market: The sector view relative to the market is the responsibility of the strategy team. Overweight/Underweight implies upside/downside of 10% or more and Neutral implies less than 10% upside/downside.

Target price: The target price is the level the stock should currently trade at if the market were to accept the analyst's view of the stock and if the necessary catalysts were in place to effect this change in perception within the performance horizon. In this way, therefore, the target price abstracts from the need to take a view on the market or sector. If it is felt that the catalysts are not fully in place to effect a re-rating of the stock to its warranted value, the target price will differ from 'fair' value.

Asset allocation: The asset allocation is the responsibility of the economics team. The recommended weight (Over, Neutral and Under) for equities, cash and bonds is based on a number of metrics and does not relate to a particular size change in one variable.

Stock borrowing rating: The stock borrowing rating is the subjective view and responsibility of the ABN AMRO equity finance team: Easy implies ready availability. Moderate implies some availability. Hard implies availability is tight. Impossible implies no availability.

Distribution of recommendations

The tables below show the distribution of ABN AMRO's recommendations (both long term and trading). The first column displays the distribution of recommendations globally and the second column shows the distribution for the region. Numbers in brackets show the percentage for each category where ABN AMRO has an investment banking relationship.

Long Term recommendations (as at 12 Mar 2008)

	Global total (IB%)	Asia Pacific total (IB%)
Buy	608 (15)	393 (3)
Add	0 (0)	0 (0)
Hold	418 (18)	249 (5)
Reduce	0 (0)	0 (0)
Sell	76 (12)	48 (6)
Total (IB%)	**1102 (16)**	**690 (4)**

Trading recommendations (as at 12 Mar 2008)

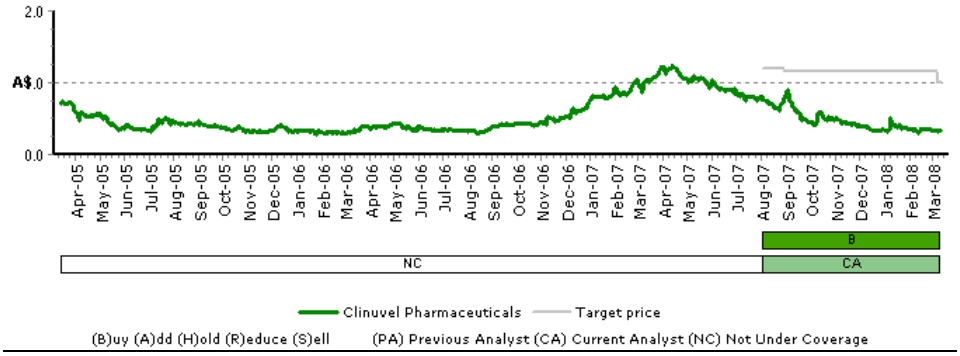
	Global total (IB%)	Asia Pacific total (IB%)
Trading Buy	4 (0)	3 (0)
Trading Sell	0 (0)	0 (0)
Total (IB%)	**4 (0)**	**3 (0)**

Valuation and risks to target price

Clinuvel Pharmaceuticals (RIC: CUV.AX, Rec: Buy, CP: A$0.330, TP: A$1.00): Our valuation of CUV is based on a discounted cash flow model, from which we derive our target price. Upside risks include the faster-than-expected progression to production of CUV's anti-skin allergy technology, while downside risks include any delay or failure to progress clinical trials.

Clinuvel Pharmaceuticals

Stock performance, recommendations and coverage (as at 11 Mar 2008)



Dr David Stanton started covering this stock on 2 Aug 07
New recommendation structure from 7 November 2005

Trading recommendation history (as at 12 Mar 2008)

Date	Rec	Analyst
	n/a	

Regulatory disclosures

Subject companies: **CUV.AX**

DISCLOSURES APPENDIX

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