

Change in recommendation

Netherlands

Crucell

Discounting vaccine success

Pharmaceuticals

03/08/05

€18.45

Crucell has risen over 60% since the start of 2005 and is now trading at a 65% premium to our fair value. The current share price in our view now discounts a successful launch of Crucell's three most advanced vaccines. SELL.

We believe the Crucell share price has been driven by momentum investors investing largely on the back of Crucell's potential ability to provide solutions to 'bioterrorism' and pandemic flu threats. While none of Crucell's vaccines are yet in the clinic we would argue that the current share price is already discounting successful launch and combined peak sales of over US\$1.5bn for the three most advanced products, ie, the PER.C6 flu, West Nile and Ebola vaccines.

We believe that hopes for Crucell's STAR technology have also driven the stock to recent highs but that expectations have now spun out of control. While technology that would improve predictability, yield and stability of protein expression would undoubtedly be of considerable value, the road to commercialisation for STAR remains unclear.

While we increase our target price from €10.8 to €11.2, largely to include the STAR technology, and based on our NPV methodology, with the stock now trading at a 65% premium to this, we downgrade our recommendation from Hold to **SELL** on valuation grounds.

Forecasts and ratios

Yr to Dec	Turn over (€m)	Net profit (€m)	Prev EPS (€)	New EPS (€)	Div (€)	PER (x)	EV/ EBITDA (x)	Yield (%)
2004	22.6	(21.6)	(0.6)	(0.6)	0.00	N/M	N/M	0.0
2005F	31.6	(20.5)	(0.5)	(0.5)	0.00	N/M	N/M	0.0
2006F	39.4	(25.3)	(0.6)	(0.6)	0.00	N/M	N/M	0.0
2007F*	123.2	10.3	(0.6)	0.2	0.00	75.0	44.5	0.0

Source: Company data, ING estimates. * Now includes assumed US\$90m Ebola contract award.

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FTSE E300: 1,160.63

AEX All Share: 392.88

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Previously: Hold

Sell

4 August 2005

Target price: 12 month

€11.20

Reuters

CRCLAS

Key ratios

	2004	2005F
Revenue	22.6	31.6
Operating profit	(22.8)	(22.2)
Net loss	(21.4)	(20.5)
Cash	76.7	115.3

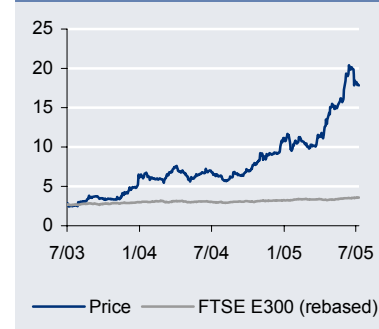
Performance (%)

	12m	3m	Target
Absolute (%)	173.4	60.8	(39.0)
FTSE E300	971.5	1,064.6	
AEX All Share	328.8	355.9	
Relative to (%)			
FTSE E300	128.8	47.5	
AEX All Share	128.7	45.7	

Share data

No. of shares (m)	40.8
Volume	475,716
Free float (%)	97.0
Market cap (€m)	753
Enterprise value (€m)	633

Share price performance



Source: ING

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Discounting vaccine success

Share price assumes significant success

Crucell's share price could be significantly impacted by any disappointments

Crucell has seen its shares rise by over 65% since the start of 2005. We believe this has been driven by momentum investors investing largely on the back of the 'fear' factor and Crucell's potential ability to provide solutions to 'bioterrorism' and pandemic flu threats. In addition, most recently we believe hopes that Crucell's STAR technology could provide short-term solutions to manufacturing and pricing issues surrounding biologic therapies have driven the stock to recent highs.

While none of Crucell's vaccines are yet in the clinic we would argue that the current share price is already discounting successful approval and launch of the three most advanced, ie, the PER.C6 flu, West Nile and Ebola vaccines. Thus, we would caution that any disappointments or delays associated with the development of these vaccines could have a significant impact on the share price. While the West Nile programme is under Crucell's control the Ebola and flu vaccine are not.

In addition, we believe expectations for the STAR technology have spun out of control. While technology that would improve predictability, yield and stability of protein expression would undoubtedly be of considerable value, the road to commercialisation for STAR remains unclear. Thus, while we have now incorporated the technology into our valuation we remain cautious on the prospects for it making a significant contribution to the value of the business in the short term.

Largely reflecting the incorporation of STAR into our valuation we have increased our NPV valuation from €10.8 to €11.2. Most stocks in our universe trade at a significant discount to NPV fair value. In contrast, Crucell has for some time traded at a premium. Although a small premium relative to other unprofitable companies could, we believe, be argued due to Crucell's significant and growing revenue stream and the lower-risk nature of the vaccines it is developing versus novel drug development, the current 60% premium to NPV cannot be justified in our view. While we acknowledge the progress made by management in the past two years, we downgrade our recommendation from Hold to **SELL** on valuation grounds.

What is STAR worth?

STAR, while exciting, is still being assessed for its commercial feasibility

Crucell acquired the STAR technology in its March 2004 acquisition of Chromagenics. Crucell paid around €4m as an upfront cash payment. In January 2005 Crucell announced that Genentech was evaluating the STAR technology for the production of antibodies and other proteins. The first phase of the evaluation, which Genentech is funding, looked at production yields in screening assays. Based on these results, Genentech decided to enter into a second phase, which will test the effectiveness of STAR under scaled-down production conditions. Thus, Genentech's evaluation will be key in determining the potential utility of this technology. If the evaluation proves successful, Genentech has an option to sign a non-exclusive STAR licence agreement. We believe this could result in a €5-10m upfront. In addition, it would likely lead to further licensing deals.

STAR technology is a technology that could prove useful for the production of recombinant human antibodies and proteins. It has a potentially broad application including for production of antibodies and proteins on mammalian cell lines such as

Crucell's PER.C6 human cell technology and the widely used Chinese hamster ovary (CHO) cell line. STAR technology contains genetic elements, called STAR elements, that enable stable and high-yield gene expression important to recombinant antibody and protein production in mammalian cells. The technology has the potential to increase production yields, thereby reducing production costs. Early data that has been generated has suggested yields could be improved by up to 3x.

We believe the road to commercialisation for STAR will be similar to PER.C6

However, another key question regarding STAR is whether its incorporation into the production process will be seen by regulatory authorities as sufficiently 'novel' as to mean they will require complete new clinical trials rather than just the demonstration that the products are 'biosimilar'.

We believe that Crucell's share price has been partly driven by expectations that currently marketed multi-billion-dollar biologic drugs would be quickly converted to production techniques utilising STAR technology, and through royalties on sales Crucell could be generating significant revenues from the technology within the next few years.

However, at this stage (and as guided by the company) we believe it is prudent to assume that clinical trials would be required for products produced using the STAR technology and, as such, we believe companies will generally license the technology for preclinical programmes where they are having difficulty producing proteins or antibodies efficiently.

We believe the road to commercialisation will thus be similar to PER.C6. The potentially broad applicability of the STAR technology may lead to early additional licensing revenues for Crucell. However, royalties on sales may not be seen for many years.

We have therefore added the STAR technology into our valuation using the following assumptions. Assuming full clinical trials are required and using standard development timelines we estimate that first launch of a product using STAR is unlikely before 2013. Again, on the basis that full trials would be required we have assumed a 3-4% royalty could be achieved by Crucell on sales of such products.

We have then assumed every year from 2013 into perpetuity a product with sales potential of US\$500m could be launched that is produced using STAR technology. On the basis that Genentech is currently evaluating the utility of the technology we assign a 5% probability to this scenario. This leads us to add in €12.5m to our NPV fair value for the technology at this stage.

Pipeline progress critical to underpin the valuation

Flu vaccine due into clinical development shortly

HHS grant to accelerate US licensure of pandemic flu vaccine

Earlier this year Crucell announced that its partner, sanofi-aventis, had been awarded a US\$97m contract by the US Government, to accelerate the development of its PER.C6-based influenza vaccine. The contract was part of the US Government's effort to increase influenza-vaccine-manufacturing capacity in the event of a pandemic or other influenza health emergency. While we believe Sanofi will receive the vast majority of the award, Crucell will be a subcontractor for the programme and will also be reimbursed for some work already performed. We have assumed that Crucell will receive 10-20% of the contract over the next two to three years.

Flu vaccine should move into the clinic during this quarter

The next news we expect from the flu programme is confirmation that the annual vaccine will enter clinical trials during this quarter. This will mark a major milestone for the company and, once dosing has been confirmed, we would likely increase our probability of success.

In December 2004 Baxter stopped enrolment in a European Phase II/III trial of its PreFluCel influenza vaccine after seeing a rate of mild fever and associated symptoms that was higher than marketed flu vaccines. Further studies that were planned for 2005 are currently on hold while the company analyses data from the Phase II/III trial. The PreFluCel vaccine uses Baxter's VERO cell technology, which is derived from kidney cells of the African green monkey.

While we are certainly not suggesting Crucell will experience similar issues, the case illustrates that, while risks for development of such a vaccine are undoubtedly lower than compared with traditional drug development, even once the product has entered clinical trials risks remain.

Ebola vaccine under control of NIH and Army

More recently, Crucell has been awarded a US\$28m manufacturing contract (we believe on a cost-plus basis) by the US National Institutes of Health (NIH) to supply PER.C6-based Ebola vaccine. Under the terms of the contract, Crucell will manufacture up to ten batches of clinical material which will be used for Phase I and early Phase II clinical studies in humans. We expect trials to begin in 4Q05, although again this is largely out of the control of Crucell, who is developing the vaccine in collaboration with the NIH and US Army.

We continue to believe that Crucell is in a strong position to win any contracts that the US Government may award related to an Ebola vaccine. We see the main competitor as Vical.

West Nile vaccine due into the clinic before year end

Also during the fourth quarter we expect Crucell to advance its West Nile vaccine into clinical trials. Crucell is developing an inactivated whole virus vaccine in contrast to competitors developing live attenuated or DNA vaccines.

Crucell has already developed a PER.C6-based veterinary vaccine, which received market approval in June 2004 and protects against the Israel 1998 Goose strain of West Nile virus, closely related to the NY 1999 strain.

Competition

Vical has Ebola, West Nile and HIV programmes in development

DNA vaccines developed by Vical against Ebola and West Nile are currently in Phase I safety testing. Both are being developed in collaboration with the NIH. In particular, Vical believes that its Ebola programme should have completed Phase I and the compulsory two animal studies by mid-2006.

Also set to enter Phase II is a DNA vaccine against HIV, for which Vical also recently received US\$12.1m in production orders from the NIH's Vaccines Research Center. Trials are due to start next year. In addition, under an expanded 1997 deal, Merck has rights to Vical's technology for therapeutic vaccines against HIV.

Acambis has completed Phase I studies of its live attenuated West Nile vaccine

In May Acambis gave an update on its West Nile programme. Development of Acambis's investigational vaccine, ChimeriVax-West Nile, has been supported by a US\$3m grant from the NIH. Acambis is developing the ChimeriVax-West Nile vaccine

using its proprietary ChimeriVax technology, which uses a live weakened yellow fever virus to create chimeric viruses.

Acambis evaluated its vaccine in an 80-subject randomised double-blind controlled Phase I trial. In total, 30 healthy adult subjects received a single inoculation of a high dose of ChimeriVax-West Nile, 15 received a low dose and 30 control subjects received placebo. Five additional subjects received a licensed yellow fever vaccine as an active control.

The primary immunogenicity endpoint in the trial was the development of neutralising antibodies. Of the subjects who received ChimeriVax-West Nile, 96% in the high-dose group and 100% in the low-dose group developed West-Nile-neutralising antibodies 28 days after vaccination. The data also indicated that there was no notable difference in the incidence of treatment-emergent systemic reactions between the ChimeriVax-West Nile high-dose (40.0%), ChimeriVax-West Nile low-dose (46.7%) or placebo (43.3%) groups. One subject in the ChimeriVax-West Nile group experienced the sole potentially treatment-related serious adverse event – elevated muscle enzyme (creatin phosphokinase) levels associated with mild muscle soreness following strenuous weight-lifting. After extensive evaluation, Acambis concluded that previous strenuous exercise rather than the vaccine candidate was responsible. The next trial is envisioned to be further safety and immunogenicity testing at various doses and should start before the end of the year.

***Acambis also entering
the flu market***

Acambis also recently announced that it is looking to develop a universal influenza vaccine with protection against both A and B strains of the virus. As such, the vaccine could theoretically protect against pandemic and endemic flu and would not require the annual changes to its formulation that are required for current vaccines. It could thus constitute a 'one-shot' protection against influenza. In addition, the vaccine would be manufactured using recombinant bacterial fermentation technology, which aims to provide time- and cost-efficiencies compared with traditional egg-based production methods. At present, though, the vaccine remains in preclinical development.

Financially strong

***Crucell should finish
2005 with over €110m
on the balance sheet***

Crucell's revenues for 2Q05 were €10.1m (US\$12.2m), up from €8.0m (US\$9.7m) in the same quarter last year and included a second milestone payment from DSM. Net loss for 2Q05 was €3.4m (US\$4.1m), compared with a net loss of €2.0m (US\$2.5m), for 2Q04, reflecting increasing spend on proprietary programmes. Crucell expects a full-year cash burn of €15-20m.

Crucell remains extremely well funded with cash and cash equivalents of €120.3m (US\$145.1m) on 30 June 2005, reflecting the €50m raised in 2Q05. We do not currently foresee the company having to return to the market for cash if its vaccine programmes are successful.

Newsflow appears discounted

***Significant newsflow
already discounted***

Over the next six months, while we anticipate a continued stream of newsflow from Crucell, we believe it is already discounted in the current share price (see Figure 2).

We believe that the three most critical pieces of newsflow will be confirmation that each of the flu, Ebola and West Nile vaccines have moved into clinical development, all due before the end of the year. However, this would only impact our valuation by 11%, taking it to €12.4, still suggesting 33% downside from current levels.

Other news that could be announced but that would be unlikely to have a significant impact on our valuation includes an update on the TB vaccine programme, the potential announcement of a collaboration with GSK on the malaria programme and further PER.C6 licensing deals.

Within 12 months we expect a decision from Genentech on whether it will take up its option on the STAR technology. This could lead to a significant upfront payment and would certainly be positive news helping to clarify the potential utility of the technology. However, it is clarification of the regulatory view that is more critical in our view in terms of determining how quickly the technology can generate significant value.

Valuation difficult to justify

We value Crucell using our NPV methodology

As yet, none of Crucell's proprietary programmes are in clinical development. Despite this and to reflect in our view the likely lower-risk nature of its vaccine development compared with traditional NCE development, we have valued three of its most advanced proprietary programmes. Our NPV valuation suggests a fair value for Crucell of €456m. Excluding its cash this suggests a technology value of €336m. Crucell currently has a technology value of €618m.

Only when we factor in that all three of Crucell's most advanced vaccine programmes successfully reach the market (ie, factor in 100% probability) and achieve combined peak sales of over US\$1.5bn does our fair value reach the current share price.

As a sense check we also suggest a comparison with another European vaccine company that we follow, Acambis. Acambis currently has four vaccine programmes in clinical development, two of which are in Phase III although, granted, both represent relatively niche market opportunities. In addition, it has a West Nile programme, ahead of Crucell's own programme that has completed Phase I trials. Finally, it is competing with one other company, Bavarian Nordic, to win a US smallpox vaccine contract that could be worth up to US\$900m, news on which could come before the end of the year. Acambis has previously won a US\$428m smallpox contract awarded by the US Government. Acambis currently has a technology value of around €230m, which we see as fair value.

Crucell summary NPV

Fig 1 Crucell NPV

Drug	Indication	Stage	Launch	Peak year	Peak sales (US\$m)	Probability (%)	Net royalty (%)	NPV/share (€)
PER.C6	Revenues	Various	3x sales					2.4
PER.C6	Gene therapy prods	Various	2009	2013	220-325	20-30	2	0.6
PER.C6	Protein/ab production	Various	2009	2013	>1,000	30	2	0.7
PER.C6	Flu vaccine	Preclinical	2009	2012	>1,000	30	Up to 11	1.8
PER.C6	Merck vaccines	Phase II	2008	2012	1,100	20	4	0.7
PER.C6	Ebola vaccine	Preclinical	2007	2007	90	50	40	0.4
PER.C6	West Nile vaccine	Preclinical	2009	2013	400	30	30	1.2
STAR	Protein/ab production	Research						0.3
Galapagos	Functional genomics		-	-	-	-	-	0.2
Cash								2.9
Total NPV								11.2

Source : ING estimates

NPV evolution analysis

If all the newsflow we forecast over the next six to twelve months is positive we still see 23% downside from the current share price to our NPV fair value.

If all newsflow is negative downside rises to 59% (see Figure 2).

Fig 2 NPV analysis

Date	Potential Event	Positive outcome		Negative outcome		Comment
		NPV impact €/share	NPV impact %	NPV impact €/share	NPV impact %	
3Q05	Update on TB programme	-		-		Unlikely to impact our valuation.
3Q05	IND filing for annual flu vaccine	1.2	11	(1.8)	(16)	With an IND filing we would increase our probability of success to 50%. A negative outcome assumes the programme is halted. We see this as a low probability. A delay in any IND filing would not likely impact our valuation but could have a significant impact on sentiment.
2H05	Deal with GSK on malaria	-		-		Unlikely to significantly impact our valuation until an IND filing announced. A deal, however, would be good for sentiment.
4Q05	IND filing for Ebola vaccine	-		(0.4)	(4)	An IND filing would have little impact on our valuation as we already factor in 50% probability of success.
4Q05	IND filing for West Nile vaccine	-		(1.2)	(11)	An IND filing would have little impact on our valuation as we already factor in 30% probability of success.
2005-06	Genentech option on STAR	1.5	13	(0.3)	(3)	With a positive evaluation from Genentech we would reassess our valuation of STAR but as an example assuming a cash upfront and increasing our probability of its use as based on our outlined scenario to 30% would have a €1.5 positive impact.
2Q06	IND filing for malaria vaccine	0.3	3	-		We would factor in this vaccine with a 10% probability on start of Phase I trials and assuming peak sales of US\$200m.
Total NPV		14.2	27	7.5	(33)	

Source: ING estimates

Fig 3 Newsflow

Date	Description
2005	Further PER.C6 licensing deals
3Q05	Proof of concept & outline of development plans for TB vaccine
3Q05	IND filing for flu vaccine – annual and pandemic
2H05	Deal with GSK on Malaria vaccine development
4Q05	IND filing for Ebola vaccine
4Q05	IND filing for West Nile vaccine
2Q06	IND filing for malaria vaccine
2H05/1H06	Decision from Genentech on option for STAR technology

Source: ING

Fig 4 SWOT analysis

Strengths	Weaknesses
Strong balance sheet	No products in clinical development
Revenue stream from PER.C6 licensing deals	PER.C6 pivotal to the entire story
Opportunities	Threats/Risks
Bioterrorism regulations offer quick route to market for vaccines	Safety issue with PER.C6
Licensing opportunities	Delays with proprietary programmes

Source: ING

Equity story

Crucell leverages its patented technologies, PER.C6 and AdVac, for discovery, development and production of antibodies and vaccines.

PER.C6 is a cell line developed for safer and more efficient large-scale manufacture of biopharmaceutical products. Crucell's aim is to make PER.C6 the industry standard for vaccine and antibody production. The growing list of PER.C6 licensees (40) should ensure a continuing steady revenue flow to Crucell. In addition, should any products that use the PER.C6 cell line reach the market, Crucell will collect royalties on sales. Crucell is now concentrating on developing proprietary vaccines for diseases including Ebola, Malaria and West Nile virus. All are currently preclinical.

Risks

Unanticipated newsflow.

If the road to commercialisation of STAR is much shorter than we currently envisage then this could significantly impact our valuation upwards.

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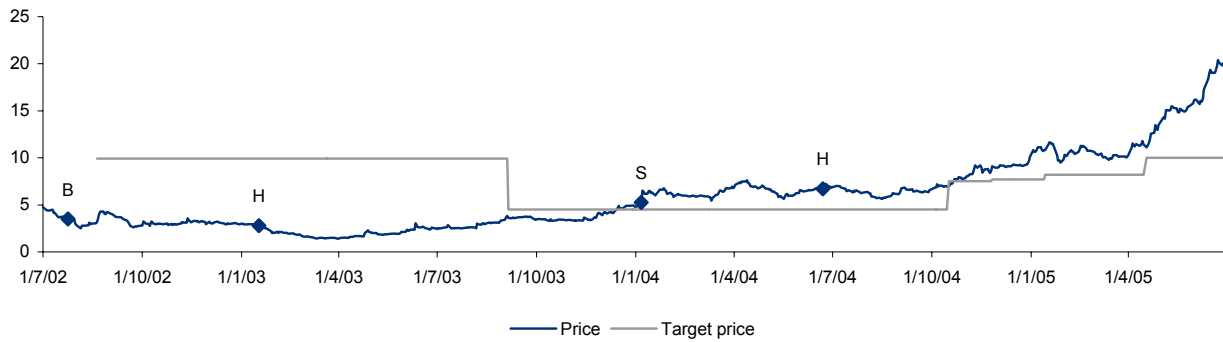
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PRICE AND RATINGS CHART: CRUCELL (CRCL.AS)



Current analyst

SB = Strong Buy; B = Buy; H = Hold; S = Sell; NR = Not Rated

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