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Diurnal Group

1 April 2022

Share Price	**15p**
CP Fair Value	**155p**

Market Cap (£m)	25
Net Cash (£m)	24.5
Enterprise Value (£m)	0.5

Country	UK
Code	DNL
Index	FTSE AIM

Source: Calvine Partners Research

Dr Brian White
Partner
bw@calvinepartners.com

Andrew Keith
Partner
ak@calvinepartners.com

A challenging start to 2022, but potential remains

Although 2021 has been a period of significant regulatory and commercial progress for Diurnal, this performance has been overshadowed by the recent decision of the Scottish Medicines Consortium (SMC) not to recommend automatic reimbursement of Efmody in CAH. This is disappointing and has blunted Efmody's immediate UK wide potential despite its clear benefits. Efforts are underway to address the SMC's concerns, with two trials ongoing in both AI and CAH. Elsewhere, despite the impact of the pandemic, the increase in Alkindi sales has demonstrated the effectiveness of the existing European commercial infrastructure, with some operating leverage already evident. Efmody pricing discussions are ongoing in Europe, and there have been successful conclusions in several geographies, including Germany and Norway.

Broader ambitions apparent

The cortisol franchise in Europe extends beyond CAH with the next data point from the larger adrenal insufficiency (AI) indication. CHAMPAIN is expected to readout at the end of 2022 and will provide the first opportunity for Diurnal to revisit the SMC with new confirmatory data. It is worth remembering that AI is a significantly larger and more lucrative opportunity for Efmody. Our analysis suggests that CHAMPAIN has a good chance of a successful outcome suggesting an H1 2024 European launch. The US potential for DNL-0200 (Efmody) has taken on greater importance given the commercial travails in the UK and the start of the Phase 3 CONNECT study in CAH. CONNECT will provide a thorough evaluation of DNL-0200 in CAH with a pre-agreed protocol. This includes administration over 52 weeks which better reflects DNL-0200's role as a chronic therapy.

Endocrinology pipeline progress

We have previously highlighted the potential of DNL-0300 (DITEST) to provide important attributes over existing testosterone replacement therapies (TRT). DNL-0300 offers the prospect of being the first oral native testosterone therapy that is associated with lower levels of dihydrotestosterone and doesn't require administration with a high-fat meal. Diurnal has secured a branded generic (505(b)(2)) regulatory pathway in the key US market. This route is usually associated with shorter, lower-cost clinical development and lower risk. TRT is a very large market opportunity, with DNL-0300 potentially representing a best-in-class oral therapy. We estimate a modest 15% market share would deliver end-market sales of $500m.

Taking the long road

Determined to deliver for CAH patients

The development and commercialisation of Efmody have been far from straightforward. The failure of the European Phase 3 trial to deliver a positive result at the chosen primary endpoint was clearly unhelpful. However, management's efforts to resurrect fortunes and achieve EMA and UK approval for Efmody have been highly creditable. The delivery of a product that we believe manifestly benefits CAH patients is also a testament to management's determination.

Regulator supportive

Indeed, as we have highlighted on numerous occasions since approval, the SPC (Summary of Product Characteristics) associated with Efmody's approval highlighted several beneficial properties attributed to its ability to deliver hydrocortisone that best mimics its physiological release. These included 1. Improved hormonal balance, which could be maintained in the longer term, 2. The potential to use lower doses of corticosteroid in some patients, and 3."…. *the ability to offer clinical value by allowing dosing that resembles the daily rhythm of natural cortisol secretion.*"

Reimbursement mixed to date

Despite recognising these apparent benefits and approval extended to include adolescent CAH patients, Efmody failed to gain orphan drug status. Our view was that this event would likely limit the ability of Efmody to command a premium price over existing delayed-release preparations like Plenadren. Additionally, reimbursement in Europe is usually protracted, often taking 12 months or more to complete as new countries are added.

SMC decision disappointing

With European approval achieved and a price sought in line with Plenadren, an existing delayed-release therapy, we expected a positive reimbursement result in the UK, a key market. However, on March 7, the Scottish Medicines Consortium (SMC) concluded that it was unable to grant automatic reimbursement to Efmody. The reason given by SMC was that Diurnal had not supplied sufficiently robust clinical and economic analysis.

Phase 3 result unhelpful

The publicly available commentary provides some background, although, in essence, the decision appears to have been driven by the result of the European Phase 3 study with the SMC opining that "*…androgen suppression was similar with hydrocortisone modified-release compared with standard of care in adults*".

Several limitations but PACE recommendations are good

While highlighting the (now well recognised) limitations of the Phase 3 study design, SMC did recognise the positive impact on early morning androgens and the potential reduction in glucocorticoid dose compared with standard of care. Also, SMC acknowledged that 24-week data may have been sufficient for biomarker analysis but less so with respect to clinically relevant outcomes. Reassuringly, the patient and clinician engagement (PACE) element of the review appeared to be broadly supportive of Efmody's profile, recognising that it could be particularly relevant to CAH patients who are poorly controlled on standard of care.

More data required

Anyway, be that as it may, it is clear that SMC will require additional confirmatory data if automatic reimbursement is to be forthcoming. In this regard, Diurnal has recently announced that the first patient has entered the Phase 2 registration study CHAMPAIN, where Efmody will be compared to Plenadren.

CHAMPAIN the earliest opportunity

A positive result from CHAMPAIN should provide the earliest opportunity for Diurnal to re-engage with the SMC as it pertains to new data. Additionally, CHAMPAIN is important to the extent that it should highlight the potential of the broader adrenal insufficiency opportunity outside of the current focus on CAH. It is also an active comparator study, comparing Efmody with Plenadren. If successful, we believe that a demonstration of superiority would remove any lingering doubt over Efmody's profile.

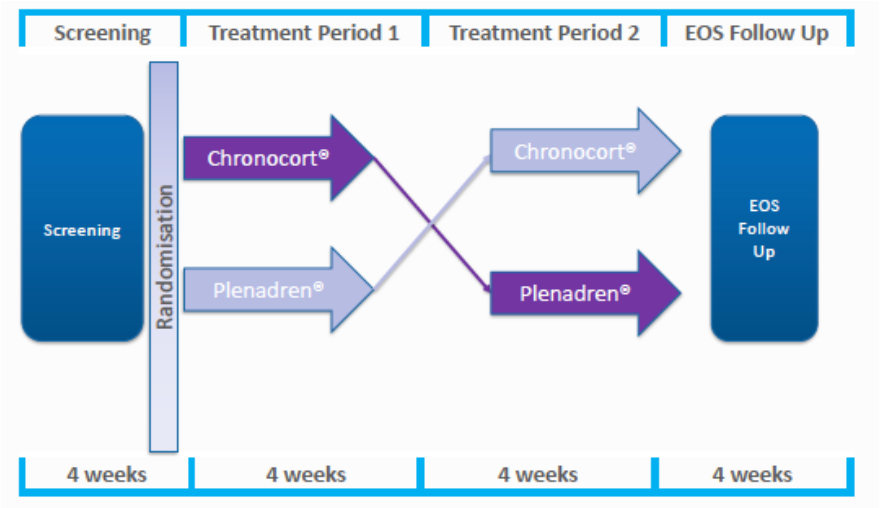
Efmody profile suggests a positive outcome

We have previously intimated that we expect CHAMPAIN to deliver a positive result. This is based on the different delivery technologies, with Plenadren providing a higher concentration of hydrocortisone during the first 4 hours after administration, but this rapidly tails off during the day and completely misses out on the natural early morning increase in cortisol and peak on awakening. Efmody, on the other hand, has already demonstrated its ability to deliver physiological levels of hydrocortisone in the critical early morning period.

Approval in AI by 2024

At this stage, it is not clear what confirmatory data will be required by SMC. We note that the CHAMPAIN study is in AI patients and not CAH. Additionally, Plenadren was previously not recommended for automatic reimbursement by SMC. At the same time, it is worth highlighting that the early morning hydrocortisone peak associated with Efmody is important with respect to preventing the overnight accumulation of androgens – much more pertinent to the treatment of CAH patients. Additionally, CHAMPAIN uses a double-blind, double-dummy design, whereas data from the extension study was open-label. CHAMPAIN is scheduled to complete at the end of 2022. We expect a filing during the calendar year 2023 and approval in the AI indication in Europe in 2024.

CHAMPAIN Study



Source: Company presentation

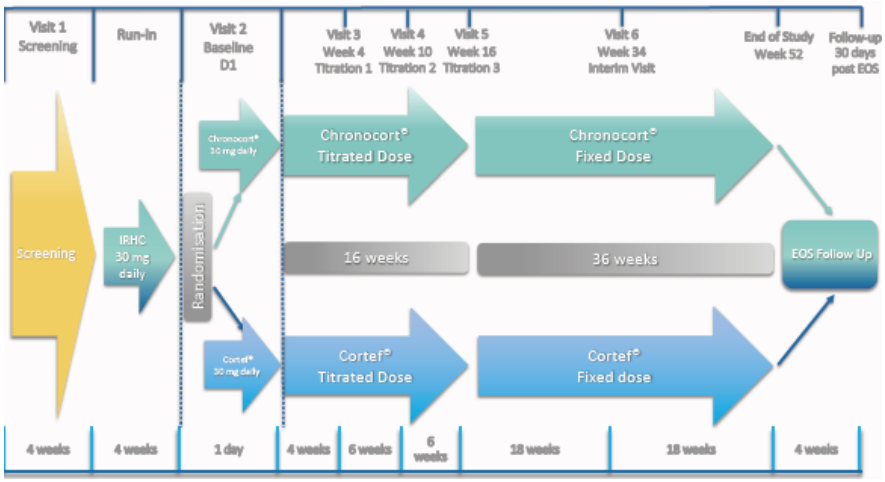
Although we are hopeful that the result of CHAMPAIN may be helpful in discussions with SMC, the study which should deliver compelling data in CAH patients is the US Phase 3 CONnECT study.

CONnECT a comprehensive evaluation of Efmody

CONnECT is different from the failed European Phase 3 study with a different endpoint and a longer duration. It is a double-blind 52-week study with a biochemical responder analysis versus immediate-release (IR) hydrocortisone as the primary endpoint in a non-inferiority design. Secondary endpoints should also provide important information comparing Efmody with IR hydrocortisone on key measures, including steroid-sparing, fertility, body weight and quality of life. CONnECT is a comprehensive investigation of the benefits of Efmody with 28 secondary endpoints and 31 other outcome measures. Should the trial be successful, we expect that Efmody should be able to gain approval in the US, orphan drug status, and a differentiated prescribing label.

CONnECT is ongoing, with 150 patients expected to be enrolled. The primary completion date for CONnECT is likely to be towards the end of 2023, suggesting an H1 2024 filing and a 2025 commercial launch.

CONNECT - US Phase 3 CAH study



Source: Company presentation

DNL-0300 – moving into the clinic in the key US market

DNL-0300 is not in our forecasts yet

Despite our enthusiasm for the development of an effective and convenient oral native testosterone product, DNL-0300 (formerly DITEST) currently sits outside of our financial model and valuation. This is perhaps overly conservative given the streamlined Phase 3 development pathway secured in the key US market and supportive early clinical data.

TRT is a large market opportunity

Nevertheless, we are approaching an interesting time for this programme, particularly given the challenges facing the adrenal franchise and the need to evaluate non-dilutive funding. There is little doubt that the TRT market is very large, with approximately 6% of US males affected by low testosterone levels (4-5 million men). There is a very clear need for better oral products with fewer limitations that are more convenient than topical or injectable products.

Large but difficult regulatory opportunity

Unsurprisingly, given the potential to transform the market dynamics of the TRT segment, there have been various efforts to develop oral treatments. However, these efforts have been more protracted than originally anticipated, and approval was significantly delayed. Jatenzo (testosterone undecanoate) was eventually approved in March 2019, while Antares Pharma only announced approval of Tlando this week (29 March 2022).

Regulatory pathway clear

Regulatory challenges have mainly been caused by the initial desire to gain approval for the broader low testosterone segment, including those with idiopathic origin. However, as concerns have mounted regarding the safety profile of TRT, FDA narrowed the applicability only to those with a specific medical condition. This narrowing has resulted in the treatment of ageing males with low testosterone levels as off-label. Strange as this may seem, clarity

now prevails, and TRT remains a large unmet need with the requirement for safer, more convenient alternatives. DNL-0300 is showing the potential to provide a best-in-class addition.

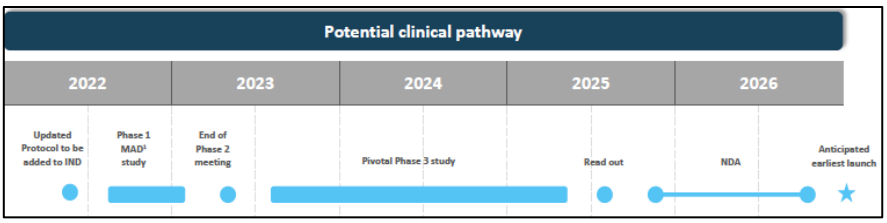
This is also a fragmented market with no clear leadership, and we sense that this is a highly promotionally sensitive therapeutic area. Since the approval of Jatenzo, originator Clarus has invested significant resources in maximising awareness (including DTC advertising). Hopefully, these efforts to raise awareness should also be helpful for DRL-300 when it is approved (likely in the 2025/26 timeframe). With the regulatory environment clearer and DNL-0300's lower risk development pathway secured, we are hopeful that, if desired, a commercial partner could be forthcoming, given the need for Diurnal's non-dilutive funding. Previously, we have suggested that the earliest that Diurnal can achieve a satisfactory partnering agreement would be post a Type B (end of Phase 2) meeting with FDA in the CY 2023 timeframe. Diurnal's timing could be helped by regulatory actions that have effectively limited the target population to patients with hypogonadism, specifically those with structural issues.

DNL-0300 should be an attractive asset for partnering discussions

From a commercial perspective, we note that Clarus has previously suggested that each incremental percentage point of market share equates to $33m of sales. With the right partner in place, we believe that a mid-teens market share should be achievable, given DNL-0300's potential to be a best-in-class oral TRT. This would equate to end market sales approaching $500m.

$500m market potential

The DNL-0300 clinical pathway



Source: Company presentation

Risks

The principal risks associated with Diurnal are mainly clinical and commercial. Clinical trials of novel drugs can be associated with risk of failure as well as delays, and we note that the ongoing COVID-19 pandemic has resulted in enrolment delays in clinical trials in general.

Diurnal has retained European rights to its adrenal disorder franchise, bringing commercialisation risks, exemplified by the impact of the recent SMC decision. The pace of uptake is difficult to predict, particularly given the ongoing COVID-19 dislocation, which could affect our forecasts, although we recognise that market expectations for Alkindi are modest. Following Efmody's launch in Europe, we expect that Diurnal will benefit from the existing sales platform, with only incremental costs required to support the commercial launch.

Diurnal is seeking to launch its products into what is primarily a generic market environment. Accordingly, we have assumed a price for Efmody that is consistent with the European price of Plenadren, a once-daily formulation of hydrocortisone, which looks to be a reasonable proxy. We note that there is no equivalent product in the US and have assumed that Efmody is priced at a premium. With Diurnal retaining US rights for now, we look forward to the company securing a price which reflects Efmody's orphan designation.

With Diurnal looking to partner several of its products in the US, including DNL-0300, there is an associated partnering risk.

As a development stage company, Diurnal is currently a loss-making enterprise, and our forecasts assume that further funding will be required to reach sustainable profitability. However, the company has sufficient funds to continue with its near term pipeline development ambitions and support the launch of Alkindi and Efmody in Europe.

Financial Model and Summary

Significant regulatory and commercial progress overshadowed

The recent Diurnal interim results presentation reflected a period of significant achievement and highlighted the potential impact of previously unforeseen challenges. Alkindi's sales potential in Europe may be modest, but commercial progress in Europe has continued. For Efmody, pricing discussions in Germany and Norway have been successful. However, the UK's first response, with the SMC not willing to provide automatic reimbursement in Scotland, has important ramifications for those Clinical Commissioning Groups (CCGs) in England which rely on SMC. Although there may well be larger endocrinology groups who will make up their own minds regarding the importance of Efmody's attributes over generic immediate-release hydrocortisone, the decision will clearly impact Efmody's UK rollout.

SMC decision unhelpful

This is clearly a disappointing outturn, particularly as the UK represents an important element of Efmody's European commercial potential and a market in which it already directly sells Alkindi. However, the UK has a somewhat convoluted process when new therapies fall below the threshold for evaluation by NICE. Therefore we hope the SMC decision will not have ramifications for other European health technology assessments of Efmody.

Refocusing to reflect financial consequences

The financial consequence of SMC's decision has been to push back revenue expectations in Europe by 18-24 months. Diurnal is now guiding for revenues in the region of £4.6m for the year to the end of June 2022. Additionally, the company has withdrawn its previous guidance to reach sustainable profitability with current cash resources and has recognised that additional funding will be required.

AI indication is an important addition

While this is disappointing, it is perhaps inevitable given the short-term financial consequences of the SMC decision. As a result, the company's efforts in AI in Europe as well as in CAH and AI in the US have come into focus. Success at the end of the year in CHAMPAIN should confirm the benefit of Efmody over Plenadren and facilitate approval in the AI indication by 2024. CONNECT is now underway in the US, with Diurnal guiding towards recruitment competing in H1 2023. As a 52-week study, we expect it to read out in the middle of 2024, with marketing approval in CAH in H2 2025.

R&D Day on September 7

We look forward to the R&D Day now rescheduled for September 7. Hopefully, we can expect to hear more regarding the commercial rollout of Efmody in Europe and progress in recruiting into the CHAMPAIN and CONNECT studies. Additionally, the R&D day should provide greater insight into the potential for DNL-0300 in hypogonadal men. This is a significant opportunity, and we look forward to the oral TRT market developing ahead of DNL-0300's availability.

From a promising start, 2022 has turned out to be significantly more challenging than we initially anticipated. Nevertheless, the company has two launched products in Europe serving the continuum of CAH patients. With no obvious competition on the near-term horizon, we

remain hopeful that the longer-term outlook for Efmody has been left untarnished by this development.

Sufficient funds to reach the next value inflection point

Thankfully, recruitment in the registration stage CHAMPAIN trial has already started. We have highlighted our confidence in a positive outcome which should go some way to address SMC issues and help Diurnal realise its ambitions to create a broad endocrinology franchise. Plans for the US are now in place, and we look forward to Efmody delivering on its promise in CAH as well as the broader AI indication. Despite the impact on near term finances, the company has the funds to reach the next value inflection point for Efmody at the end of 2022.

Move to CY end and changes to forecasts

We have updated our forecasts to reflect recent developments and the move to a calendar year-end (from a June year year-end. Given the uncertainty, we have assumed that sales growth in the near term will be constrained until at least the readout from CHAMPAIN. However, for conservatism, we have assumed that a full appreciation of Efmody's benefits awaits the readout from CONnECT.

Sustainable profitability 2025 by our forecasts

As a result, our forecasts suggest that sustainable profitability will be achieved by 2025. However, much will depend on the company's commitment to direct selling of the adrenal franchise in Europe and the ongoing commitment to current levels of R&D spending. As a result, we model a shortfall in cash in calendar year 2023, in line with company guidance. As we have intimated before, Diurnal is in this for the long term. Our expectation remains that Efmody will be a profitable endeavour in the treatment of disorders characterised by low cortisol (CAH & AI), albeit with a lower ramp-up.

Potential for non-dilutive funding

We also note management's commentary surrounding the potential for non-dilutive funding. Although we have been hopeful that Diurnal retains commercial rights to Efmody in the US, we concede that it could well be a desirable asset, particularly given the heightened awareness of CAH through efforts from other participants such as Spruce Biosciences and Neurocrine Biosciences.

DNL-0300 partner would be helpful

Elsewhere, we recognise that native testosterone (DNL-0300) will require a partner to capitalise on its undoubted potential in the treatment of hypogonadal men suffering from low testosterone. With the dose-escalation study due to start later this year, now could be a good time to seek a development partner, particularly given that the Phase 3 programme is well defined and has a lower risk design (505(b)(2)). Should Diurnal attract a suitable partner, we suspect it could choose to structure an agreement with a reasonable upfront payment.

DCF valuation revised to 155p

The events of the past several weeks have added a degree of unexpected uncertainty to the Diurnal investment case. As a result, we have revisited our NPV calculation assumptions. A combination of lower near-term revenues and an increase in our discount rate, from 15% to 20% to reflect the increased risk, take our DCF price per share price calculation to 155p.

Diurnal Group Income Statement (£m)

Year to December	2021A	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Sales	**5.32**	**4.72**	**9.33**	**21.71**	**72.50**	**162.10**	**246.85**	**322.45**
COGS	(0.79)	(1.18)	(1.87)	(4.34)	(14.50)	(32.42)	(49.37)	(64.49)
Gross profit	**4.53**	**3.54**	**7.46**	**17.37**	**58.00**	**129.68**	**197.48**	**257.96**
gross margin	85.1%	75.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%
SG&A	(10.26)	(10.39)	(10.73)	(10.86)	(11.60)	(17.83)	(22.22)	(32.24)
R&D	(9.12)	(17.47)	(17.72)	(17.37)	(17.40)	(21.07)	(24.69)	(32.24)
Other operating income	(0.68)	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Operating profit	**(15.54)**	**(24.31)**	**(20.99)**	**(10.86)**	**29.00**	**90.77**	**150.58**	**193.47**
Finance income	0.04	0.20	(0.00)	(0.14)	(0.19)	0.03	0.68	1.79
Finance expense	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PBT	**(15.50)**	**(24.12)**	**(20.99)**	**(11.00)**	**28.81**	**90.80**	**151.26**	**195.26**
Tax	2.16	1.49	5.25	2.75	(7.20)	(22.70)	(37.82)	(48.81)
Net income	**(13.35)**	**(22.63)**	**(15.74)**	**(8.25)**	**21.61**	**68.10**	**113.45**	**146.44**
EPS Basic (p)	-8.50	-13.47	-9.37	-4.91	12.87	40.55	67.56	87.20
EPS Diluted (p)	**-8.50**	**-13.47**	**-9.37**	**-4.91**	**12.87**	**40.55**	**67.56**	**87.20**

Source: Calvine Partners Research

Diurnal Group Cash Flow (£m)

Year to December	2021A	2022E	2023E	2024E	2025E
Net income	(12.98)	(22.63)	(15.74)	(8.25)	21.61
Licensing income received as non-cash					
Fair value adjustment to investments	0.68				
Dep/Amort/Impair	0.15	0.05	0.05	0.16	0.28
Share- based payment	0.38	0.84	0.84	0.84	0.84
Net Fx gain	0.11				
Financial income	(0.04)	(0.20)	0.00	0.14	0.19
Financial expense	0.00	0.00	0.00	0.00	0.00
Tax	(2.16)	0.00	(5.25)	(2.75)	7.20
(Increase) in receivables	(5.73)	(1.29)	0.99	2.65	(1.81)
Increase in payables	1.42	2.39	0.37	0.66	(0.71)
(Increase) in inventories	(0.10)	0.62	0.03	0.45	(0.49)
Interest paid	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
Tax paid/ received	1.51	0.00	5.25	2.75	(4.20)
CFO	(16.74)	(20.21)	(13.45)	(3.34)	22.90
PP&E	(0.06)	(0.05)	(0.62)	(0.75)	(1.33)
R&D capitalised	(0.06)				
Investments	**1.57**	**0.00**	**0.00**	**0.00**	**0.00**
Interest received	0.04	0.20	(0.00)	(0.14)	(0.19)
CFI	1.49	0.14	(0.63)	(0.89)	(1.51)
Net proceeds from issuance of share capital	19.92	0.00	0.00	0.00	0.00
Repayment of borrowings	0.00	0.00	0.00	0.00	0.00
Net proceeds from new borrowings	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**
CFF	19.92	0.00	0.00	0.00	0.00
Increase in cash	4.67	(20.06)	(14.08)	(4.23)	21.39
Cash brought forward	**20.34**	**24.36**	**4.29**	**(9.79)**	**(14.02)**
Fx					
Cash EOP	**24.36**	**4.29**	**(9.79)**	**(14.02)**	**7.37**

Source: Calvine Partners Research

Diurnal Group Balance Sheet (£m)

Year to December	2021A	2022E	2023E	2024E	2025E
Intangible assets	0.13	0.09	0.10	0.10	0.10
PP&E	0.02	0.15	0.72	1.30	2.35
Inv held at fair value through P&L	0.00	0.00			
Non-current assets	0.15	0.24	0.82	1.40	2.45
Trade and other receivables	8.30	4.72	3.73	1.09	2.90
Inventory	1.76	1.00	0.97	0.52	1.01
Inv held at fair value through P&L	0.00	0.00	0.00	0.00	0.00
Financial assets	0.00				
Cash & Cash equivalents	24.36	4.29	(9.79)	(14.02)	2.76
Current assets	34.42	10.02	(5.09)	(12.41)	**6.67**
Total Assets	**34.57**	**10.26**	**(4.27)**	**(11.01)**	9.12
Loans and borrowings	0.00	0.00	0.00	0.00	0.00
Trade and other payables	(4.58)	(3.00)	(1.40)	(0.74)	(1.45)
Current liabilities	(4.58)	(3.00)	(1.40)	(0.74)	(1.45)
Loans and borrowings	0.00	0.00	0.00	0.00	0.00
Trade and other payables	(0.07)				
Non-current liabilities	(0.07)	0.00	0.00	0.00	**0.00**
Total Liabilities	**(4.65)**	**(3.00)**	**(1.40)**	**(0.74)**	(1.45)
Share capital	8.46	8.46	8.46	8.46	8.46
Share premium	77.46	77.46	77.46	77.46	77.46
Consolidation reserve	(2.94)	(2.94)	(2.94)	(2.94)	(2.94)
Other reserve	0.00	0.00	0.00	0.00	0.00
Retained earnings	(53.06)	(75.19)	(90.43)	(98.18)	**(76.07)**
Total equity	**29.92**	**7.79**	**(7.45)**	**(15.20)**	6.91

Source: Calvine Partners Research

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