Diurnal Group

9 August 2021

Share Price	**60p**
CP Fair Value	**241p**

Market Cap (£m)	100
Net Cash (£m)	34
Enterprise Value (£m)	66

Country	UK
Code	DNL
Index	FTSE AIM

Source: Calvine Partners Research

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Commercial execution the key for now

The approval of Efmody in Europe and the UK for the treatment of congenital adrenal hyperplasia (CAH) represents a significant achievement for Diurnal. This was the largest interventional trial in CAH at the time, and approval followed a missed primary endpoint but included data from a long-term extension study. Diurnal's commercial platform is already in place as the commercialisation of Alkindi continues. Despite the impact of the pandemic, growth in key territories has been good and the message has clearly been communicated with most newborns receiving treatment. This is important to the extent that Efmody will capitalise on the existing infrastructure targeting hospital-based endocrinologists. The promise here is an expeditious rollout of Efmody (pandemic restrictions allowing) and significant operating leverage with more sales through a similar cost base.

Europe and UK will take time – US (and Japan) beckons

Despite our expectation that the existing commercial infrastructure will aid Efmody commercialisation, Europe remains fragmented with respect to reimbursement. Although we currently have no insight into Diurnal's activities beyond the pre-launch activities underway, we usually factor in 12 months to complete most reimbursement discussions. Fortunately for Diurnal, Plenadren provides an obvious proxy with respect to pricing and this remains the expectation in our financial model despite the lack of orphan status. The US on the other hand is a more attractive proposition, we believe, with awareness growing regarding improved treatments for CAH and now an SPA in place. Not only do orphan drugs generally attract premium pricing in the US, Efmody should represent the first and only glucocorticoid based treatment which mimics physiological circadian release required to best manage overnight androgen accumulation while providing steroid sparing.

Managing commercial execution while delivering on the pipeline

Diurnal aspires to create a broad endocrinology (ex diabetes) franchise in the longer term. DITEST as an orally available native testosterone, which should be an important new addition to the treatment of hypogonadism. Data so far have been encouraging and a streamlined development pathway has been secured in the key US market. Despite this, DITEST remains outside of our financial model and valuation for now suggesting significant upside if successful. We look forward to further detail on the pipeline later in the year.

Plans for the adrenal franchise coming together

All eyes on roll out of Efmody

Following a faltering start, the plans to create a global adrenal franchise based on cortisol replacement are now coming together. Efmody has been approved in Europe and the UK with pre-launch activities well underway. Launch has been scheduled for Q3 2021 and all eyes will be on sales progress in the key geographies of Northern Europe where Alkindi sales have enjoyed good growth, despite the impact of the pandemic.

Encouraged by execution of Alkindi launch

Following the European and UK approvals for Efmody, we believe that Diurnal's is well prepared for its most important commercial launch to date. Although Diurnal's child-friendly hydrocortisone preparation, Alkindi, has been available in Europe for some time, our sales expectations remain modest. At the same time, and despite the impact of the ongoing dislocation caused by the pandemic, we are encouraged by the commercial execution on Alkindi to date. Most newborns with AI are now treated with Alkindi instead of an inherently variable compounded hydrocortisone product.

Lack of orphan status unhelpful

The failure of Efmody to gain orphan status in Europe and the UK was disappointing to the extent that the company clearly felt that there was sufficient evidence of superiority despite the failure of Efmody to meet its primary endpoint in the European Phase 3 study. We note that historically, EMA has considered reduction of glucocorticoid overtreatment while providing physiological levels of cortisol as a significant benefit. However, EMA thinking on this front has clearly changed. In support of the significant benefit associated with Efmody, there have been important findings during the Phase 3 clinical programme which, it should be remembered, was the largest interventional study in CAH. These include a better control of the androgen precursor 17-OHP, as well as improvements in fertility and a reduction in adrenal crises. We also note that Efmody is not associated with a decrease in bone mineral density and offers better compliance. We suspect that additional clinical studies may have been required to definitively prove these observations and gain orphan status, particularly given the missed primary endpoint. As a result, given the time and expense involved Diurnal withdrew its application. Although the lack of orphan status may have taken the shine off the commercial package, approval remains a major positive for Diurnal.

Plenadren provides a useful proxy for European pricing

A major element of our positive stance is based on the observation that the availability of the controlled release hydrocortisone treatment Plenadren in Europe provides a useful proxy. Plenadren was approved to treat patients with AI in Europe despite the observation that control of overnight androgens was limited and indeed a higher risk of adrenal AI symptoms were observed as patients switched from standard glucocorticoid therapy to Plenadren. Our financial model has always assumed a similar price to Plenadren in Europe, while any orphan benefit would have provided potential upside. It is also important to remember here that there is still the very real prospect that Efmody could achieve orphan

drug status in the US which could have positive implications for our financial model and valuation.

European reimbursement discussion can be protracted

Nevertheless, reimbursement discussions in Europe can be protracted. While it can take 12 months or more to complete reimbursement discussions on a country-by-country basis, the key countries remain in Northern Europe where we note that Diurnal has made significant progress commercially with Alkindi.

Widening of label to include adolescent CAH patients positive

Europe represents a relatively straightforward commercial opportunity for Diurnal, thanks not only to the existing commercial infrastructure, but also because there a limited number of key endocrinology centres that treat CAH patients. Although, Alkindi doesn't offer a circadian release profile like Efmody, Diurnal now offers hydrocortisone-based treatments for children (Alkindi) as well as adolescents and adults (Efmody). Efmody did not receive orphan status in Europe or the UK, however, we view positively the widening of the label to include adolescents as well as adults.

Diurnal has a strong European adrenal portfolio

Consequently, Diurnal should be well placed to offer an appropriate treatment for those Efmody patients (aged 12 and over) transitioning through puberty and those currently receiving less effective glucocorticoid preparations. Particularly reassuring, we believe, is the observation that Alkindi has been in the main European markets for some time, and that the effectiveness of the salesforce is reflected in the treatment of most newborns with Alkindi. Certainly, our impression is that their efforts have resulted in a productive relationship with the endocrinology specialist physician community.

AI indication promises additional revenues for modest additional costs

As Diurnal seeks to build on its adrenal franchise in Europe, a successful regulatory outcome for Efmody in CAH has important implications for the larger adrenal insufficiency indication. AI may be an orphan disorder but represents a larger opportunity for Efmody for little additional cost. As a line extension, clinical development should be relatively straightforward. The remaining clinical hurdle comprises a comparator study versus an existing (outside the US) alternative modified-release hydrocortisone (Plenadren). The study which will start later in 2021 should allow the company to position Efmody optimally in the AI indication in Europe.

Promise of significant operating leverage

Operationally, the continuing roll out of the adrenal franchise should drive operating leverage with Efmody firstly in CAH and then in AI, sold through a similarly sized promotional force throughout Europe.

US adrenal franchise plans now funded

Diurnal's fundraising activities have successfully bolstered the company's cash position with £34m in cash at end June 2021. Retaining development (and commercial) rights in the US re-establishes the initial desires of Diurnal management to retain the full margin for its adrenal franchise in this key market. What has changed and provided management with additional encouragement

European approval drives confidence in US opportunity

we suspect, has been the receipt of formal approval in Europe and the UK, de-risking the ongoing clinical development of Efmody.

US trial design endorsed by SPA

The recent trading update has effectively listed all of the achievements during the previous financial year. The decision to seek a Special Protocol Assessment (SPA) from FDA likely reflects the challenges faced when developing Efmody in Europe and the need to identify appropriate endpoints that will both demonstrate the ability of Efmody to control overnight androgens, deliver androgen sparing and meet the requirements of FDA. Given the protracted nature of the deliberations with FDA over several years, along with learnings from the completed EU trial, we believe that Diurnal should have achieved those objectives in a trial design endorsed by the receipt of an SPA.

Clarifying suitable endpoints, reducing regulatory risk

While Diurnal may have initially focussed on Europe and the UK, the US has always been a key target market for the company, particularly in the longer term. Efmody has orphan drug designation for both CAH and AI in the US. With the receipt of Special Protocol Assessment, the design and endpoints for the US Phase 3 trial have been agreed. As a result, should the study drug perform as expected, and deliver a positive result at the requisite endpoints, regulatory risk should be significantly reduced. While we await details of the endpoints, this will be a 52-week double-blind active control study.

Activity elsewhere should increase awareness

The design appears broadly similar to that of the CRF1 inhibitors. Tildacerfont is progressing through CAHmelia-203 (androgen reduction study) and CAHmelia-204 (GC reduction study) which involves a 12 & 24-week treatment period respectively and a 58 & 52-week open-label extension period respectively. The primary endpoint in ‘203 is change in A4 to 12 weeks, while the primary endpoint in ‘204 is change in glucocorticoid at week 24. Many of the additional endpoints are looking at the impact on metabolism, bone turnover, body composition and BMD, likely associated with supraphysiological dosing of glucocorticoids. For crinercerfont, Phase 3 involves 24 weeks of treatment with a primary endpoint the reduction in GC followed by 12 months of active treatment.

Efmody well placed for future CAH treatment

While the development of the CRF1 inhibitors may have raised awareness of cortisol deficiency generally, we suspect that it may also have confused with respect to how future standard of care in CAH may develop should this approach prove successful. We have previously stated our view that the main opportunity for the CRF1 inhibitors, as we see it, is for those patients who struggle to control their androgens with standard glucocorticoid therapy. We note for example that Spruce Biosciences is pursuing two patient populations (poorly and well-controlled), endeavouring to demonstrate that treatment can reduce the requirement for supraphysiological glucocorticoid treatment as well as reduce androgens generally.

We believe that Diurnal will establish its own sales and marketing function in the US. Fortunately, the treatment of orphan diseases such as CAH and AI are usually tractable to a small, specialised

salesforce. Additionally, thanks to the efforts of neonatal screening, the efforts of advocacy groups (such as the CARES Foundation and the Adrenal Alternatives Foundation), CAH awareness is improving.

Retention of US commercial rights should bring not only the full margin for the CAH indication, but also facilitate future development opportunities. We have previously highlighted the importance of the broader AI indication noting that Efmody also has orphan drug designation for this indication. Consequently, launching Efmody into the broader AI patient population should deliver not only significant additional revenue but also substantial operating leverage.

US should also deliver significant operating leverage

Capitalising on the full potential of Efmody's circadian delivery

The need to deliver cortisol in a form that mimics its normal physiological circadian release is applicable to all indications which are caused by cortisol deficiency. The broader adrenal insufficiency disorder is also an important target although reduction of overnight androgens is not an issue (consequently CRF1 inhibition is not relevant here).

Cortisol deficiency market large – circadian delivery important

Diurnal has previously announced that it will compare Efmody with Plenadren in the larger AI indication. We believe this is a sensible approach as Diurnal seeks to optimally position Efmody in Europe and establish Efmody as the glucocorticoid preparation of choice for patients with AI.

In AI, there is a clear need for a treatment that more accurately mimics the circadian release pattern of cortisol to provide an improvement in both disease control (metabolic outcomes) and quality of life. Despite significant efforts to provide near to physiological dosing with existing glucocorticoid preparations, patients with AI still suffer from periods of hypo and hyper cortisolism. Hypocortisolism runs the risk of adrenal crises while hypercortisolism can also result in fatigue, low libido and cognitive issues. Moreover, there remains significant inter and intra-patient variability with no easy diagnostic means of ensuring that patients are adequately controlled.

High androgens may not be an issue but hyper and hypocortisolism are

There has long been a recognition of the inability of immediate-release glucocorticoids to provide adequate control of the symptoms of cortisol deficiency in AI. Mimicking the normal circadian release of cortisol is important to help regulate the sleep-wake cycle but also more broadly for the attainment of normal physical and mental health. Disturbance of circadian activity is associated with various negative physiological, psychological, and clinical issues. These included an elevated risk of metabolic syndrome, diabetes and cardiovascular events.

Important to mirror circadian availability of cortisol

The importance of a glucocorticoid release profile which best mimics the circadian cycle has not been lost on the pharmaceutical industry with efforts such as modified release (Plenadren) and subcutaneous infusion explored to satisfy these concerns. In particular, the observation that cortisol levels peak just before

Efmody offers benefit here too

waking has provided significant challenges in optimising the release profile. While AI patients may not have high androgens, it is still important to ensure that glucocorticoid delivery is optimised. Indeed, we believe that endocrinologists understand the need to replicate circadian availability to best manage the consequences of adrenal insufficiency.

Endocrinology pipeline diversifying adrenal portfolio

The near-term value in Diurnal has unsurprisingly been focussed on the travails of the adrenal franchise. Indeed, the focus now will be on the roll out of Efmody in Europe and the development of the US CAH franchise.

DITEST is an emerging asset

Nevertheless, Diurnal's pipeline continues to progress, and we have previously highlighted the potential of DITEST, Diurnal's native testosterone preparation, as a product which could transform the treatment of hypogonadism.

Current TRT preparations suffer from several limitations

While testosterone replacement therapy (TRT) has been used since the 1950s, due to the poor bioavailability of oral testosterone, the market has been dominated by topical formulations and injectable products. However, compliance rates with injectable and gel formulations have generally been poor. Administration of injectable products can be painful while topical formulations are associated with skin reactions and transference to women and children (hence a Black Box warning of virilisation). While oral formulations of testosterone have been available for some time outside the US, until the approval of Jatenzo (testosterone undecanoate), the only US approved oral product was a 17-alpha-alkyl preparation methyltestosterone (Android) which has been associated with significant liver toxicity and as a result has not been widely used.

DITEST is well positioned, overcoming some of the limitations of other treatments

DITEST is a native testosterone which has been formulated for oral administration but designed to provide normal physiological levels of testosterone irrespective of the need for food. Potentially, DITEST should overcome some of the limitations associated with the current TRT profile of testosterone undecanoate. In a Phase 1 study, Diurnal confirmed the differentiated nature of DITEST compared to testosterone undecanoate.

Importantly, discussions with the FDA have confirmed that DITEST can be developed using the branded generic pathway (505(b)(2)). This means that clinical development can be streamlined. The 505(b)(2) pathway is associated with significantly lower costs and risks than traditional drug development. As a result, Diurnal has progressed DITEST using its own resources, although a partner will ultimately be required we suspect. Effectively, Diurnal (and a potential partner) can take advantage of data previously provided by other testosterone-based products as it seeks to provide a regulatory package that fulfils the Agency's requirement that DITEST is safe and efficacious.

Clear need for better oral products

TRT is a large market opportunity, with approximately 6% of US males affected by low levels of testosterone (approx. 4-5 million men). There is a very clear need for oral products with fewer limitations, that are more convenient than topical or injectable products.

DITEST profile and clearer regulatory backdrop should help attract partner when required

This is also a fragmented market with no clear leadership, and we sense that it is a highly promotionally sensitive therapeutic area. Given the challenges faced in diagnosis, concerns over abuse, and the significantly higher prescribing of TRT in the US versus Europe, we believe that a development partner with relevant experience will be required to ensure optimal positioning and drive uptake in the relevant patient populations. This is a significant market opportunity, and we believe that Diurnal should be able to deliver a suitable commercial development partner particularly given the well-defined low-risk pathway agreed with FDA, as well as positive Phase I data. Diurnal's timing could be helped by the regulatory actions which have effectively limited the target population to patients with hypogonadism, and specifically those with structural issues.

DITEST offers significant upside to our model and valuation

DITEST sits outside of our financial model and valuation but believe that it could deliver peak sales of over $1bn should the appropriate commercial partner be secured. As highlighted previously, the regulatory pathway for Jatenzo (now approved) and Tlando (tentative approval) has been chequered but much has been learnt from a regulatory perspective which should reduce concerns from potential partners.

Risks

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

Diurnal has retained European rights to its adrenal disorder franchise, which brings commercialisation risks. The pace of uptake is difficult to predict, which could affect our forecasts, although we recognise that market expectations for Alkindi are modest. Following Efmody launch in Europe our expectation is that Diurnal will benefit from the existing sales platform, with only incremental costs required to effect a successful launch.

Following Efmody commercialisation in Europe, we note that Diurnal is seeking to launch its products into what is largely a generic market environment. 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 in this regard there is no equivalent product in the US, and have assumed that Efmody is priced at a premium. With Diurnal also now retaining US rights, we look forward to the company securing a price which reflects its orphan status.

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

As a development stage company, Diurnal is currently a loss-making enterprise. Diurnal has successfully raised funds to continue with its development plans and aid the launch of Alkindi in Europe. Even with this near-term funding, our forecasts suggest that in order to progress its pipeline assets expeditiously, Diurnal may require additional funding.

Financial Model and Summary

Diurnal's existing European commercial infrastructure should facilitate a successful roll out of Efmody

Alkindi represents a modest opportunity for Diurnal in Europe. Additionally, reimbursement has been predictably prolonged, and the pandemic has been unhelpful. For us, however, it is the awareness of Diurnal's efforts in treating low cortisol disorders and the establishment of a European commercial presence that is important as the roll out of Efmody approaches. Efmody reflects the smart delivery approach epitomised by Diurnal and represents its flagship treatment for low cortisol disorders. The recent trading update has certainly provided encouraging evidence of the impact of the European commercial infrastructure with the majority of newborns now apparently treated with Alkindi.

COVID-19 restrictions hampered Alkindi sales but peak sales forecast are unaffected

Following approvals for Efmody in Europe and the UK, Diurnal is approaching an important period in its evolution. Frustratingly, the ongoing pandemic restrictions will likely continue to hamper efforts to launch new products generally but ultimately our expectation is that Diurnal will be successful in its endeavours, and peak sales potential should be unaffected.

Our pricing assumptions for Efmody were conservative and are unaffected by the lack of orphan status in Europe

The failure to gain orphan drug status in Europe and the UK is disappointing. The data generated certainly suggested superiority for Efmody over standard of care (immediate-release hydrocortisone) but it would appear that evolving thinking and the primary endpoint miss were high hurdles for the regulators. Fortunately, our pricing assumptions were conservative, assuming a European price for Efmody in line with Plenadren.

Orphan drug status in the US could provide upside to our forecast

The receipt of an SPA for US CAH development is welcome and provides reassurance after the uncertainty caused by the use of an inappropriate primary endpoint in the European Phase 3 study. Hopefully, a successful US Phase 3 result should result in a smooth regulatory review and the conferring of orphan drug status. The latter could provide upside to our current pricing assumptions. We note also the confirmation that the US study should be sufficient for Japanese approval and presumably for orphan drug status there too.

Efmody and CRF1 inhibitors can co-exist and competitive noise has increased awareness of CAH

The US is an important market for Diurnal, particularly as it relates to its longer-term ambitions. Potentially, the US CAH treatment market could be transformed with the development of both Efmody and perhaps also the CRF1 inhibitors. Although the competitive noise may have increased as a result of the efforts of Spruce and Neurocrine, it is clear that even if this approach is successful in reducing overnight androgens, the glucocorticoid component will still be required and will need to be optimised. Given that there is substantial evidence that glucocorticoid delivery should best mimic the normal circadian rhythm and Efmody also has shown potential for glucocorticoid sparing, Efmody should become a well-established component of standard of care for CAH treatment in the US as well as in Europe in future treatment approaches.

Details of the DITEST regulatory pathway will be provided later this year

Thankfully, Diurnal is now well funded allowing the company to not only launch Efmody in Europe and the UK, but also progress its development in the US for CAH as well as in Europe for AI. Additionally, largely behind the scenes, the broader endocrinology pipeline has progressed during the year with a streamlined and truncated development pathway secured for DITEST. We look forward to further details later in the year.

The adrenal insufficiency market is the big opportunity for Efmody

Finally, as Diurnal seeks to fully exploit its Efmody franchise in the US, a Phase 2 study in AI will begin in 2022. This is a very attractive market opportunity where Efmody also has orphan drug designation. Arguably this represents a more straightforward cortisol replacement market with no overnight androgens to control and no supraphysiological doses (or CRF1 inhibitors) required. The combination of both CAH and Addison's suggests a total market opportunity of $3bn compared to our peak sales forecast of £700m.

Near-term expectations for Alkindi have been trimmed but peak sales potential is unchanged

We have updated our financial model post the approvals of Efmody in Europe and the UK, and to reflect the recent trading update which provided revenue performance. We await the full-year results presentation for costs and profitability performance in 2021. Given the ongoing effect of the pandemic, we have moderated our near-term revenue expectations for Alkindi and its potential impact on the roll-out of Efmody, but ultimately expect peak sales potential to be unaffected.

Diurnal Group Adrenal Franchise Sales (£m)

	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Alkindi sales US	-	1.01	1.96	2.73	4.25	5.31	5.52	5.75
Alkindi sales EU	-	4.61	7.20	9.99	10.39	10.81	11.25	11.70
Efmody sales US	-	-	-		-	11.13	38.58	71.68
Efmody sales EU	-	6.04	24.65	109.94	172.98	300.57	326.56	363.67
Adrenal franchise sales	2.35	11.66	33.82	122.65	187.63	327.81	381.92	452.80
Adrenal franchise sales unrisked	**2.35**	**11.66**	**33.82**	**127.88**	**198.30**	**353.29**	**419.20**	**505.00**

Source: Calvine Partners Research

Diurnal Group Income Statement (£m)

Year to June	2019A	2020A	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Sales	**1.04**	**6.31**	**4.45**	**11.66**	**33.82**	**122.65**	**187.63**	**327.81**	**381.92**	**452.80**	**510.80**	**608.27**
COGS	(0.22)	(0.67)	(0.74)	(2.92)	(6.76)	(24.53)	(37.53)	(65.56)	(76.38)	(90.56)	(102.16)	(121.65)
Gross profit	**0.82**	**5.65**	**3.12**	**8.75**	**27.05**	**98.12**	**150.10**	**262.25**	**305.53**	**362.24**	**408.64**	**486.62**
gross margin	78.5%	89.4%	70.0%	75.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%
SG&A	(6.66)	(7.04)	(9.80)	(9.33)	(11.84)	(18.40)	(30.02)	(42.62)	(42.01)	(54.34)	(61.30)	(85.16)
R&D	(8.69)	(4.63)	(10.21)	(18.66)	(22.32)	(26.98)	(30.96)	(32.78)	(38.19)	(45.28)	(51.08)	(60.83)
Other operating income	0.00	0.63	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Operating profit	**(14.53)**	**(5.39)**	**(16.89)**	**(19.24)**	**(7.10)**	**52.74**	**89.12**	**186.85**	**225.33**	**262.62**	**296.26**	**340.63**
Finance income	0.13	0.11	0.15	0.28	0.10	0.04	0.43	1.12	2.52	4.24	6.24	8.50
Finance expense	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PBT	**(14.40)**	**(5.28)**	**(16.74)**	**(18.96)**	**(7.00)**	**52.78**	**89.56**	**187.97**	**227.85**	**266.86**	**302.51**	**349.14**
Tax	2.11	1.21	0.00	0.00	1.75	(13.20)	(22.39)	(46.99)	(56.96)	(66.72)	(75.63)	(87.28)
Net income	**(12.29)**	**(4.07)**	**(16.74)**	**(18.96)**	**(5.25)**	**39.59**	**67.17**	**140.98**	**170.89**	**200.15**	**226.88**	**261.85**
EPS Basic (p)	-19.70	-4.30	-11.56	-11.29	-3.13	23.57	40.00	83.95	101.76	119.18	135.10	155.93
EPS Diluted (p)	**-19.70**	**-4.30**	**-11.56**	**-11.29**	**-3.13**	**23.57**	**40.00**	**83.95**	**101.76**	**119.18**	**135.10**	**155.93**

Source: Calvine Partners Research

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