EDISON

Diurnal Group

Financial update

FY21 results reflect puts and takes

Pharma & biotech

Diurnal's H122 results were hindered by COVID-19 pandemic restrictions muting the benefits from the H2 CY21 Efmody launches in Germany, UK and Austria. Further, the recent Scottish Medicines Consortium (SMC) decision to not recommend Efmody for automatic reimbursement in NHS Scotland poses as a headwind and has caused management to lower revenue guidance. Despite management's focus on expanding into incremental markets, it now expects that for Efmody to become a profitable franchise, the product will require approval for the treatment of AI (projected in CY24). Hence, the company expects it will require additional funding to reach profitability. Martin Whitaker, CEO and board member, has announced plans to step down immediately. The adverse market sentiment has put significant pressure on shares, which are trading below the cash value. We have placed our valuation and financial forecasts under review.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
06/20	6.3	(5.1)	(4.1)	0.0	N/A	N/A
06/21	4.4	(11.1)	(7.0)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

H122 update

Diurnal recently reported H122 results; revenue was up 75.0% (y-o-y) to £2.13m due to improved Alkindi sales (45.7% y-o-y) with continued growth in core markets (UK, Germany, Italy and Austria) and initial Efmody sales (£0.39m). Efmody was launched in September 2021 in Germany, the UK and Austria. In October, Diurnal signed a distribution agreement with ExCEEd Orphan for Central and East European countries (for Alkindi and Efmody), with an agreement with Vector Pharma for the Middle East and North Africa (Alkindi) signed in March as part of its global roll-out plan.

The SMC has decided not to recommend Efmody

The SMC announced it has not recommended Efmody for automatic reimbursement in NHS Scotland for the treatment of congenital adrenal hyperplasia (CAH) in adults. Diurnal plans to re-submit further clinical and health-economic data; however, it has shifted its near-term focus to the commercial launch of Efmody in other European markets and to exploring more distribution deals.

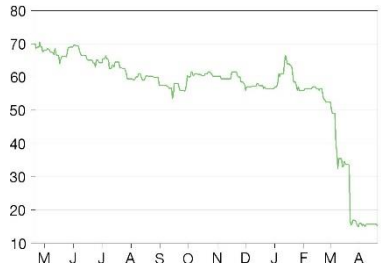
Valuation: Forecasts under review

Given the company's disclosure that it only expects Efmody to become a profitable franchise once regulatory approval in AI is attained, which is not anticipated before CY24, we are placing our forecasts and valuation under review.

21 April 2022

Price	**15.25p**
Market cap	**£26m**
	US$1.31/£
Net cash (£m) at 31 December 2021	24.4
Shares in issue	169.3m
Free float	68.1%
Code	DNL
Primary exchange	LSE
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(53.1)	(75.0)	(78.5)
Rel (local)	(54.2)	(74.8)	(80.1)
52-week high/low		71p	15p

Business description

Diurnal Group is a specialty pharma company developing new formulations of hormone-based products for the treatment of endocrine disorders. Alkindi is marketed for paediatric adrenal insufficiency (AI) in the US and EU. Efmody is approved for the treatment of CAH in the EU and UK.

Next events

CHAMPAIN study headline data	End-CY22

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Edison profile page

Financials update

In H122, the company reported revenue of £2.13m, up 75.0% y-o-y, from £1.21m in H121, mainly led by improved Alkindi sales and initial product sales of Efmody. Alkindi sales grew 45.7% y-o-y to £1.73m due to continued growth in core markets (the UK, Germany, Italy and Austria) amid the continued impact of COVID-19 pandemic-related restrictions. Efmody recorded initial product sales of £0.39m as the product was launched in Germany in September 2021, followed by launches in the UK and Austria. The company's operating loss increased to £9.20m in H122 from £5.26m in H121, mainly due to increased R&D expenditure in clinical studies and enhanced selling and distribution expenses for Efmody launch preparations across Europe. Diurnal's operating cash burn rate has accelerated in H122 (£10.6m vs £4.2m in H121), reflecting increased SG&A expenses due to ongoing commercialisation activity and higher R&D spending.

Net cash was £24.4m at H122 (H121: £34m), which, according to recent burn rates, should be sufficient to fund its clinical programmes until CY23.

Exhibit 1 includes some of the important catalysts to look for in 2022 and 2023.

Exhibit 1: Key catalysts

Anticipated acceptance of revised DNL 0300 protocol by FDA	Q2 CY22
R&D day (7 September)	Q3 CY22
Read out of modified release hydrocortisone AI line extension study	H2 CY22
European regulatory submission of modified release hydrocortisone AI line extension	H1 CY23
Recruitment complete in modified release hydrocortisone Phase III CONNECT study	H1 CY23

Source: Diurnal Group, Edison Investment Research

Global roll-out for Alkindi

Diurnal's first launched product, Alkindi, is an immediate-release formulation of hydrocortisone intended to treat paediatric AI and the related condition, CAH. Alkindi is a niche product for a relatively small population, but it is a group of patients that has historically been underserved. Alkindi is the first and only product approved for paediatric AI. It was launched directly by Diurnal in its core markets (the UK, Germany, Italy and Austria), and through its distribution partners, such as Frost Pharma in Sweden, Denmark, Norway and Iceland, and Eton Pharmaceuticals in the United States. In November 2021, Swissmedic (the authorisation and supervisory authority for drugs and medical products in Switzerland) approved Alkindi, which added one more territory for the upcoming launch of the product.

In H122, the company expanded its geographical reach by entering into more distribution agreements to ensure global roll-out for Alkindi, such as the distribution agreement with ExCEEd Orphan in October 2021 to market its products (both Alkindi and Efmody) in Central and East European countries and a distribution deal with Vector Pharma in March 2022 for the Middle East and Africa for Alkindi.

Although Diurnal has made significant progress towards setting up the supply chain for Alkindi, revenue growth has been modest mainly due to the impact of the COVID-19 pandemic on patients' ability to visit hospitals and physicians' ability to switch patients to Alkindi. In another effort to push for Alkindi sales, in November 2021, Eton Pharmaceuticals (Diurnal's US partner for Alkindi Sprinkle) signed a co-promotion deal with Tolmar Pharmaceuticals to promote Alkindi Sprinkle to its targeted physicians. The deal is likely to be helpful in promoting the adoption of Alkindi Sprinkle in United States. As a reminder, Alkindi was approved in the United States in 2020. This agreement is

in addition to Eton's digital marketing campaign to raise awareness, indicating a significant focus on ramping up sales.

Efmody hits roadblock after SMC decision

Diurnal's second commercial product, Efmody, is a modified-release oral formulation of hydrocortisone for adults with CAH (measured by androgen), which is designed to closely mimic the natural circadian rhythm of cortisol release from the adrenal glands. Following European Economic Area and Great Britain approval in 2021, Diurnal launched Efmody in three of its key markets (Germany, the UK and Austria). Diurnal plans to use Alkindi's supply chain and distribution network for Efmody as well, and therefore most of its existing Alkindi distribution agreements have been extended to incorporate Efmody (eg Consilient Health in the Netherlands, ExCEEd in CEE countries, etc.).

In a discouraging development, in March 2022 the SMC announced it has not recommended Efmody for automatic reimbursement in NHS Scotland. The SMC indicates its decision was mainly due to Diurnal 'not presenting sufficiently robust clinical and economic analysis to gain acceptance by SMC'. The company plans to re-submit further clinical and health-economic data in the near future. A further opportunity to engage with SMC could be following results from the CHAMPAIN study for the treatment in AI, expected in late CY22, and discussed further below. Headline data for Efmody's Phase III clinical trial in US (also described below) in anticipated in H1 CY24 and may also provide Diurnal an opportunity to present its case. We expect to have more clarity on the product pipeline and commercialisation status at the R&D day in September 2022.

The SMC's decision will likely have a material impact on Efmody's UK roll-out plan as a number clinical commissioning groups within the UK rely on SMC. There is also a possibility that after the SMC decision, other reimbursement authorities' approvals might take longer, which may have a larger effect on overall Efmody sales forecasts; however, the recent reimbursement approval from Norway is a positive step. Ultimately, management guided that Efmody will not be able to meet the company's prior near-term sales expectations due to the SMC decision and the company also states there is a need for a further capital raise to reach profitability. Moreover, it now expects that for Efmody to become a profitable franchise, the product will require approval for the treatment of AI (which it expects in CY24).

Investors reacted to these events, as Diurnal's share price declined 20% on the day of the SMC announcement (7 March) and dropped a further 50% after Efmody guidance was downgraded with the H122 results.

In response, the company has shifted its near-term focus to the commercial launch of Efmody in other European markets and to exploring more distribution deals. In CY22, the product is likely to be launched in other important markets, such as Italy, Spain and the Netherlands. We remain confident about Diurnal's ability to scale up sales of its products in other territories in the near future, given the supply chain and distribution infrastructure is already in place.

Exhibit 2: Diurnal distribution partnerships/distribution agreements

Company	Territories	Products	Type of deal	Financials	Upfront/milestones
Eton Pharmaceuticals	US, Canada	Alkindi Sprinkle	License	Royalties + milestones	Upfront: $5m; Milestone: $47.5m
Rarestone	China	Alkindi and Efmody	License	Royalties + milestones	Upfront: $1.5m; Milestone: $41.5m
Er-Kim	Turkey, Bulgaria, Romania	Alkindi and Efmody	Distribution	Revenue share	-
Frost Pharma	Nordics	Alkindi	Distribution	Revenue share	-
Consilient Health	Nordics, Benelux	Alkindi and Efmody	Distribution	Revenue share	Undisclosed
Chiesi	Australia, New Zealand	Alkindi and Efmody	Distribution	Revenue share	-
Medison	Israel	Alkindi and Efmody	Distribution	Revenue share	-
EffRx	Switzerland	Alkindi	Distribution	Revenue share	-
Exceed Orphan	Central and Eastern Europe	Alkindi and Efmody	Distribution	Revenue share	-
Vector Pharma	Middle East and North Africa	Alkindi	Distribution	-	-

Source: Diurnal, Edison Investment Research

Management changes

On 4 April, Diurnal announced that Martin Whitaker (CEO and member of the board) has decided to step down from both roles with immediate effect to pursue other business opportunities. The CFO, Richard Bungay, has taken over as interim CEO until the company finds someone else. While the sudden departure of the CEO may provoke short-term investor anxiety, particularly after the SMC issues with Efmody and lowered guidance, we do not anticipate material changes to the roll-out strategy of Efmody/Alkindi in other markets in FY22.

Pipeline update

CONnECT study (DNL-0200)

After Efmody's approval in Europe, Diurnal is seeking to obtain approval for Efmody in the United States. Efmody (previously Chronocort, DNL-0200) is in a registration study for CAH in the United States called 'A randomised, double-blind, active-controlled, Phase 3 study of Chronocort compared with immediate-release hydrocortisone replacement therapy in participants aged 16-years and over with CAH' (CONnECT). The Phase III trial has been started; the first clinical site was opened for recruitment in December 2021, following a special protocol assessment with the FDA announced in July 2021. The trial will enrol up to 150 patients with CAH, who will be treated for 52 weeks.

The study design is complex. There is four weeks of screening followed by a four-week run-in period in which patients switch to immediate release hydrocortisone (IRHC) 30mg daily, before beginning the double-blind, placebo-controlled, 12-month treatment. The proposed primary endpoint is biochemical responder non-inferiority of Efmody twice daily versus twice daily IRHC after 52 weeks of randomised treatment. The company has estimated that the trial could be completed in 2023, with an NDA filing in 2024. This study will be accepted by the Japanese Pharmaceutical and Medical Devices Agency on the condition that a cohort of Japanese patients will also be included in the study. As a further step, the company intends to include sites in France and Turkey to maximise patient accrual rates. The first sites have been opened in United States for recruitment and management guides that the headline data will be released in H1 CY24.

CHAMPAIN study (DNL-0200)

Diurnal plans to develop and expand Efmody's franchise towards the related condition of AI (currently approved in CAH only) across Europe and the United States. Diurnal is working on Efmody's European Phase II study in AI, called the CHAMPAIN study. This European Phase II

study started against the approved product Plenadren in Europe; the first sites have been opened for recruitment and the first patient has been dosed. Phase II headline data are expected at end CY22. We believe a Phase III study will also be required for approval in this indication.

DITEST study (DNL-0300)

In addition to its hydrocortisone products, Diurnal is also developing a novel oral formulation of testosterone (DNL-0300, formerly called DITEST) for the treatment of hypogonadism. Oral testosterone supplements can avoid the issue of transference that gel-based products usually have. Currently available oral products use an undecanoate ester of testosterone, which dramatically improves bioavailability over uncodified testosterone by avoiding first-pass metabolism. However, testosterone undecanoate has a substantial food effect. The DNL-0300 product is a formulation of unmodified testosterone that seeks to avoid the issues of poor bioavailability (generally associated with unmodified testosterone) by using a proprietary, oil-based excipient mixture, and without a high fat meal requirement. After encouraging results reported in November 2019 from a Phase I study in the United States, the FDA confirmed that DNL-0300 can progress to a new drug application via the abbreviated 505(b)(2) route (which allows for accelerated time to approval compared to FDA-designated new chemical entities). In this route, Diurnal will be working on only two clinical studies, that is a Phase I multiple-ascending dose study and a single pivotal Phase III trial, before applying for marketing approval. The company submitted an Investigational new drug application (IND) in January 2022 and, in March 2022, received feedback from the FDA to resubmit a revised protocol as part of the IND filing for initiation of the Phase I clinical study, enabling it to potentially finalise the clinical trial design.

Exhibit 3: Diurnal's other assets in clinical trials

Candidate	Indication	Region	Clinical status	Estimated regulatory opinion	Annual addressable market
DNL-0200 (Modified-release hydrocortisone)	CAH	US	Phase III	2025	$0.1bn
	AI	Europe	Phase II	2024	$2.9bn
	AI	US	Phase I	2026	
DNL-0300 (Oral Native Testosterone)	Classical hypogonadism	US	Phase I	2026	$5.1bn
		Europe	Phase I	TBC	
DNL-0400 (Modified-release T3)	Hypothyroidism (T4 non-responders)	US	Pre-clinical	TBC	$0.7bn
		Europe	Pre-clinical	TBC	
DNL-0500 (Oligonucleotide therapy)	Cushing's disease	US	Pre-clinical	TBC	$0.5bn
		Europe	Pre-clinical	TBC	

Source: Diurnal, Edison Investment Research

Valuation

Given the company's disclosure that it only expects Efmody to become a profitable franchise once regulatory approval in AI is attained, which is not anticipated before CY24, we are placing our forecasts and valuation under review.

Exhibit 4: Financial summary

£000s	2020	2021
30-June	IFRS	IFRS
INCOME STATEMENT		
Sales	2390	2267
Royalties & Milestones	3923	2104
Revenue	6,313	4,371
Cost of Sales	(668)	(779)
Gross Profit	5,645	3,592
EBITDA	(5,151)	(11,125)
Operating Profit (before amort. and excepts.)	(5,176)	(11,149)
Amortisation of acquired intangibles	0	0
Exceptionals	627	15
Share-based payments	(843)	(466)
Reported operating profit	(5,392)	(11,600)
Net Interest	114	62
Joint ventures & associates (post tax)	0	0
Exceptionals	0	0
Profit Before Tax (norm)	(5,062)	(11,087)
Profit Before Tax (reported)	(5,278)	(11,538)
Reported tax	1,206	1,489
Profit After Tax (norm)	(3,905)	(9,656)
Profit After Tax (reported)	(4,072)	(10,049)
Minority interests	0	0
Discontinued operations	0	0
Net income (normalised)	(3,905)	(9,656)
Net income (reported)	(4,072)	(10,049)
Average Number of Shares Outstanding (m)	95	137
EPS - basic normalised (p)	(4.1)	(7.0)
EPS - normalised fully diluted (p)	(4.1)	(7.0)
EPS - basic reported (p)	(4.3)	(7.3)
Dividend (p)	0.0	0.0
BALANCE SHEET		
Fixed Assets	1,770	240
Intangible Assets	79	92
Tangible Assets	23	148
Investments & other	1,668	0
Current Assets	19,206	41,550
Stocks	1,241	1,625
Debtors	1,337	3,433
Cash & cash equivalents	15,434	34,037
Other	1,194	2,455
Current Liabilities	(2,555)	(4,163)
Creditors	(2,555)	(4,163)
Tax and social security	0	0
Short term borrowings	0	0
Other	0	0
Long Term Liabilities	(36)	(63)
Long term borrowings	0	0
Other long term liabilities	(36)	(63)
Net Assets	18,385	37,564
Minority interests	0	0
Shareholders' equity	18,385	37,564
CASH FLOW		
Operating Cash Flow	(5,151)	(11,125)
Working capital	(380)	(845)
Exceptional & other	(1,398)	109
Tax	2,120	1,199
Net operating cash flow	(4,809)	(10,662)
Capex	(45)	(163)
Acquisitions/disposals	0	0
Net interest	114	62
Equity financing	10,670	28,762
Dividends	0	0
Other	0	713
Net Cash Flow	5,930	18,712
Opening net debt/(cash)	(9,147)	(15,434)
FX	357	(109)
Other non-cash movements	0	0
Closing net debt/(cash)	(15,434)	(34,037)

Source: Diurnal, Edison Investment Research. Note: Diurnal's financial year end has changed to December, therefore, the next results will be interim.

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