EDISON

Diurnal Group

Regulatory update

Positive CHMP opinion on Chronocort/Efmody

Pharma & biotech

On 26 March 2021, the EMA announced a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) on granting a marketing approval for Efmody, Diurnal's formulation for controlled release hydrocortisone (developed under the name Chronocort) for the treatment of adults and adolescents aged 12 and over with congenital adrenal hyperplasia (CAH). Formal approval for the product is set to be June 2021 and Diurnal expects to begin commercialisation in calendar Q321.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
06/19	1.0	(13.6)	(18.6)	0.0	N/A	N/A
06/20	6.3	(5.1)	(4.1)	0.0	N/A	N/A
06/21e	5.0	(11.5)	(7.0)	0.0	N/A	N/A
06/22e	7.9	(17.8)	(9.9)	0.0	N/A	N/A

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

Diurnal to market Efmody directly in Europe

The positive opinion from CHMP likely ensures that Efmody will receive marketing authorisation in Europe. This will be Diurnal's second product to be approved in Europe; its first product, Alkindi, is its formulation of hydrocortisone for paediatric adrenal insufficiency (AI). Like Alkindi, the company stated that it intends to market Efmody directly in core European markets.

Official orphan status pending

The formal EMA approval decision is mostly a formality at this point. However, an official opinion on the orphan status of the product will also be announced at that time by the Committee of Orphan Medical Products (COMP). The product had orphan status during its development and substantiation of the claim would entitle it to 10 years of market exclusivity in Europe if CAH is viewed as a disease with a prevalence under 5 in 10,000. We believe that this is well supported by the literature on the disease.

Next steps: US approval and expansion to AI

In addition to the current application the company also has plans for US approval. It formally requested a special protocol assessment (SPA) meeting from the FDA; if granted, this should happen shortly (H121) and will provide clarity on the path forward in the United States. Additionally, Diurnal is planning a head-to-head study with the controlled release hydrocortisone product Plenadren to support an application for the broader indication of adult AI in Europe, to start as soon as 2021.

Valuation: Increased to £230.0m on Efmody upgrade

We have increased our valuation to £230.0m or 166p per basic share from £199.6m or 144p per basic share due to upgrades to our valuation of Efmody in Europe to £93.25m from £62.83m. We have increased the probability of success (100% from 80%) and decreased the discount (to 10% from 12.5%). We expect the company to need £25m in additional capital to reach profitability.

29 March 2021

Price	**89p**
Market cap	**£123m**
	$1.40/£
Net cash (£m) at 30 December 2020	20.3
Shares in issue	138.3m
Free float	45.9%
Code	DNL
Primary exchange	LSE
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	58.9	66.4	192.1
Rel (local)	53.1	59.9	141.8
52-week high/low		89p	28p

Business description

Diurnal Group is a speciality pharma company developing new formulations of hormone-based products for the treatment of endocrine disorders. Its product Alkindi is marketed for paediatric adrenal insufficiency in the United States and Europe, and it is seeking approval of Chronocort for the treatment of congenital adrenal hyperplasia. It has a novel oral testosterone DITEST entering patient dosing studies.

Next events

DITEST IND submission	Q221
Efmody launch	Q321

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Edison profile page

Efmody to receive marketing approval in Europe

Both the EMA and the company issued press releases announcing the positive opinion from CHMP on Diurnal's product Efmody during the committee's March 22–25 meeting. Efmody is the new trade name for the company's controlled release formulation of hydrocortisone for the treatment of CAH. The last step before marketing approval will be the affirmation of the approval decision by the EMA, which is scheduled for June 2021 based on the statutory timeline. At that time, the EMA will also affirm the product's orphan status, which will entitle it to 10 years of marketing exclusivity. We are confident that there are unlikely to be hang-ups in this process, and that it will receive official orphan status.

We are very pleased to see this positive opinion from CHMP, because we were confident based on the prior clinical data that the product could provide superior control of cortisol levels compared to existing treatments. However, there were some issues with the interpretation of the clinical data gathered in Phase III and the study officially missed its primary endpoint. Please see our initiation report for a more thorough discussion of the Phase III data. This endpoint finding increased the uncertainty of the current application, but we are now pleased that overhang has been removed.

CAH is a hormone deficiency caused by congenital mutations that prevent affected individuals from producing the hormone cortisol, a key regulator of alertness, mood, inflammation and many other systems. Moreover, these patients have a build-up of androgenic hormones like testosterone due to these mutations, which can cause a range of issues, especially in women. The disease is estimated to affect from 1/10,000 to 1/18,000 live births. Efmody was designed to achieve around the clock control of cortisol and androgen levels when administered once in the morning and once at night. It will be the second extended release hydrocortisone product approved in Europe (the other being Plenadren from Takeda), but the only product approved specifically for CAH. Based on the clinical data, Efmody should provide superior control of androgens compared to Plenadren, and Diurnal has stated the intent to study the two products head-to-head in future studies.

The next steps for Efmody are to start a series of clinical studies to expand its marketing reach, both in Europe as well as into the United States. The above head-to-head study with Plenadren would support a marketing application for the treatment of adult AI in Europe, and the study could start as soon as CY21. Diurnal has also submitted a request for a SPA meeting to the FDA. If granted, the SPA would provide concrete guidance on what endpoints need to be met for approvability. The company has guided to the meeting taking place in calendar Q121 and Diurnal is targeting starting a new US Phase III study in calendar H221.

Valuation

We have increased our valuation to £230.0m or 166p per basic share from £199.6m or 144p per basic share. This is driven exclusively by upgrades to our valuation of Efmody (formerly Chronocort) in Europe to £93.25m from £62.83m. We have increased the probability of success for the product to 100% (from 80%) in this geography, and we have reduced our discount rate to 10% (our standard for approved medical products) from 12.5% (our standard for unapproved products). Our peak sales and other aspects of our model remain unchanged. We expect the product to have initial sales in FY22/calendar Q321 in accordance with company guidance.

Exhibit 1: Valuation of Diurnal

Product	Indication	Geography	Clinical stage	Prob. of success	Launch year	Peak sales ($m)	rNPV (£m)
Alkindi	Paediatric AI	Europe	Approved	100%	2018	16	7.28
		US	Approved	100%	2020	10	4.70
Efmody (aka Chronocort)	Adult CAH	Europe	Approved	100%	2021	63	93.25
		US	Phase III	50%	2024	84	29.25
	Adult AI	Europe	Phase III	50%	2023	131	44.35
		US	Phase II	30%	2026	150	20.15
Ditest	Hypogonadism	US	Phase II	25%	2025	70	10.73
Total							209.69
Net cash and deposits (December 2020) (£m)							20.34
Total firm value (£m)							230.04
Total basic shares (m)							138.34
Value per basic share (p)							166
Dilutive options (m)							4.83
Total diluted shares (m)							143.17
Value per diluted share (p)							161

Source: Diurnal reports, Edison Investment Research

Financials

Our financial forecasts remain unchanged. We expect the company to require £25m in additional cash (in FY22) to advance its clinical programme before it achieves profitability (forecast in FY24).

Exhibit 2: Financial summary

£000s	2019	2020	2021e	2022e
Year end 30 June	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT				
Sales	1044	2390	3134	7802
Royalties & Milestones	0	3923	1876	137
Revenue	1,044	6,313	5,010	7,939
Cost of Sales	(224)	(668)	(2,324)	(720)
Gross Profit	820	5,645	2,686	7,219
EBITDA	(13,679)	(5,151)	(11,621)	(17,847)
Normalised operating profit	(13,701)	(5,176)	(11,646)	(17,872)
Amortisation of acquired intangibles	0	0	0	0
Exceptionals	0	627	0	0
Share-based payments	(825)	(843)	(843)	(843)
Reported operating profit	(14,526)	(5,392)	(12,489)	(18,715)
Net Interest	130	114	122	122
Joint ventures & associates (post tax)	0	0	0	0
Exceptionals	0	0	0	0
Profit Before Tax (norm)	(13,571)	(5,062)	(11,524)	(17,750)
Profit Before Tax (reported)	(14,396)	(5,278)	(12,367)	(18,593)
Reported tax	2,108	1,206	2,318	3,485
Profit After Tax (norm)	(11,584)	(3,905)	(9,363)	(14,422)
Profit After Tax (reported)	(12,288)	(4,072)	(10,048)	(15,107)
Minority interests	0	0	0	0
Discontinued operations	0	0	0	0
Net income (normalised)	(11,584)	(3,905)	(9,363)	(14,421)
Net income (reported)	(12,288)	(4,072)	(10,048)	(15,107)
Basic average number of shares outstanding (m)	62	95	134	145
EPS - basic normalised (p)	(18.6)	(4.1)	(7.0)	(9.9)
EPS - diluted normalised (p)	(18.6)	(4.1)	(7.0)	(9.9)
EPS - basic reported (p)	(19.7)	(4.3)	(7.5)	(10.4)
Dividend (p)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	82	1,770	1,826	1,826
Intangible Assets	49	79	79	79
Tangible Assets	33	23	79	79
Investments & other	0	1,668	1,668	1,668
Current Assets	13,381	19,206	19,233	31,474
Stocks	672	1,241	5,809	1,801
Debtors	1,457	1,337	1,235	1,958
Cash & cash equivalents	9,147	15,434	10,995	26,522
Other	2,105	1,194	1,194	1,194
Current Liabilities	(2,503)	(2,555)	(2,734)	(4,239)
Creditors	(2,503)	(2,555)	(2,734)	(4,239)
Tax and social security	0	0	0	0
Short term borrowings	0	0	0	0
Other	0	0	0	0
Long Term Liabilities	(16)	(36)	(36)	(25,036)
Long term borrowings	0	0	0	(25,000)
Other long term liabilities	(16)	(36)	(36)	(36)
Net Assets	10,944	18,385	18,290	4,025
Minority interests	0	0	0	0
Shareholders' equity	10,944	18,385	18,290	4,025
CASH FLOW				
Op Cash Flow before WC and tax	(13,679)	(5,151)	(11,621)	(17,847)
Working capital	(2,331)	(380)	(4,288)	4,791
Exceptional & other	(10)	(1,398)	0	0
Tax	2,279	2,120	2,318	3,485
Net operating cash flow	(13,741)	(4,809)	(13,590)	(9,570)
Capex	(62)	(45)	(81)	(25)
Acquisitions/disposals	0	0	0	0
Net interest	130	114	122	122
Equity financing	5,526	10,670	9,136	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(8,147)	5,930	(4,413)	(9,473)
Opening net debt/(cash)	(17,284)	(9,147)	(15,434)	(10,995)
FX	10	357	(26)	0
Other non-cash movements	0	0	0	0
Closing net debt/(cash)	(9,147)	(15,434)	(10,995)	(1,522)

Source: Diurnal reports, Edison Investment Research

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