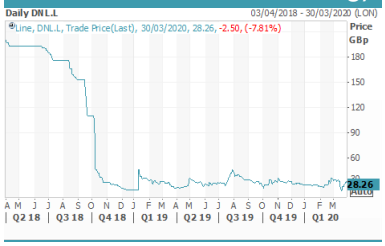
Pharmaceuticals & Biotechnology



Source: Refinitiv

Market data	
EPIC/TKR	**DNL**
Price (p)	**29.0**
12m High (p)	46.5
12m Low (p)	21.0
Shares (m)	121.6
Mkt Cap (£m)	35.3
EV (£m)	18.2
Free Float*	49%
Market	AIM

**As defined by AIM Rule 26*

Description

Diurnal is a European specialty pharma company targeting patient needs in chronic, potentially life-threatening, endocrine (hormonal) diseases. Alkindi is approved in Europe and has been filed in the US. Chronocort has completed the largest and only Phase III trial in CAH and is awaiting EMA approval.

Company information

CEO	Martin Whitaker
CFO	Richard Bungay
Chairman	Peter Allen
	+44 29 2068 2069
	www.diurnal.co.uk

Key shareholders

Directors	2.9%
IP Group	36.2%
Finance Wales	9.5%
Polar Capital	8.1%
Amati VCT	7.8%
Richard Griffiths	5.1%

Diary

1Q'20	DITEST presentation
Sep'20	Final results
29 Sep	Alkindi PDUFA date
1Q'21	Chronocort EMA approval

Analyst

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DIURNAL GROUP

$52.5m US deal strengthens balance sheet further

Diurnal is a commercial-stage specialty pharmaceutical company focused on diseases of the endocrine system. Its two lead products are targeting rare conditions where medical need is currently unmet, with the aim of building a long-term 'Adrenal Franchise'. Alkindi® is currently being rolled out through key European markets and has been submitted to the FDA for approval, with a PDUFA date set at 29 September 2020. Meanwhile, Diurnal has signed an exclusive US commercial deal with Eton Pharmaceuticals, a specialty pharma company focused on hospital and paediatric products. This, together with the recent Placing, has strengthened the balance sheet.

- **Strategy:** DNL's goal is to create a valuable 'Adrenal Franchise' that can treat patients with chronic cortisol deficiency diseases from birth and for the rest of their lives. The long-term vision, once Alkindi and Chronocort are established in Europe and the US, is to expand the product offering to other endocrine conditions.

- **Alkindi:** Diurnal has announced an exclusive US licensing agreement with Eton Pharmaceuticals (Eton) for the commercialisation of Alkindi Sprinkle, as it will be known. Eton is paying Diurnal $5m upfront, in cash and shares, and pre-set milestones worth up to $47.5m in total, plus royalties on net sales.

- **Placing:** This deal comes shortly after Diurnal concluded a successful Placing of 34.89m new Ordinary shares at 32p per share to raise gross funds of £11.2m (£10.7m net) to strengthen its balance sheet. These funds will be used predominantly to progress the commercialisation of Alkindi and Chronocort.

- **Risks:** Ideally, Diurnal would have liked to sign a deal that also included rights to Chronocort. Given the deal with Eton, this is now going to be a two-stage process and Diurnal will continue to seek a partner for the US development and commercialisation of Chronocort. This could be with Eton or another party.

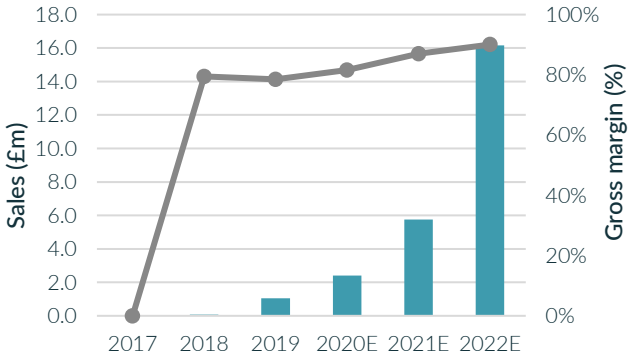
- **Investment summary:** The shares have been languishing for three reasons: global macroeconomics denting general market conditions; poor sentiment towards UK biotech; and the market's knowledge that Diurnal needed to strengthen its balance sheet. The recent Placing together with the Eton licensing deal have greatly strengthened its balance sheet and with several further announcements likely, the market should become more appreciative of the opportunity.

Financial summary and valuation

Year-end Jun (£000)	2017	2018E	2019	2020E	2021E	2022E
Sales	0.00	0.07	1.04	2.41	5.76	16.16
SG&A	-3.23	-6.21	-5.83	-5.50	-6.15	-7.53
R&D	-8.34	-10.02	-8.69	-4.78	-4.54	-5.90
EBITDA	-12.07	-16.97	-14.50	-5.16	-6.56	0.19
Underlying EBIT	-12.08	-16.98	-14.53	-5.18	-6.58	0.17
Reported EBIT	-12.08	-16.98	-14.53	-5.18	-6.58	0.17
Underlying PBT	-12.16	-17.11	-14.40	-5.13	-6.50	0.21
Statutory PBT	-12.16	-16.91	-14.40	-5.13	-6.50	0.21
Underlying EPS (p)	-18.04	-27.16	-14.54	-4.24	-4.44	1.35
Statutory EPS (p)	-18.04	-26.78	-19.70	-4.24	-4.44	1.35
Net (debt)/cash	16.37	17.28	9.15	15.82	8.48	7.76
Equity issues	0.05	13.40	5.53	10.70	0.00	0.00

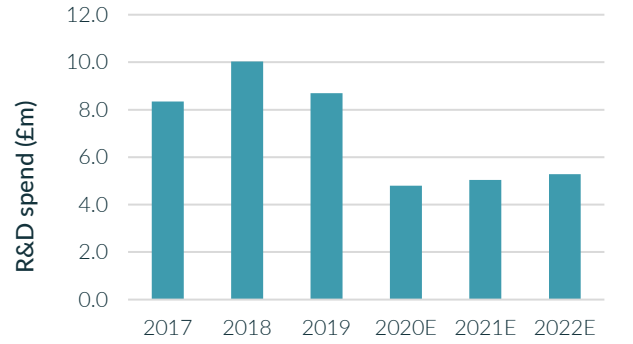
Source: Hardman & Co Life Sciences Research

Sales and gross margin



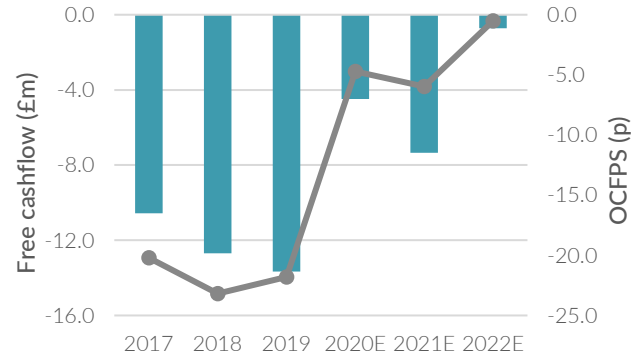
- Sales of Alkindi began in 2Q'18.
- Alkindi sales exceeded £1.1m in 1H'20 (fiscal), and Alkindi is now available in eight countries in Europe.
- Gross margin expected to stabilise at 90% in near term.
- First sales of Chronocort anticipated to start around end-2021 in Europe.

R&D investment



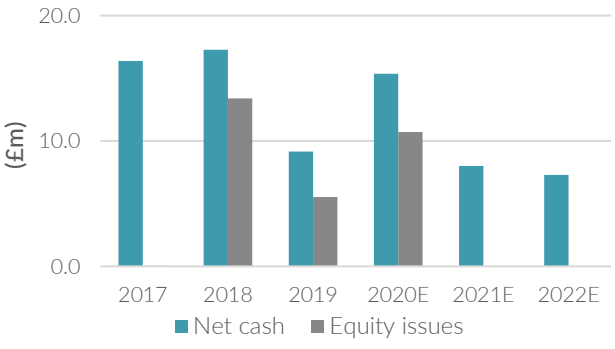
- Preparatory work for US Phase III trial (£2.3m) accounted for R&D fall between fiscal 2019 and fiscal 2020.
- R&D costs expected to reduce in coming years, as future trial costs will be shared with a US partner for Chronocort (still to be announced).
- US pivotal Phase II in AI with Chronocort now anticipated to start once a partner is on board.

Free cashflow and OFCPS



- Cashflow driven by R&D investment and corporate overheads.
- With the Chronocort US partner expected to share the US trial costs, the cashflow is forecast to improve with DNL becoming cashflow-positive in 2023.
- Monthly average cash burn at ca.£0.78m for 2020.

Net cash and equity issues



- Gross and net cash was £4.63m at 31 December 2019.
- Placing to raise £11.2m gross (£10.7m net) concluded on 27 March 2020.
- $3m/£2.4m received as upfront cash payment from Eton on signing exclusive Alkindi deal.
- Further Alkindi milestones due during calendar 2020; and upfront payments from potential US Chronocort partner(s).

Source: Company data; Hardman & Co Life Sciences Research

Alkindi US licensing deal

Strategy to out-licence in the US to maximise commercial opportunity…

…has concluded with a deal with specialist pharma, Eton, for Alkindi

Diurnal had a stated strategy to engage with a specialty pharma partner with expertise in endocrinology in order to maximise the commercial potential of Alkindi in the US. Ideally, Diurnal was looking to conclude a deal which encompassed both Alkindi and Chronocort. However, whereas the situation with Alkindi is straight forward, with all the trials completed and the drug under FDA review, any deal for Chronocort is more complex, with a pivotal trial still needed for filing. Consequently, Diurnal has adopted a two-stage process, on the one-hand concluding a deal for Alkindi, while continuing to negotiate a development and licensing deal for Chronocort. This could be either with Eton again, or with another party.

Terms of the deal

Traditional pharma deal with upfront, milestones and royalties…

…with a headline potential value of $52.5m

The exclusive deal announced with Eton for Alkindi has a headline value of $52.5m plus royalties. As is usual with such a deal, it is a combination of an upfront payment to reflect the work that Diurnal has already invested in, and pre-set sales milestones. In addition, Diurnal will receive tiered royalties, in the low double-digit to high-teens percentage range, based on net sales. Diurnal retains the responsibility for getting Alkindi through the regulator, while Eton will be responsible for all the commercial aspects, including pricing and reimbursement. The full terms of the deal are provided in the following table.

Terms of Eton deal

Term	Condition	Value
Upfront cash	Received on signing	$3.5m
Upfront shares in Eton	379,474 shares @ $3.95	$1.5m
Total upfront		**$5.0m**
Milestone 1 – cash	First commercial sale	$2.5m
Sales-based milestones – cash	Subject to pre-defined annual sales thresholds	Up to $45m
Royalties on net sales	Tiered % – low double digit to high teens	
Total potential value		**Royalties + up to $52.5m**

Source: Diurnal, Hardman & Co Life Sciences Research

Status of Alkindi

Alkindi was accepted for review in February 2020…

…and the PDUFA date has been set at 29 September 2020

Alkindi is an immediate-release hydrocortisone preparation for the control of adrenal insufficiency (AI), including congenital adrenal hyperplasia (CAH), in children. Alkindi was approved by the European Medicines Agency (EMA) in February 2018 for the treatment of newborns to 18-year-olds and is currently being rolled out across Europe. Diurnal submitted a New Drug Application (NDA) with the US Food and Drug Administration (FDA) in November 2019, which was accepted for review in February 2020. The Prescription Drug User Fee Act (PDUFA) date, the earliest possible approval date, has been set at 29 September 2020.

Alkindi – current status

Territory	Status	Comments
Europe	Approved	DNL selling/distributing Alkindi itself in main European countries, and uses partners in territories that recognise EMA market authorisation
US	NDA filed with FDA	NDA submission accepted by FDA; approval due end-3Q'20 and end-4Q'20 (PDUFA date 29 September 2020). DNL will use Eton to commercialise Alkindi in the US

Source: Diurnal, Hardman & Co Life Sciences Research

Diurnal is also seeking Orphan Drug status in AI

In parallel with its NDA submission, DNL is seeking confirmation that Alkindi has Orphan Drug Status in paediatric AI. In order to achieve this, the company will need to provide evidence of significant clinical benefit over existing therapies.

Eton Pharmaceuticals

Eton listed on NASDAQ in November 2018…

…raising $22.0m of cash, which reduced to $12.1m at 31 December 2019

Specialty pharma company with nine other in-licensed drugs in its portfolio

Eton was founded in April 2017 as a US-based specialty pharmaceutical company focused on developing innovative formulations of drugs for use, predominantly, in the hospital, specialist clinic or paediatric settings. All of its products have been in-licensed from other companies. Consequently, the deal with Diurnal fits well with its stated strategy. Eton was listed on NASDAQ (ETON.OQ) in November 2018, raising gross new capital of $22.0m. In its latest accounts to 31 December 2019, Eton had gross cash of $12.1m and long-term debt of -$4.5m.

Including Alkindi, Eton has 10 products – one approved, four filed with the FDA, and five expected to be filed during 2020 – which are listed below. Biorphen, in-licensed from Sintetica SA, is the first and only FDA-approved formulation of ready-to-use phenylephrine injection for the treatment of hypotension resulting primarily from vasodilation in the setting of anaesthesia; it was launched in December 2019.

Eton Pharmaceuticals – product portfolio

Drug	Generic	Indication	Formulation	Category	FDA status/ action date	*Sales potential ($m)
Biorphen	Phenylephrine	Hypotension	Injection	Hospital	Approved	45.0
ET-100	Ketotifen	Allergic conjunctivitis	Ophthalmic	OTC**	Filed/Aug'20	50.0
Alkindi Sprinkle	Hydrocortisone	Adrenal insufficiency	Oral (granules)	Paediatric	Filed/Sep'20	
DS-300			Injectable	Hospital	Filed/Oct'20	60.0
ET-105	Lamotrigine	Epilepsy	Oral (liquid)	Paediatric	Re-submit 2020	700.0
ET-104			Oral (liquid)	Paediatric	Filing 2020	65.0
ET-103	Levothyroxine	Hypothyroidism	Oral (liquid)	Paediatric	Filing 2020	2.5
ET-203			Injection	Hospital	Filing 2020	70.0
DS-101			Injection	Hospital	Filing 2020	100.0
ET-101		Neurology	Oral (liquid)	Paediatric	Filing 2020	800.0

**Market size of reference product; **Product will be marketed by Bausch Health*
Source: Eton Pharmaceuticals

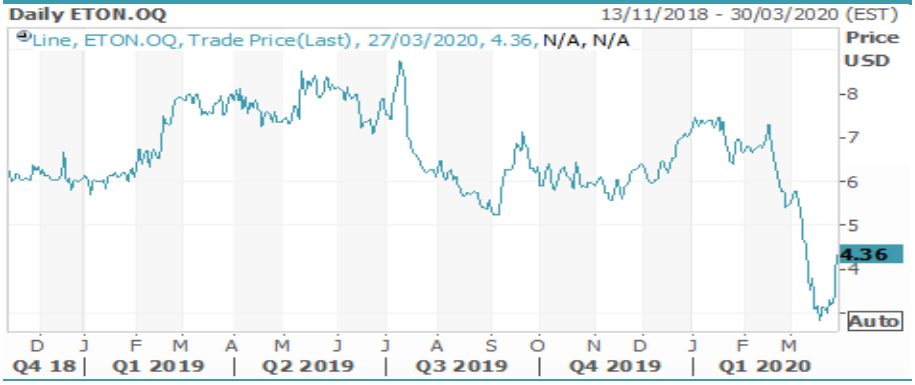
The FDA has set the PDUFA date for Alkindi Sprinkle at 29 September 2020

Alkindi will complement Eton's existing portfolio of paediatric drugs. In February 2020, Diurnal announced that the FDA had accepted its NDA for Alkindi in its Sprinkle formulation for review. Diurnal is seeking approval of Alkindi in the US as a replacement therapy for adrenal insufficiency in infants, children and adolescents (from birth to <17 years old). The PDUFA date set by the FDA, which would be the earliest date on which approval could occur, is 29 September 2020. Eton will be responsible for all commercialisation activities, including pricing and reimbursement.

Eton's share price responded positively to news, giving the company a market cap of $79.6m

Eton now has 18.26m shares in issue, giving it a market capitalisation of $79.6m based on its share price at the close of business on 27 March 2020 which responded very favourably to the announcement, rising 31% compared with the previous close.

Eton Pharmaceuticals – share price performance



Source: Refinitiv

Recent Placing

The need to strengthen its balance sheet was clear

Diurnal had gross (and net) cash of £4.63m 31 December 2019 and, based on forecasts, we concluded that the company would need a cash injection of about £10m during the next six months to cover the working capital requirement for fiscal 2021 – see our research report on the interim results, *…and more to come*, published on 28 February[1]. In this publication, we suggested that the cash could come from an upfront payment as part of any US licensing deal(s) and/or from one or more equity issues.

High demand in a Placing of shares announced and concluded on 6 March…

…raising net proceeds of £10.7m

On 6 March, Diurnal announced its intention to raise a minimum of £7.0m through a Placing of new Ordinary shares at 32p per share, a modest 4.5% discount to the mid-market closing price from the previous day. Institutional demand was high, such that, later in the day, the company was able to announce that it had raised a total of £11.2m gross (£10.7m net) through the issue of 34.89m shares in the Placing. The issue was conditional on approval at a General Meeting of shareholders, which was held on 25 March. Following approval of all the resolutions, the enlarged share capital now consists of 121, 620,424 Ordinary shares.

At the time of writing, stock exchange announcements indicated that the following existing institutional shareholders participated in the Placing: IP Group (IPO.L) increased its holding to 44.1m shares, but now has a lower percentage of the enlarged share capital at 36.2% (was 40.0%) and Polar Capital maintained its stake at 8.1%. New shareholder, Amati VCT fund, purchased 9.5m shares (7.8%) in the Placing.

Use of proceeds

Most of the proceeds will be used to support the group's activities in relation to Alkindi and Chronocort, although some will be used to progress products at an earlier stage of development. The Circular to shareholders highlights that the new funds will be used to:

- continue development of the European commercial organisation and rollout of Alkindi in Europe;
- commence market access activities for Chronocort in Europe ahead of anticipated approval in 1Q calendar 2021;
- strengthen the balance sheet in connection with licensing discussions for Alkindi and Chronocort in the US and the rest of the world; and
- progress the early-stage pipeline into clinical trials, including proof-of-principle studies and further development of DITEST™, its native oral testosterone formulation.

Updated balance sheet

Estimated gross (and net) cash of £15.0m today

This placing, together with the cash element of the US licensing deal for Alkindi, has left Diurnal much better positioned, with estimated gross cash of about £17.0m today. Given that the company will probably have some upcoming US expenditure in $, the $3.5m upfront cash payment by Eton might be retained in a $ account (largely dependent on short-term forex opportunities that might arise). In addition, Diurnal will have a non-core shareholding in Eton, which could be sold should an opportunity/need arise, although it should be stressed that this holding is currently considered to be a long-term investment to provide exposure from the anticipated successful launch of Alkindi.

In the event that a US partnership deal for Chronocort takes longer or is difficult to achieve on good terms, the bigger decision for Diurnal's management will be whether to start the pivotal trial in the US still needed for FDA approval.

[1] https://www.hardmanandco.com/wp-content/uploads/2020/02/Diurnal-Interim-update-28-Feb-2020.pdf

Financial summary

- **Forecasts:** No changes to operating forecasts since our interim results note published on 28 February[1].
- **Eton deal:** Diurnal will supply Eton with finished product only, at cost. All US commercial costs will be borne by Eton.
- **Net cash:** Forecasts have been adjusted to reflect the Placing of shares (27 March) and the upfront payment from Eton.
- **Shares in issue:** The enlarged share capital is 121.62m Ordinary shares.
- **Investment in Eton:** At each period-end, Diurnal's shareholding in Eton (379,474 shares) will be priced-to-market and any gains/losses, together with any forex adjustment, will be carried through the P&L account.

Diurnal – Financial summary						
Year-end Jun (£m)	2017	2018	2019	2020E	2021E	2022E
Profit & Loss						
Sales	0.00	0.07	1.04	2.41	5.76	16.16
COGS	0.00	-0.02	-0.22	-0.45	-0.75	-1.61
Selling & distribution	-2.08	-5.21	-4.51	-4.00	-4.60	-5.75
Admin expenses	-1.15	-1.00	-1.33	-1.50	-1.55	-1.78
Share-based costs	-0.52	-0.81	-0.83	-0.87	-0.91	-0.96
R&D	-8.34	-10.02	-8.69	-4.78	-4.54	-5.90
Underlying EBIT	**-12.08**	**-16.98**	**-14.53**	**-5.18**	**-6.58**	**0.17**
Share-based costs	-0.52	-0.81	-0.83	-0.87	-0.91	-0.96
Exceptional items	0.00	0.00	0.00	0.00	0.00	0.00
Statutory EBIT	-12.08	-16.98	-14.53	-5.18	-6.58	0.17
Underlying pre-tax profit	**-12.16**	**-17.11**	**-14.40**	**-5.13**	**-6.50**	**0.21**
Tax liability/credit	2.73	2.28	2.11	1.16	1.10	1.43
Weighted average (m)	52.24	54.60	62.39	93.80	121.62	121.62
Underlying basic EPS (p)	**-18.04**	**-27.16**	**-14.54**	**-4.24**	**-4.44**	**1.35**
Balance sheet @30 Jun						
Share capital	0.00	0.00	0.00	0.00	0.00	0.00
Reserves	14.46	13.81	6.72	13.44	8.04	9.68
Loans/debt	0.00	0.00	0.00	0.00	0.00	0.00
***less:* Cash**	**19.88**	**17.28**	**9.15**	**15.82**	**8.48**	**7.76**
Invested capital	0.71	-0.40	1.80	1.85	3.78	6.14
Cashflow						
Underlying EBIT	-12.08	-16.98	-14.53	-5.18	-6.58	0.17
Change in working capital	1.09	0.66	-2.33	-1.78	-2.79	-3.05
Company op. cashflow	-10.74	-15.50	-16.01	-6.07	-8.44	-1.91
Tax received/(paid)	0.00	2.74	2.28	2.10	1.13	1.27
Capital expenditure	-0.02	-0.02	-0.03	-0.03	-0.04	-0.04
Free cashflow	-10.57	-12.69	-13.66	-4.02	-7.34	-0.72
Equity issues	0.05	13.40	5.53	10.70	0.00	0.00
Change in net debt	**-10.51**	**0.91**	**-8.14**	**6.68**	**-7.34**	**-0.72**
Opening net cash	26.88	16.37	17.28	9.15	15.82	8.48
Closing net cash	**16.37**	**17.28**	**9.15**	**15.82**	**8.48**	**7.76**

Source: Hardman & Co Life Sciences Research

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In particular, Article 12(3) of the Directive states: 'The following benefits shall qualify as acceptable minor non-monetary benefits only if they are: (b) 'written material from a third party that is commissioned and paid for by a corporate issuer or potential issuer to promote a new issuance by the company, or where the third party firm is contractually engaged and paid by the issuer to produce such material on an ongoing basis, provided that the relationship is clearly disclosed in the material and that the material is made available at the same time to any investment firms wishing to receive it or to the general public…'

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The full detail is on page 26 of the full directive, which can be accessed here: http://ec.europa.eu/finance/docs/level-2-measures/mifid-delegated-regulation-2016-2031.pdf

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