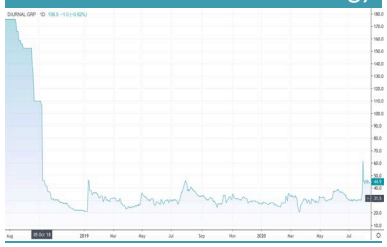
Pharmaceuticals & Biotechnology



Source: Refinitiv

Market data	
EPIC/TKR	**DNL**
Price (p)	**44.0**
12m High (p)	62.0
12m Low (p)	21.5
Shares (m)	122.0
Mkt Cap (£m)	53.7
EV (£m)	33.3
Free Float*	48%
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 (int.)	Sam Williams

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www.diurnal.co.uk

Key shareholders

Directors	2.6%
IP Group	36.1%
Finance Wales	9.4%
Polar Capital	8.1%
Amati VCT	7.8%
Richard Griffiths	4.7%

Diary

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

Analyst

Martin Hall 020 7194 7622
mh@hardmanandco.com

DIURNAL GROUP

Flow of regulatory approvals

Diurnal is a commercial-stage specialty pharmaceutical company focused on diseases of the endocrine system. Its products are targeting rare conditions where medical need is currently unmet, with the long-term aim of building an "Adrenal Franchise". Alkindi® is currently being rolled out throughout Europe, and recent approvals in Israel and Australia will open up more markets. Approaching next month, all attention will turn towards the US, where the PDUFA date has been set for 29 September. Upfront cash from the US commercial deal with Eton Pharmaceuticals (Eton), together with the recent Placing, has strengthened the balance sheet.

- **Strategy:** Diurnal'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.

- **Trading update:** Diurnal has announced that Alkindi sales increased 130% to £2.39m (£1.04m) in fiscal 2020. The $3.5m cash upfront payment from Eton, together with the recent £11.2m (gross) Placing, has left the company with £15.4m cash at 30 June, about £0.8m higher than our forecast (adjusted).

- **Regulatory update:** Diurnal has received regulatory approval of Alkindi in both Israel and Australia; it will be launched in 2021 by partners Medison and Emerge, respectively. Attention over the next month will be focused on the PDUFA date, where Alkindi will be considered by the FDA advisory committee.

- **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.

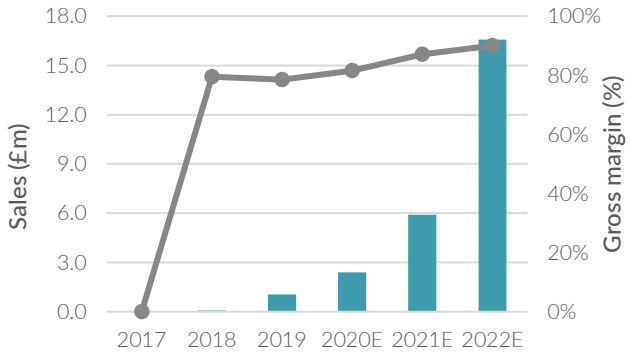
- **Investment summary:** Diurnal has not participated in the recent COVID-19-related biotech bounce, despite all the recent good news. A positive recommendation for approval from the FDA advisory committee in September would be a significant step forward and signal likely approval form the FDA, which would represent a significant value inflection point.

Financial summary and valuation

Year-end Jun (£m)	2017	2018	2019	2020E	2021E	2022E
Sales	0.00	0.07	1.04	2.39	5.91	16.58
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	-14.51	-6.32	-6.38	0.62
Underlying EBIT	-12.08	-16.98	-14.53	-6.40	-6.45	0.54
Reported EBIT	-12.08	-16.98	-14.53	-5.94	-6.45	0.54
Underlying PBT	-12.16	-17.11	-14.40	-6.35	-6.38	0.58
Statutory PBT	-12.16	-16.91	-14.40	-5.89	-6.38	0.58
Underlying EPS (p)	-18.04	-27.16	-14.54	-5.53	-4.32	1.65
Statutory EPS (p)	-18.04	-26.78	-19.70	-5.04	-4.32	1.65
Net (debt)/cash	16.37	17.28	9.15	15.40	7.73	7.53
Equity issues	0.05	13.40	5.53	11.20	0.00	0.00

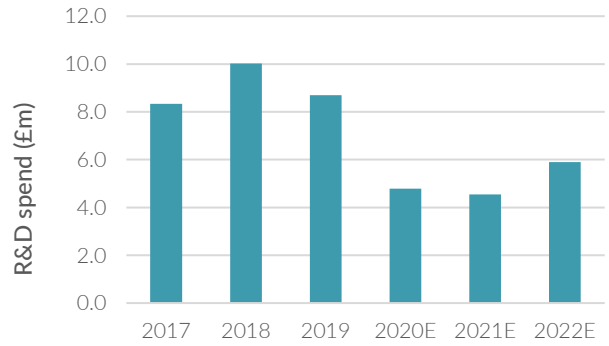
Source: Hardman & Co Life Sciences Research

Sales and gross margin



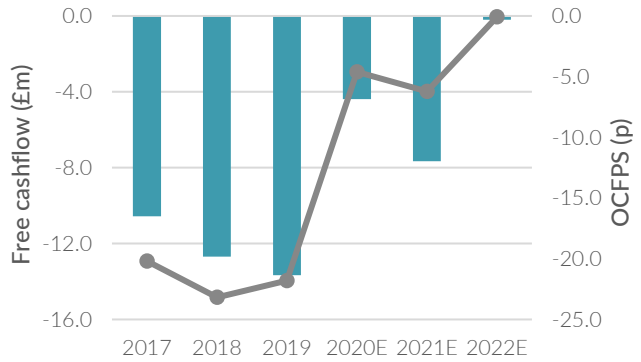
- Sales of Alkindi began in 2Q'18.
- Alkindi sales were £2.39m in fiscal 2020, and Alkindi is now available in eight countries in Europe.
- The gross margin is expected to stabilise at 90% in the near/medium term.
- First sales of Chronocort are anticipated to start at around end-2021 in Europe.

R&D investment



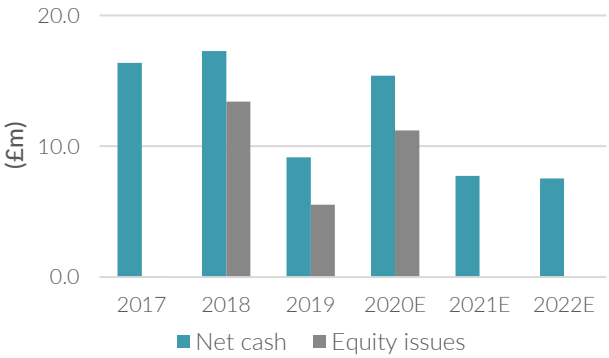
- Preparatory work for the US Phase III trial (£2.3m) accounted for the R&D fall between fiscal 2019 and fiscal 2020.
- R&D costs are expected to reduce in coming years, as future trial costs will be shared with a US partner for Chronocort (still to be announced).
- The US pivotal Phase II in adrenal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

Free cashflow and OFCPS



- Cashflow is 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.
- The monthly average cash burn is estimated at ca.£0.7m for 2020.

Net cash and equity issues



- Gross and net cash was £15.4m at 30 June 2020.
- In March 2020, Diurnal undertook a Placing to raise £11.2m gross (£10.7m net).
- $3.5m/£2.4m was received as an upfront cash payment from Eton on signing the exclusive Alkindi deal.
- Further Alkindi milestones are due during calendar 2020, as well as upfront payments from potential US Chronocort partner(s).

Source: Company data, Hardman & Co Life Sciences Research

2020 trading update

At the end of July, Diurnal updated the market on the financial key performance indicators for its fiscal year 2020, which ended in June. In addition, it emphasised a number of operational highlights that have occurred during the period.

Financial features

- **Sales:** Total Diurnal/Alkindi revenues in fiscal 2020 increased 130% to £2.39m (£1.04m), which was in line with our forecasts. While most of this growth has been derived from Germany and the UK, Alkindi is now fully launched also in Italy, Austria, Sweden, Norway, Denmark and Iceland.
- **Cash:** At the end of June, Diurnal's cash balance was £15.4m. This was £0.8m higher than our forecast of £14.6m, adjusted for the higher-than-expected capital increase and the $3.5m/£2.8m cash upfront receipt from Eton (see below).

Diurnal – 2020 results, actual vs. expectations

Year-end Jun (£m)	2019 actual	2020 actual	Growth %	2020 forecast	Delta Δ
Sales	1.04	2.39	130%	2.41	-0.02
Net cash/(debt)	9.2	15.4	-	14.6	+0.8

Source: Company data, Hardman & Co Life Sciences Research

2020-21 milestones

PDUF review in US on 29 September next most significant event

Earlier this year, we highlighted[1] that Diurnal was going to be characterised by several important milestones over the next two years, many with significant value inflection points. Several of these have now been achieved, most notably the conclusion of a licensing deal to commercialise Alkindi in the US with Eton. Latterly, two regulatory approvals have been received, in Israel and Australia. However, the pending PDUFA review in the US on 29 September is the next most significant event.

2020-21 news flow

Timeline	Event	Status
13 Jan	FDA acceptance of Alkindi NDA	✓
6 Mar	Placing to raise gross new capital of £11.2m	✓
27 Mar	US partnering deal with Eton for Alkindi	✓
1 Apr	Chronocort validation stage passed by EMA	✓
30 Jul	DITEST regulatory pathway agreed with US FDA	✓
5 Aug	Regulatory approval of Alkindi in Israel	✓
10 Aug	Regulatory approval of Alkindi in Australia	✓
29 Sep	Alkindi PDUFA date	
2H'20	Conclude US development and commercialisation deal for Chronocort	
1Q'21	Potential approval of Chronocort in Europe	

Source: Company data, Hardman & Co Life Sciences Research

COVID-19

Given that most of the company's activities are outsourced, Diurnal is well positioned to minimise the impact of COVID-19. It has sufficient supplies of Alkindi to satisfy foreseeable demand across all its European territories.

[1] https://www.hardmanandco.com/research/corporate-research/and-more-to-come-news-flow/

Alkindi approvals

Approved in Israel

Approval in Israel took eight months…

…with launch expected in 1Q'21

On 5 August, Diurnal announced that Alkindi had received approval from the Ministry of Health in Israel as a replacement therapy of AI in infants, children and adolescents (from birth to <18 years of age). This had been largely expected, as the submission was filed with this regulator in December 2019.

In 2018, DNL signed a marketing and distribution agreement with Medison Pharma (Medison) to exploit the commercial opportunities for both Alkindi and Chronocort (once approved) in Israel and the Palestinian Authority. Medison provides a spectrum of integrated services for companies looking to enter the Israeli healthcare market, and, more specifically, the niche indications such as AI and congenital adrenal hyperplasia (CAH). Diurnal anticipates the first sales in Israel will be in 1H'21, following completion of pricing and market access activities by Medison. Israel has an affected population of ca.1,000 patients, which would generate a market opportunity of ca.$7m.

Approved in Australia

Approval in Australia took 12 months…

…with launch expected in 2H'21

On 10 August, Diurnal announced that Alkindi had received approval from the Australian Therapeutic Goods Administration (TGA) as a "*Replacement therapy of adrenal insufficiency*", with no age restriction. Again, this news had been largely expected, given that the submission was filed with this regulator in July 2019.

In 2018, Diurnal licensed exclusive commercial rights to both Alkindi and Chronocort in Australia and New Zealand to Emerge Health (Emerge), a specialist hospital pharma company. In Australia, Alkindi has been granted orphan drug status, which provides significant regulatory benefits, including waiver of application and evaluation fees. Diurnal anticipates that the first sales in Australia will be in 2H'21, following completion of pricing and market access activities. Around 1,750 patients are thought to be affected by paediatric AI and CAH, giving a commercial opportunity of ca.$11m. Emerge will now pursue approval in New Zealand.

US PDUFA date set

Diurnal becomes only third AIM company to have reached this milestone

In November 2019, Diurnal filed its first-ever New Drug Application (NDA) with the FDA for Alkindi (Alkindi Sprinkle) in paediatric AI and CAH (from birth to 17 years of age), joining an elite few AIM companies to have reached this milestone. This submission was accepted for review by the FDA, and a PDUFA date of 29 September 2020 has been scheduled, in line with the 10-month period set for the review of NDAs. On the basis of a successful vote by the specialist advisory committee, approval could come in 4Q'20.

Concomitant with this process, Diurnal has been seeking confirmation of Orphan Drug Status for Alkindi in paediatric AI. To achieve this, the company will need to provide evidence of significant clinical benefit over existing therapies.

On 27 March, Diurnal announced that it had signed an exclusive US commercial deal with Eton[2], a specialty pharma company focused on hospital and paediatric products, in order to maximise its commercial opportunity. On a conservative basis, we estimate this opportunity to be ca.$30m, but Eton believes it could be as much as $100m (Eton website), indicating considerable upside potential to forecasts. In its 2Q'20 results announcement[3], Eton stated that it is "*confident of approval…is working aggressively on launch preparation activities… and expects to be in position to launch the product shortly after the PDUFA date, if approved*".

[2] https://www.hardmanandco.com/research/corporate-research/52-5m-us-deal-strengthens-balance-sheet-further/
[3] https://ir.etonpharma.com/news-releases/news-release-details/eton-pharmaceuticals-announces-second-quarter-2020-financial

Cash position

Eton Pharmaceuticals (ETON.OQ)

Eton listed on NASDAQ, and had gross cash of $10.3m at 30 June 2020

Eton is a specialty pharmaceutical company focused on in-licensing innovative formulations of drugs for use, predominantly, in the hospital, specialist clinic or paediatric settings. Its deal with Diurnal for Alkindi is entirely consistent with this strategy and will complement Eton's existing portfolio of paediatric drugs.

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

US approval for Alkindi, in its Sprinkle formulation, is being sought as a replacement therapy for adrenal insufficiency in infants, children and adolescents (from birth to <17 years of age). 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.

Value of Diurnal's Eton shareholding has risen almost 100% to $2.9m since acquisition

Diurnal received $1.5m of its $5.0m upfront payment in the form of Eton stock – 379,474 shares at $3.95 a share. Since the announcement, Eton shares have performed strongly, trading at $7.8 (close of business 10 August 2020), giving Diurnal an unrealised gain of $1.4m (+97%), on the assumption that it is still holding the shares.

Eton Pharmaceuticals – share price performance

Source: Refinitiv

Placing

Diurnal's gross cash position at the period-end was also helped by strong demand for its Placing in March. The company intended, originally, to raise a minimum of £7.0m. However, high institutional demand allowed the company to increase the size of the offering to £11.2m gross (£10.7m net) through the issue of 34.89m shares at 32p.

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. Some of the proceeds are likely to be used to progress DITEST now that its US development programme has been clarified with the FDA (see next section).

Net cash at 30 June

Cash of £15.4m at end-June

The Placing, together with the cash element of the US licensing deal for Alkindi, has left Diurnal better positioned, with gross/net cash at 30 June stated to be £15.4m.

In addition, it has considerable flexibility through its 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.

DITEST™

Clear regulatory pathway

Positive Phase I trial results with DITEST…

As part of the group's strategy to evolve into a leading specialty endocrine company, Diurnal has been developing DITEST, its novel native oral testosterone formulation, for the treatment of hypogonadism. In November 2019, the company published results from a Phase I proof-of-concept trial to evaluate the pharmacokinetic (PK, i.e. level of testosterone) characteristics of DITEST, and to assess the safety and tolerability of the drug, in a target patient group of 24 adult men with primary or secondary hypogonadism.[4]

…led to a meeting with FDA…

Following the successful outcomes, where both the primary and secondary endpoints were met, Diurnal sought confirmation of the regulatory pathway for DITEST from the FDA. At a pre-Investigational New Drug (IND) meeting with the US regulator, the FDA confirmed that DITEST could progress to a an NDA via the 505(b)(2) route – approval of pharmaceutical products that incorporate an already approved pharmacological agent. As a consequence, the future development programme for DITEST will comprise only two further clinical studies to support its regulatory submission:

…resulting in less onerous clinical trial programme for approval

- a multiple ascending dose study; followed by
- a single pivotal Phase III trial.

It is anticipated that data from the pivotal trial will be available in 2024. In line with the stated streamlined provisions of the 505(b)(2) regulatory pathway, this programme significantly accelerates the timeline to DITEST's potential approval and at a greatly reduced cost.

Market opportunity

Global TRT market estimated to be worth $4.8bn

DITEST is an oral testosterone-replacement therapy (TRT) that provides a more convenient route of administration and in a formulation that avoids hepatic toxicity. The current market is highly fragmented, with a number of TRT products that encompass oral administration, topical application and other routes, and is valued globally at $4.8bn. Topical formulations tend to be inconvenient and messy, while the effectiveness of oral formulations is influenced by the variability in absorption rates and requires a high-fat meal to achieve therapeutic testosterone levels. Even a small share of this market would generate a level of DITEST sales that would have a significant positive impact on Diurnal.

Main testosterone replacement modalities

Product type	Delivery	Regimen	Advantages	Disadvantages
Testosterone undecanoate	Oral	40-80mg, 2-3 times daily with meal	Convenient	Variable testosterone levels and clinical responses, nausea, high DHT/T ratio
Buccal testosterone	Buccal	30mg controlled release	Convenient	Taste disturbance, gum irritation and potential transfer to partner
Testosterone esters	Intramuscular	Regimen dependent on the ester	Low-cost, self-administration, corrects hypogonadal symptoms	Highly variable pharmacokinetics, fluctuation in libido and mood, pain at injection site
Testosterone patch	Transdermal	4-8mg applied nightly to skin	Convenient, mimics circadian rhythm	Skin irritation in 66% of men, sweating interference with patch adherence,
Testosterone gel	Transdermal	5-10mg daily	Convenient, mimics circadian rhythm, good skin tolerability	Potential transfer to partner, skin irritation, need to cover application site

Source: adapted from Carson Schlich et al 2016, Hosp. Pharm. 51(9), 712-720

[4] https://www.hardmanandco.com/research/corporate-research/successful-ditest-phase-i-trial-outcome/

Financial summary

- **Forecasts:** No changes have been made to our operating forecasts since our interim results note published on 28 February.[1]
- **Eton deal:** Diurnal will supply Eton with a finished product only, at cost. All US commercial costs will be borne by Eton.
- **Net cash:** Our forecasts have been adjusted to reflect the Placing of shares (27 March) and the upfront cash payment from Eton.
- **Shares in issue:** The enlarged share capital is currently 122.0m 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. For fiscal 2020, we estimate the gain to be £0.46m.

Diurnal – financial summary

Year-end Jun (£m)	2017	2018	2019	2020E	2021E	2022E
Profit & Loss						
Sales	0.00	0.07	1.04	2.39	5.91	16.58
COGS	0.00	-0.02	-0.22	-0.44	-0.77	-1.65
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**	**-6.40**	**-6.45**	**0.54**
Share-based costs	-0.52	-0.81	-0.83	-0.87	-0.91	-0.96
Exceptional items	0.00	0.00	0.00	0.46	0.00	0.00
Statutory EBIT	-12.08	-16.98	-14.53	-5.94	-6.45	0.54
Underlying pre-tax profit	**-12.16**	**-17.11**	**-14.40**	**-6.35**	**-6.38**	**0.58**
Tax liability/credit	2.73	2.28	2.11	1.16	1.10	1.43
Weighted average (m)	52.24	54.60	62.39	93.90	122.02	122.02
Underlying basic EPS (p)	**-18.04**	**-27.16**	**-14.54**	**-5.53**	**-4.32**	**1.65**
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	11.31	6.04	8.05
Loans/debt	0.00	0.00	0.00	0.00	0.00	0.00
***less:* Cash**	**19.88**	**17.28**	**9.15**	**15.40**	**7.73**	**7.53**
Less: Non-core invests.	0.00	0.00	0.00	1.67	1.67	1.67
Invested capital	0.71	-0.40	1.80	0.34	2.74	4.95
Cashflow						
Underlying EBIT	-12.08	-16.98	-14.53	-6.40	-6.45	0.54
Change in working capital	1.09	0.66	-2.33	-0.98	-3.29	-2.95
Company op. cashflow	-10.74	-15.50	-16.01	-6.44	-8.76	-1.38
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	-4.39	-7.67	-0.20
Equity issues	0.05	13.40	5.53	11.20	0.00	0.00
Change in net debt	**-10.51**	**0.91**	**-8.14**	**6.25**	**-7.67**	**-0.20**
Opening net cash	26.88	16.37	17.28	9.15	15.40	7.73
Closing net cash	**16.37**	**17.28**	**9.15**	**15.40**	**7.73**	**7.53**

Source: Hardman & Co Life Sciences Research

Company matters

Registration

Incorporated in the UK, with company registration number 05237326

UK Headquarters:

Diurnal Limited
Cardiff Medicentre
Heath Park
Cardiff, CF14 4UJ
UK

+44 29 2068 2069
www.diurnal.co.uk

Board of Directors

Board of Directors

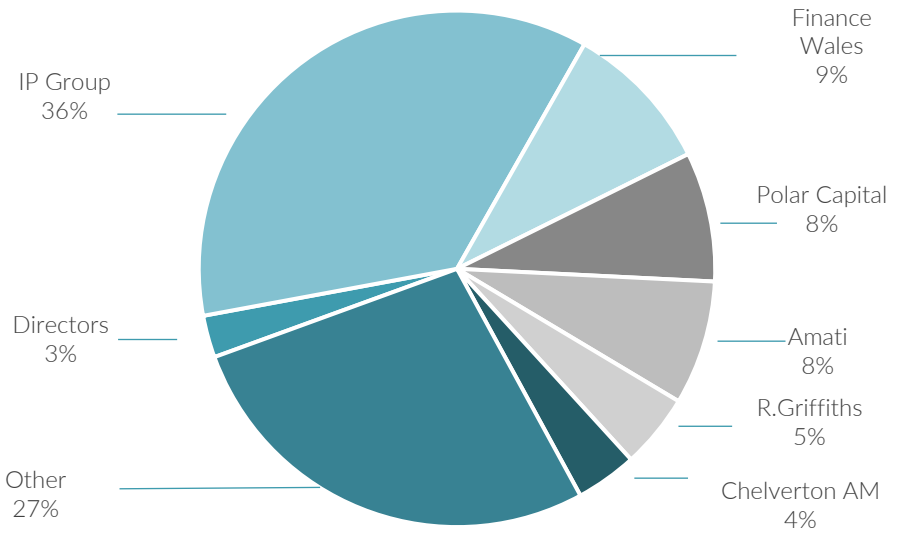
Position	Name	Nominations	Remuneration	Audit
Chairman (interim)	Sam Williams	C	M	
Chief Executive Officer	Martin Whitaker			
Chief Financial Officer	Richard Bungay			
Chief Scientific Officer	Richard Ross			
Non-executive director	John Goddard	M	M	C
Non-executive director	Alan Raymond	M	C	M

M = member, C = chair
Source: Company reports

Share capital

The company has 122,016,718 Ordinary shares of 0.05p in issue and 5,132,824 options.

Major shareholders



Source: Company reports

Appendix

FDA 505(2)(b) regulatory pathway

Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act is intended to streamline the development and US Food and Drug Administration approval of pharmaceutical products that incorporate already approved pharmacological agents. This provision is aimed at encouraging innovation, while reducing the amount of duplicative research required for the approval of a clinically significant improvement to a well-characterised chemical entity. The 505(b)(2) regulatory pathway provides for FDA approval of a drug based, in part, on data not developed by the sponsor of the application, including published literature references and data previously reviewed by the FDA for the approval of a separate application. The scope of data from a prior application that can be referenced by a new sponsor is determined with FDA input and can include part of the required pre-clinical or clinical studies for approval.

Notes

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