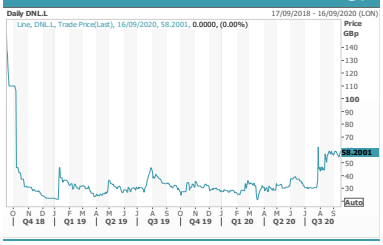
Pharmaceuticals & Biotechnology



Source: Refinitiv

Market data

EPIC/TKR	**DNL**
Price (p)	**58.0**
12m High (p)	62.0
12m Low (p)	21.0
Shares (m)	122.0
Mkt Cap (£m)	70.8
EV (£m)	55.3
Free Float*	48%
Market	AIM

**As defined by AIM Rule 26*

Description

Diurnal is a UK-based specialty pharma company targeting patient needs in chronic, potentially life-threatening, endocrine (hormonal) diseases. Alkindi has received approval in Europe, and is awaiting clearance from the FDA in the US; Chronocort has been filed for regulatory approval in Europe.

Company information

CEO	Martin Whitaker
CFO	Richard Bungay
Chairman (interim)	Sam Williams

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www.diurnal.co.uk

Key shareholders

Directors	2.6%
IP Group	36.1%
Finance Wales	9.5%
Polar Capital	8.1%
Amati VCT	7.8%
Richard Griffiths	3.8%

Diary

29 Sep	Alkindi PDUFA date
Nov'20	AGM
1Q'21	Chronocort EMA approval

Analyst

Martin Hall 020 7194 7622
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DIURNAL GROUP

Closely watching the regulators

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 being rolled out throughout Europe, and recent approvals in Israel and Australia will open up more markets. Later this month, attention will focus on the FDA, with the approaching PDUFA date for Alkindi. Next year should see the first approval of Chronocort in Europe. Based on current assumptions and expectations, Diurnal has sufficient cash through to profitability.

- **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.

- **Results:** Considerable regulatory and commercial progress was made in fiscal 2020. Although product sales remain modest, at £2.4m, recent launches and regulatory approvals are expected to see strong growth in 2021. Planned cost control and a reduction in R&D reduced losses, and left Diurnal with £15.4m net cash at 30 June.

- **Regulation:** In the short term, all attention is focused on the PDUFA date (29 September) for Alkindi Sprinkle in the US. In 1Q'21 (calendar), there is a high expectation that the EMA will approve Chronocort in Europe. Meanwhile, the US regulatory pathway for DITEST in the US has been clarified.

- **Risks:** The company appears well positioned in relation to any risks associated with COVID-19 and Brexit. While there is always regulatory risk, dialogue with the relevant EU and US regulators appears positive. Diurnal needs a partner(s) to co-fund pivotal US trials of Chronocort and DITEST.

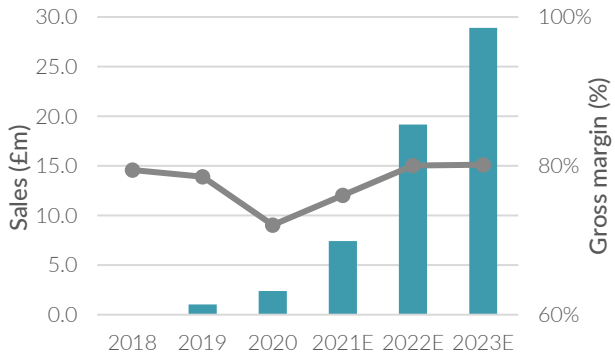
- **Investment summary:** In the event that Alkindi is approved in the US, Diurnal would become only the third listed AIM company to reach this milestone. Alkindi has paved the way for supply chain and commercial infrastructure that can be shared by future products. Diurnal is well-funded and has a number of significant value inflection points coming up in the next six months. Meanwhile, the shares are trading well below our risk-adjusted DCF valuation (221p).

Financial summary and valuation

Year-end Jun (£m)	2018	2019	2020	2021E	2022E	2023E
Sales	0.07	1.04	2.39	7.43	19.16	28.90
SG&A	-6.21	-5.83	-6.20	-6.65	-7.88	-10.24
R&D	-10.02	-8.69	-4.63	-4.50	-5.62	-8.43
EBITDA	-16.97	-14.51	-6.01	-6.37	0.92	3.53
Underlying EBIT	-16.98	-14.53	-6.02	-6.38	0.91	3.52
Reported EBIT	-16.98	-14.53	-5.39	-6.37	0.91	3.52
Underlying PBT	-17.11	-14.40	-5.91	-6.30	0.95	3.56
Statutory PBT	-16.91	-14.40	-5.28	-6.30	0.95	3.56
Underlying EPS (p)	-27.16	-14.54	-4.93	-4.22	1.98	4.72
Statutory EPS (p)	-26.78	-19.70	-4.28	-4.21	1.98	4.13
Net (debt)/cash	17.28	9.15	15.43	6.68	7.07	8.67
Equity issues	13.40	5.53	11.20	0.00	0.00	0.00

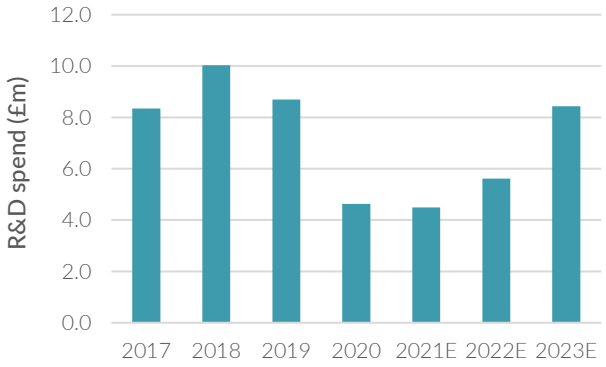
Source: Hardman & Co Life Sciences Research

Sales and gross margin



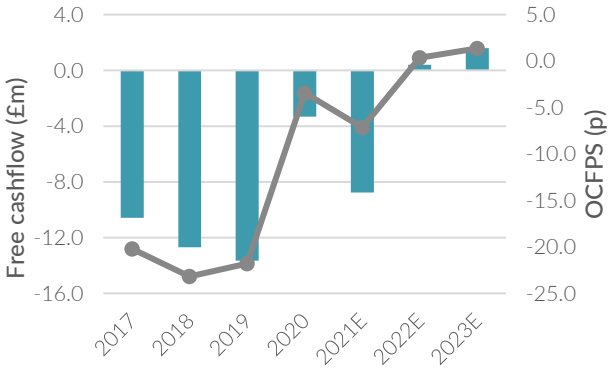
- Sales of Alkindi began in 2Q'18.
- Net group/Alkindi sales were £2.4m in 2020, as the product was expanded into more territories.
- The gross margin in fiscal 2020 was affected by external influences, but is expected to rise as volumes improve.
- First sales of Chronocort are anticipated to start during fiscal 2021 in Europe.

R&D investment



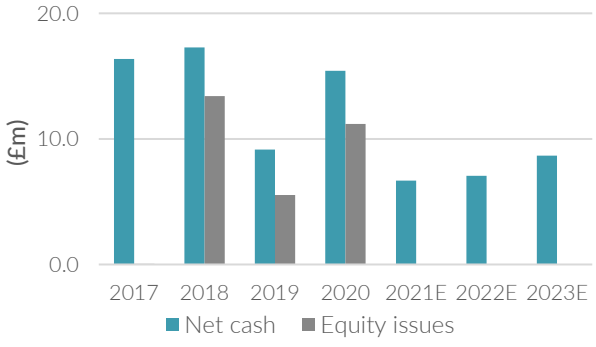
- In 2020, R&D spend reduced, as no significant clinical trials were concluded and only modest preparatory work for the upcoming US Phase III trial was performed.
- Future spend will be heavily influenced by the partnership arrangement(s) that Diurnal is seeking in the US for Chronocort and DITEST.
- US Phase II in AI with Chronocort is now anticipated to start once a partner is on board.

Free cashflow and OCFPS



- Cashflow is driven by R&D investment and corporate overheads.
- A European subsidiary was established and a sales force was recruited through Ashfield for commercial infrastructure; a distribution network was established out of the Netherlands.
- Monthly average cash burn significantly reduced in fiscal 2020, to £0.28m (ca.£0.75m), helped by the upfront from Eton and the R&D tax credit.

Net cash and equity issues



- At 30 June 2020, net cash was £15.4m. Diurnal has no debt.
- An oversubscribed institutional Placing raised £11.2m gross (£10.7m net) in March 2020.
- Based on current assumptions and expectations, Diurnal has sufficient cash through to profitability.

Source: Company data, Hardman & Co Life Sciences Research

2020 results – abundant news flow

Key features

Operational highlights

- **Alkindi – Europe/RoW:** Following successful pricing/reimbursement negotiations, Alkindi has been launched in eight European countries as a cortisol replacement therapy in Adrenal Insufficiency (AI) from birth to 18 years of age. Post the period-end, this drug has also been approved in Israel and Australia.
- **Alkindi – US:** In November 2019, Diurnal filed its first-ever New Drug Application (NDA) with the FDA for Alkindi Sprinkle in paediatric AI and (CAH) (from birth to 17 years of age). This submission was accepted for review by the FDA, and a PDUFA date of 29 September 2020 has been scheduled.
- **Chronocort – Europe:** The dossier was submitted, and subsequently validated, to the EMA for Market Authorisation Application (MAA) in CAH. Approval is expected in 1Q'21.
- **Chronocort – US:** With the benefit of outcomes in Europe, the US Phase III trial protocol has been adjusted and submitted for an FDA Special Protocol Assessment. The outcome of this is expected imminently.
- **DITEST:** Following successful trial outcomes, where both the primary and secondary endpoints were met, 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.

Commercial highlights

- **Alkindi:** This drug is now available in the UK, Germany, Austria, Sweden, Denmark, Norway, Iceland and Italy. Pricing has been agreed in the Netherlands. Additional distribution agreements have been agreed in the Benelux Union (Belgium, the Netherlands and Luxemburg) and Switzerland.
- **Eton:** In March 2020, Diurnal announced an exclusive US licensing agreement with Eton Pharmaceuticals (Eton) for the commercialisation of Alkindi Sprinkle, as it will be known. Eton paid Diurnal $5m upfront, in cash and shares, with pre-set milestones worth up to $47.5m in total, plus royalties on net sales.

Financial highlights

- **Product sales:** Alkindi sales increased 129%, to £2.39m (£1.04m), despite patient restrictions caused by the COVID-19 pandemic lockdown. The gross margin was 72% (79%), with the short-term variability caused by mix of sales by country and dose strength.
- **Licensing income:** Diurnal received $5.0m/£3.9m in the form of cash ($3.5m) and shares ($1.5m) from Eton, as part of the US licensing deal.
- **Marketing costs:** To provide greater transparency with respect to marketing costs, sales and distribution expenditure has been split out. There was an 8% reduction in spend during 2020, to -£4.1m (-£4.5m), following some cost-saving measures and reorganisation of the commercial team engaged by Ashfield Healthcare.
- **Administration:** Underlying administration costs, excluding share-based costs, were -£2.1m (-£1.3m), the previous year benefiting from a £0.6m one-off gain.
- **R&D:** Spend in 2020, at -£4.6m, was 47% lower than in 2018 (-£8.7m), with no major clinical trials being concluded during the year and a reassessment of the commencement of US Chronocort trials.

- **Placing:** In March 2020, Diurnal undertook a Placing of new Ordinary shares at 32p per share, raising gross new capital of £11.2m (£10.7m net).
- **Net cash/(debt):** At 30 June 2020, gross (and net) cash on the balance sheet was £15.4m, which is sufficient to take the company through to profitability, based on its current plans and assumptions.

Diurnal – 2020 results, actual vs. expectations

Year-end Jun (£m)	2019 actual	2020 actual	Growth %	2020 forecast	Delta Δ
Sales	1.04	2.39	+129%	2.40	-0.01
COGS	-0.22	-0.67	-	-0.44	-0.23
Gross margin	78.5%	72.1%	-	85%	-
Selling & distribution	-4.51	-4.14	-8%	-4.00	-0.14
R&D spend	-8.69	-4.63	-13%	-4.80	+0.17
Administration costs	-1.33	-2.06	-6%	-1.50	-0.56
Share-based costs	-0.83	-0.84	-	-0.83	-0.01
Licensing income	-	3.92	-	2.80	+1.12
Underlying EBIT	**-14.53**	**-6.02**	**-14%**	**-6.40**	**+0.38**
Net cash/(debt)	9.15	15.43	-	14.50	+0.93

Figures may not add up exactly due to rounding
Source: Diurnal, Hardman & Co Life Sciences Research

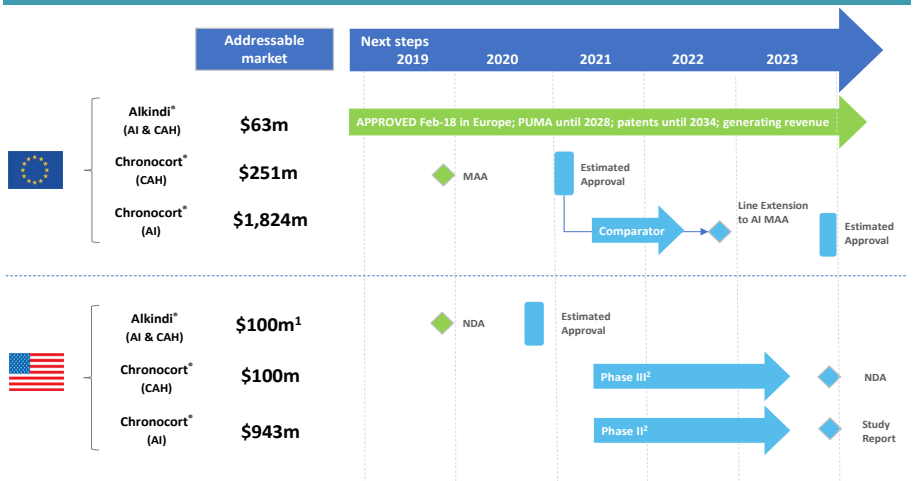
2020-21 milestones

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 Chronocort US development and commercialisation deal	
1Q'21	Potential approval of Chronocort in Europe	

Source: Company data, Hardman & Co Life Sciences Research

Diurnal – key value inflection points



[1] *Eton Pharmaceuticals estimate*
[2] *Subject to further funding or partnering*
Source: Diurnal 2020 results presentation, September 2020

Alkindi®

Europe – building a franchise

Building commercial endocrine franchise

Since it was approved by the EMA in September 2018, Diurnal has been using Alkindi to build a fully-integrated organisation that has the capabilities to design, develop and commercialise innovative products addressing key unmet patient needs in chronic endocrine diseases. Once approved, Chronocort will be plugged into this infrastructure and supply chain.

Alkindi now available in eight countries in Europe

The aim for fiscal 2020 was to conclude pricing and reimbursement negotiations in each country to enable the launch rollout. The has been achieved in eight countries, despite the lockdown caused by the COVID-19 pandemic. The progress in building out the European Alkindi franchise was evidenced by the 129% increase in net sales to £2.39m (£1.04m) during the year. Further progress was also made with marketing and distribution partnerships in territories where Diurnal does not intend to have its own infrastructure – notably, the Nordic region, the Benelux group and Switzerland.

US – focus on 29 September

Diurnal becomes only third AIM company to have reached NDA milestone

In November 2019, Diurnal filed its first-ever NDA with the FDA for 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. In its recent summary of FDA activities, due in September, the well-respected Washington Analysis Group (WAG) stated that it had "*no doubt that the application will be approved and high confidence that the FDA will act on or even before the PDUFA date*". On the basis of a successful outcome, launch could follow shortly thereafter.

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.

Eton Pharmaceuticals – US commercial partner

Eton believes commercial opportunity for Alkindi Sprinkle to be much larger, at $100m

On 27 March, Diurnal announced that it had signed an exclusive US commercial deal with Eton[1], a specialty pharma company focused on hospital and paediatric products, in order to maximise the commercial opportunity for Alkindi Sprinkle. On a conservative basis, we estimate this opportunity to be ca.$30m, but, in recent presentations, Eton stated that the US commercial opportunity could be as much as $100m (Eton website), indicating considerable upside potential to our forecasts. In its 2Q'20 results announcement[2], 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*". The beliefs of WAG and Eton augur well for Alkindi's future US prospects.

Rest of the World

In other territories, commercialisation will be through local distributors, with knowledge of either endocrine or niche markets.

Approved in Israel

Approval in Israel took eight months…

…with launch expected in 1Q'21

On 5 August, Diurnal announced that Alkindi had been approved by 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.

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

Alkindi, and Chronocort, once approved, will be marketed by Medison Pharma, a specialist provider 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.

Exclusive commercial rights to both Alkindi and Chronocort in Australia and New Zealand have been licensed 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.

Japan

First patents for Alkindi and Chronocort have been granted by the Japanese Patent Office. Diurnal is seeking a local partner in Japan, where there are ca.6,700 patients with CAH and 58,000 with AI, giving an estimated market worth of $415m.

Brexit plan

Diurnal has developed its product supply chain to minimise the potential impact of Brexit in the event that the departure of the UK is without a formal trade agreement with the EU, by:

- manufacturing products in Germany;
- packaging in France; and
- distribution from the Netherlands.

In addition, Diurnal has established a wholly-owned subsidiary, Diurnal Europe B.V., in the Netherlands, which holds the Alkindi EU marketing authorisation and Wholesaler Dealer Licence.

Summary of Alkindi marketing and distribution agreements

Country	Partner	Marketing and distribution agreement	First sales (fiscal year)	Patents granted	Addressable market[2]
Benelux	Consilient/Goodlife	Yes	2021	Yes	
Iceland		Yes	2021	Yes	
Nordics	Frost Pharma	Yes	2020	Yes	$3m
Switzerland	Undisclosed	Yes	2021	Yes	$1m
Israel[1]	Medison Pharma	Yes	2021	Yes	$7m
Australia & New Zealand	Emerge Health	Yes	2021	Yes	$11m
US	Eton Pharma	Yes	2021	Yes	$100m
Japan	TBA	TBA	TBC	Yes	$415m

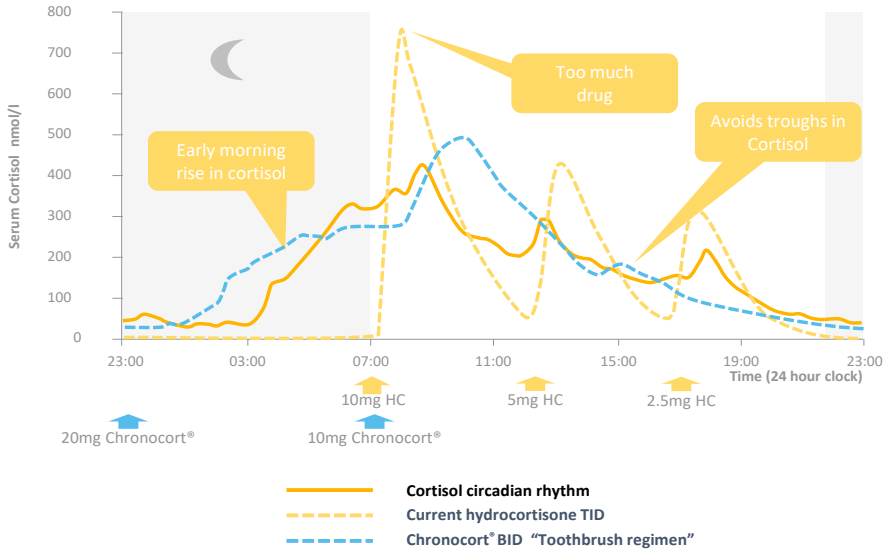
[1]Including the Palestinian Authority, [2]Diurnal estimates based on price of $6,369 per patient p.a.
Source: Diurnal, Hardman & Co Life Sciences Research

Chronocort®

Chronocort aims to mimic natural daily rhythm of cortisol

Chronocort is designed to mimic the natural circadian rhythm of cortisol, a life-sustaining adrenal hormone essential for the maintenance of homeostasis. The intention is to take the drug at night, before sleep, and first thing in the morning, to mimic the natural cortisol blood levels in healthy individuals. With Chronocort, Diurnal is targeting the large AI market, which includes CAH, estimated at $3.2bn.

Chronocort® – mimicking the circadian rhythm



Source: Diurnal

Regulatory status

EMA approval anticipated in 1Q'21

Following discussion with representatives of the EMA, the European regulatory pathway was confirmed, with Diurnal subsequently submitting its MAA for Chronocort in CAH on 16 December 2019. From the date of dossier submission, the regulator has up to 210 active days of assessment, taking the publication of the scientific opinion to the end of October 2020. Following this, the EC will give the final decision to grant market authorisation before the end of January 2021. In parallel, Diurnal has applied for Orphan Drug Status in Europe.

Change to "non-inferiority" clinical endpoint for Phase III trial in US

Experience gained in Europe has been used to guide amendments to the US Phase III trial protocol. A different statistical measure of efficacy and a non-inferiority outcome of Chronocort versus standard-of-care will be adopted as the primary endpoint. The study is anticipated to recruit up to 150 patients, and most of the groundwork has already been undertaken, including identification of the clinical sites. This Phase III study will be run with a partner, and discussions are continuing.

Chronocort – current status

Territory	Condition	Status	Comments
Europe	CAH	EMA market authorisation submitted (16 December 2019)	Committee for Medicinal Products for Human Use (CHMP) opinion expected in 1Q'21 and market authorisation in 2Q'21
Europe	AI	No further study needed	Diurnal expects to submit for MAA for AI following positive outcome from submission for CAH
US	CAH	Phase III ready	Diurnal in discussions to find a US partner to co-run and fund the Phase III trial
US	AI	Phase II ready	Diurnal contemplating its options (grant-funding, partnering or further capital)

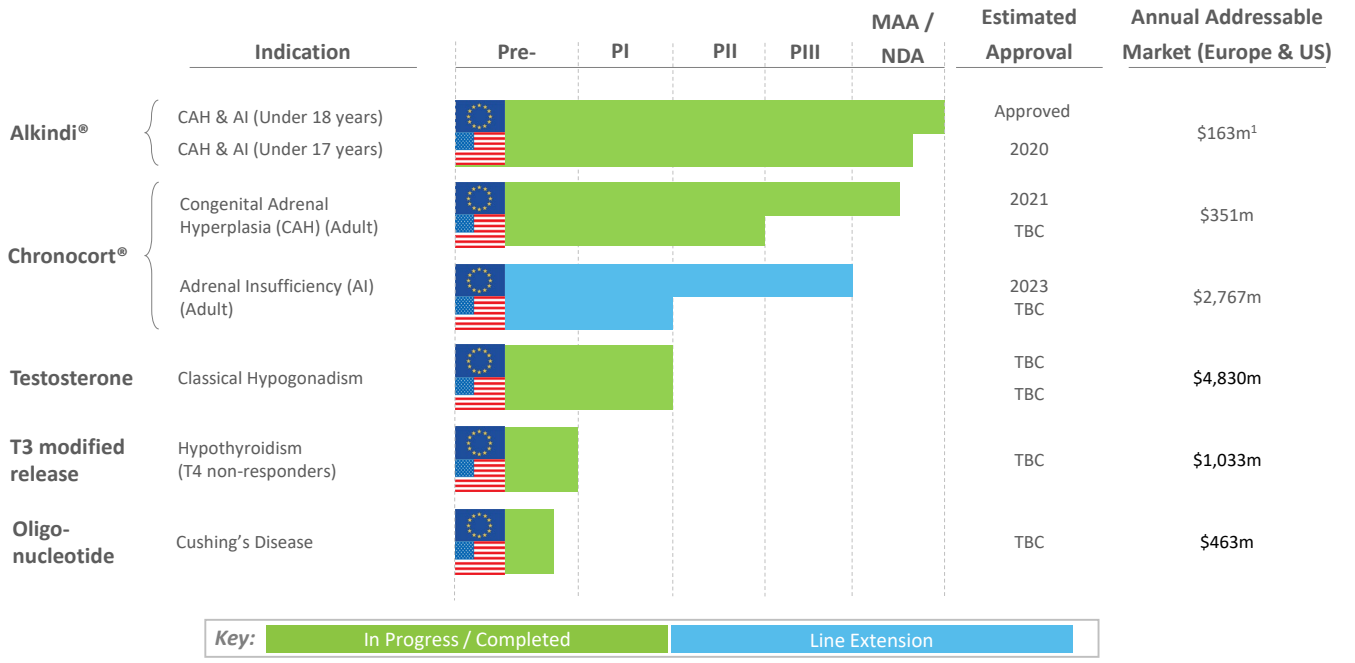
Source: Diurnal, Hardman & Co Life Sciences Research

Updated pipeline

Building the endocrine pipeline

Diurnal's vision is "*to become a world-leading endocrinology speciality pharma company*". Having developed its own infrastructure and partnerships for Alkindi, it intends to use this for its other products in the niche field of endocrinology, which is dominated currently by small biotech. As well as developing internal products, management has *always* remained open about considering all available options – product acquisition, in-licensing and partnership opportunities – in order to maximise this opportunity.

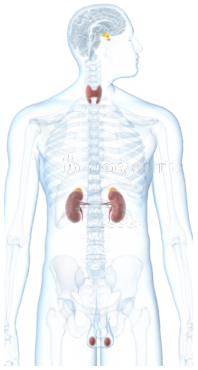
Diurnal – focused R&D pipeline



Source: Diurnal 2020 results presentation

Although the primary focus has been on Alkindi and Chronocort, two products that address the cortisol deficiency market, the group has maintained an interest in expanding into other endocrine diseases. During 2020, Diurnal has progressed the first of these, DITEST, in hypogonadism.

Building an earlier stage pipeline



	Indications	Annual Addressable Market (Europe & US)	Product
Thyroid	Hypothyroidism	$1bn	▪ Modified-release T3 (preclinical)
Adrenal	CAH AI Cushing's	$0.5bn $2.8bn $0.5bn[2]	▪ Alkindi® (completed) ▪ Chronocort® (Phase 3) ▪ Oligonucleotide therapy (preclinical)
Gonads	Hypogonadism	$4.8bn	▪ DITEST™ (positive Phase 1 study in hypogonadal subjects)

In-licensing M&A Partnerships

Source: Diurnal 2020 results presentation

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.[3]

…led to 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 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.

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

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	40mg-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	4mg-8mg applied nightly to skin	Convenient, mimics circadian rhythm	Skin irritation in 66% of men, sweating interference with patch adherence,
Testosterone gel	Transdermal	5mg-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

Financial summary

Profit & Loss

- **Sales:** Product sales increased 129%, to £2.39m (£1.04m), in fiscal 2020. As part of total revenues, Diurnal included licensing income from Eton of $5.0/£3.9m, which we separate out, as it tends to be "lumpy" and alters the cost analysis.
- **Gross margin:** Higher COGS reduced the gross margin to 72% (79%) in fiscal 2020. This has been affected by the mix of sales by country, the average dose strength used and by the impact of COVID-19. Diurnal is collaborating with manufacturing partner, Glatt, on initiatives to improve the long-term gross margin, including the installation of a higher throughput encapsulation machine and scale-up of the granule manufacturing process to approximately 150% of current levels.
- **Selling costs:** To improve transparency, Diurnal has separated out selling and distribution costs. In fiscal 2020, costs were reduced by 8% to -£4.1m (-£4.5m), as a result of lower market access activities required to secure drug pricing.
- **Administration:** Underlying administrative expenses increased from -£1.3m to -£2.1m in fiscal 2020. However, fiscal 2019 benefited from a one-off £0.6m reduction in employers' National Insurance contributions.
- **R&D:** In the absence of any major late-stage trials, R&D expenditure was lower in 2020, at -£4.6m. Depending on the outcome of licensing discussions for the development and commercialisation of Chronocort in the US, R&D expenditure may rise again over the next two years to fund the Phase III trials.

Profit & Loss account

Year-end Jun (£m)	2018	2019	2020	2021E	2022E	2023E
Sales	0.07	1.04	2.39	7.43	19.16	28.90
COGS	-0.02	-0.22	-0.67	-1.78	-3.82	-5.74
Gross profit	0.06	0.82	1.72	5.65	15.34	23.17
Gross margin	79%	79%	72%	76%	80%	80%
Selling & distribution	-5.21	-4.51	-4.14	-4.50	-5.40	-7.02
Administration	-1.00	-1.33	-2.06	-2.15	-2.48	-3.22
Share-based costs	-0.81	-0.83	-0.84	-0.89	-0.93	-0.98
R&D	-10.02	-8.69	-4.63	-4.50	-5.62	-8.43
EBITDA	-16.97	-14.51	-6.01	-6.37	0.92	3.53
Depreciation	-0.01	-0.02	-0.01	-0.01	-0.01	-0.01
Licensing/Royalties	0.00	0.00	3.92	0.00	0.00	0.00
Underlying EBIT	**-16.98**	**-14.53**	**-6.02**	**-6.38**	**0.91**	**3.52**
Exceptional items	0.00	0.00	0.63	0.01	0.00	0.00
Statutory EBIT	-16.98	-14.53	-5.39	-6.37	0.91	3.52
Net interest	-0.13	0.13	0.11	0.08	0.03	0.04
Underlying PBT	**-17.11**	**-14.40**	**-5.91**	**-6.30**	**0.95**	**3.56**
Reported PBT	-16.91	-14.40	-5.28	-6.30	0.95	3.56
Tax liability/credit	2.28	2.11	1.21	1.17	1.47	1.49
Tax rate	-13%	-15%	-23%	-19%	155%	42%
Underlying net income	**-14.83**	**-12.29**	**-4.70**	**-5.13**	**2.41**	**5.76**
Statutory net income	-14.62	-12.29	-4.07	-5.12	2.41	5.04
Ordinary 5p shares:						
Period-end (m)	61.34	84.53	121.63	122.02	122.02	122.02
Weighted average (m)	54.60	62.39	95.23	121.63	122.02	122.02
Fully-diluted (m)	59.42	66.85	99.69	126.10	126.48	126.48
Underlying basic EPS (p)	**-27.2**	**-14.5**	**-4.9**	**-4.2**	**2.0**	**4.7**
Statutory basic EPS (p)	-26.8	-19.7	-4.3	-4.2	2.0	4.1
Underlying fully-dil. EPS (p)	-24.9	-18.4	-4.7	-4.1	1.9	4.6
Statutory fully-dil. EPS (p)	-24.6	-18.4	-4.1	-4.1	1.9	4.0
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Hardman & Co Life Sciences Research

- **Unrealised gains/losses:** As part of the Alkindi licensing deal with Eton, Diurnal has acquired Ordinary shares (379,474) to the value of $1.5m in the company, which will be revalued at each period-end and could result in either unrealised gains or losses, depending on Eton's share price movement. In fiscal 2020, Diurnal booked a gain of £0.63m, which was higher than expected. At the current Eton share price, a further gain of £0.85m would be booked in 2021.

Balance sheet

- **Inventory:** As expected, the stock levels of Alkindi have nearly doubled, to £1.24m, in preparation for upcoming country launches, including the US, and to reduce the supply chain risks associated with COVID-19 and Brexit.
- **Working capital:** Despite the fact that Diurnal is in a high growth phase, the increase in working capital tied up with receivables and payables was lower than anticipated, at -£0.4m, which can be monitored through average debtor and creditors days.
- **Net cash/(debt):** At 30 June 2020, Diurnal had gross cash of £15.4m, and no debt. Based on current forecasts, we estimate that the company has sufficient cash through to profitability, based on current expectations and assumptions. Beyond this, much will depend on the US licensing deal for Chronocort and the extent to which clinical development costs are shared.

Balance sheet						
at 31 Jun (£m)	2018	2019	2020	2021E	2022E	2023E
Shareholders' funds	16.88	10.94	18.39	13.26	15.67	20.72
Cumulated goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	16.88	10.94	18.39	13.26	15.67	20.72
Share capital	3.07	4.23	6.08	6.08	6.08	6.08
Reserves	13.81	6.72	12.30	7.18	9.59	14.63
Provisions/liabilities	0.00	0.00	0.00	0.00	0.00	0.00
Deferred tax	0.00	0.00	0.00	0.00	0.00	0.00
Lease liabilities	0.00	0.00	0.00	0.00	0.00	0.00
Long-term debt	0.00	0.00	0.00	0.00	0.00	0.00
Short-term loans	0.00	0.00	0.00	0.00	0.00	0.00
less: Cash	17.28	9.15	15.43	6.68	7.07	8.67
less: Deposits	0.00	0.00	0.00	0.00	0.00	0.00
less: Non-core investments	0.00	0.00	1.67	1.67	1.67	1.67
Invested capital	**-0.40**	**1.80**	**1.28**	**4.91**	**6.93**	**10.38**
Fixed assets	0.03	0.03	0.02	0.02	0.02	0.02
Intangible assets	0.02	0.05	0.08	0.08	0.08	0.08
Inventories	0.12	0.67	1.24	3.86	4.97	7.50
Trade debtors	*0.08*	*0.51*	*0.39*	*1.86*	*3.19*	*4.82*
Other debtors	*5.02*	*0.95*	*0.94*	*0.90*	*0.85*	*0.81*
Tax credit/liability	*0.00*	*2.11*	*1.19*	*1.19*	*1.32*	*1.83*
Trade creditors	*-3.32*	*-1.15*	*-0.81*	*-1.21*	*-1.51*	*-1.71*
Other creditors	*-2.35*	*-1.37*	*-1.78*	*-1.79*	*-2.00*	*-2.98*
Debtors less creditors	-0.57	1.04	-0.06	0.95	1.85	2.77
Invested capital	**-0.40**	**1.80**	**1.28**	**4.91**	**6.93**	**10.38**
Net cash/(debt)	**17.28**	**9.15**	**15.43**	**6.68**	**7.07**	**8.67**
Stock days	615	235	146	125	84	79
Debtor days	385	178	69	55	48	51
Creditor days	nm	1,866	533	206	130	102

Source: Hardman & Co Life Sciences Research

Cashflow

- **Underlying EBIT:** The P&L is the main driver of cashflow, and we forecast that EBITDA will turn positive in 2022.
- **Working capital:** The build-up of inventories, debtors and creditors is consistent with the product launch and growth phase of a company.
- **Milestone:** In April 2020, Diurnal concluded its US commercial deal for Alkindi Sprinkle in the US with Eton. This resulted in a cash upfront payment of $3.5m as part of a total upfront of $5.0m, the remainder being in shares.
- **Capital increase:** Diurnal's gross cash position at the period-end was helped by strong institutional demand for its Placing in March. The company intended, originally, to raise a minimum of £7.0m. However, high 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.

Cashflow						
Year-end Jun (£m)	2018	2019	2020	2021E	2022E	2023E
Underlying EBIT	-16.98	-14.53	-6.02	-6.38	0.91	3.52
Depreciation	0.01	0.02	0.01	0.01	0.01	0.01
Share-based costs	0.81	0.83	0.84	0.89	0.93	0.98
Inventories	*-0.12*	*-0.55*	*-0.57*	*-2.62*	*-1.11*	*-2.53*
Receivables	*-1.54*	*1.36*	*0.12*	*-1.47*	*-1.33*	*-1.62*
Payables	*2.32*	*-3.14*	*0.07*	*-0.40*	*-0.30*	*-0.20*
Change in working capital	0.66	-2.33	-0.38	-4.49	-2.75	-4.35
Other	0.00	0.00	0.00	0.00	0.00	0.00
Company op. cashflow	**-15.50**	**-16.01**	**-5.53**	**-9.97**	**-0.90**	**0.16**
Net interest	0.11	0.13	0.14	0.08	0.03	0.04
Lease payments	0.00	0.00	0.00	0.00	0.00	0.00
Tax paid/received	2.74	2.28	2.12	1.19	1.32	1.48
Operational cashflow	**-12.66**	**-13.60**	**-3.27**	**-8.70**	**0.46**	**1.67**
Capital expenditure	-0.02	-0.03	-0.01	-0.01	-0.01	-0.01
Capitalised R&D	-0.02	-0.04	-0.04	-0.05	-0.05	-0.06
Sale of fixed assets	0.00	0.00	0.00	0.00	0.00	0.00
Free cashflow	**-12.69**	**-13.66**	**-3.32**	**-8.76**	**0.39**	**1.60**
Dividends	0.00	0.00	0.00	0.00	0.00	0.00
Acquisitions	0.00	0.00	0.00	0.00	0.00	0.00
Disposals	0.00	0.00	0.00	0.00	0.00	0.00
Cashflow after investments	**-12.69**	**-13.66**	**-3.32**	**-8.76**	**0.39**	**1.60**
Share repurchases	0.00	0.00	0.00	0.00	0.00	0.00
Share issues	13.40	5.53	11.20	0.00	0.00	0.00
Change in net debt	**0.91**	**-8.14**	**7.35**	**-8.76**	**0.39**	**1.60**
OCFPS (p)	-23.2	-21.8	-3.4	-7.2	0.4	1.4
Opening net cash	16.37	17.28	9.15	15.43	6.68	7.07
Closing net cash	**17.28**	**9.15**	**15.43**	**6.68**	**7.07**	**8.67**

Source: Hardman & Co Life Sciences Research

Changes to forecasts

No material changes have been made to forecasts since our last report (13 August 2020). The modest uplift in underlying EBIT is simply the consequence of inputting accurate full-year data for the cost lines, which has had a knock-on effect on future forecasts.

Our forecasts with respect to Alkindi expectations in the US remain conservative, especially compared with published expectations by Eton. We will be closely monitoring the launch and uptake of Alkindi Sprinkle through Eton's quarterly reports.

Valuation

DCF

DCF valuation has increased from 202p to 221p per share, +9%

There has been a slight increase in the unadjusted NPV to take account of the deal with Eton for Alkindi and the filing of Chronocort in Europe. In addition, there is increased probability of Alkindi Sprinkle being approved on, or before, the PDUFA date of 29 September. Offsetting these factors is the increased number of shares in issue following the recent Placing. The overall effect is to increase the risk-adjusted NPV by 9% to 221p. In the event that peak Alkindi sales in the US are closer to the forecasts of Eton, there is considerable upside potential to these numbers.

Diurnal – DCF valuation summary

WACC	NPV (£m)	Risk-adjusted NPV (£m)	Risk-adjusted NPV per share (p)
8%	502	330	271
9%	453	298	245
10%	**410**	**270**	**221**
11%	371	244	200
12%	336	222	182

Source: Hardman & Co Life Sciences Research

Peer group comparisons

Valuation uplift potential for Diurnal as it makes further progress in US

For our comparative valuation analysis, a group of quoted specialty pharma companies working in the field of endocrinology – but not working in diabetes/insulin – have been selected, to provide a guide for the relative valuation of Diurnal. This gives an indication of the valuation uplift potential for Diurnal, as it makes further progress in the US. Some changes have been made to this peer group, with Millendo Therapeutics (MLND) dropping out, after a failed clinical trial left the stock trading below cash levels, being replaced by Chiasma (CHMA). Also, following the commercial partnership with Diurnal, Eton has been included in the group. This peer group generates a broad range of valuations, with Ascendis commanding an EV of $6.7bn. The key to valuation is having regulatory approved products that are being commercialised. Since we last published this table, Diurnal's EV has risen 73% on the back of its strong run of positive news flow.

Comparative valuation

Company Ticker Local currency	Ascendis ASND $	Chiasma CHMA $	Corcept. CORT $	Diurnal DNL £/p	Eton ETON $	Viking VKTX $
Share price	147.5	5.5	18.4	56.5	8.1	6.0
Shares in issue (m)	48.3	57.8	115.6	122.0	12.5	72.8
Market cap. (l.c., m)	7,131.0	317.9	2,126.3	68.9	101.0	436.6
Market cap. (£m)	5,545.1	247.2	1,653.4	68.9	78.6	339.5
Cash (l.c., m)	471.6	67.1	405.4	15.4	10.3	263.0
Debt (l.c., m)	-35.5	-24.6	-3.5	0.0	-4.9	-0.5
EV (l.c., m)	6,694.9	275.4	1,724.4	53.5	95.6	174.1
EV (£m)	6,176.1	214.2	1,340.9	53.5	74.4	135.4
Relative EV (x)	**115.4**	**4.0**	**25.1**	**-**	**1.4**	**2.5**

l.c. = local currency
Share prices and currencies taken at close of business on 14 September 2020
Source: Hardman & Co Life Sciences Research

As seen many times before with UK small-cap biotech companies, US peers generally trade at much higher valuations and tend to be very well capitalised, allowing these companies to realise their full potential. However, such analysis should provide an indication of upside potential in the event that Diurnal's products become further de-risked through anticipated regulatory approvals over the next six months.

Company matters

Registration

Incorporated in the UK, with company registration number 05237326

UK Headquarters:

Diurnal Limited
Cardiff Medicentre
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Cardiff, CF14 4UJ
UK

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

Board of Directors

Board of Directors

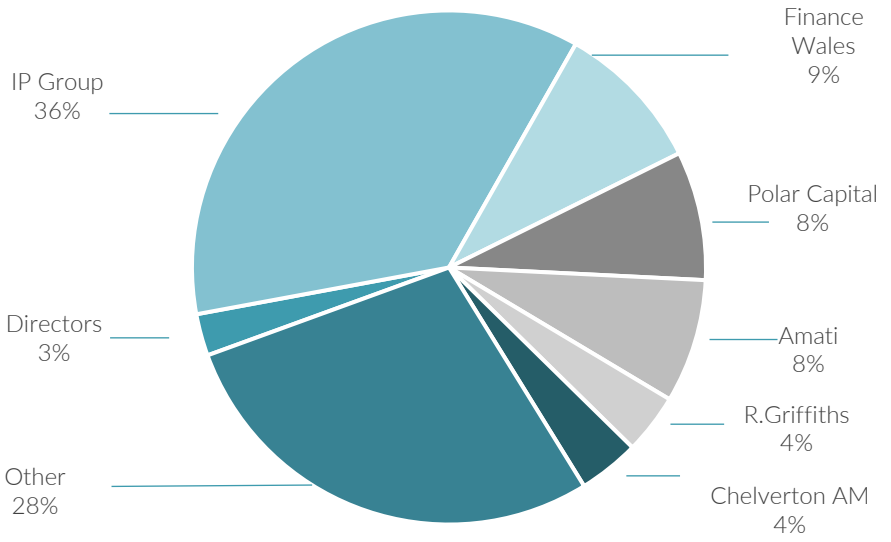
Position	Name	Nominations	Remuneration	Audit
Chairman (interim)	Sam Williams	C	M	
Chief Executive Officer	Martin Whitaker			
Chief Financial Officer	Richard Bungay			
Chief Scientific Officer	Richard Ross			
Non-executive director	John Goddard	M	M	C
Non-executive director	Alan Raymond	M	C	M

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.

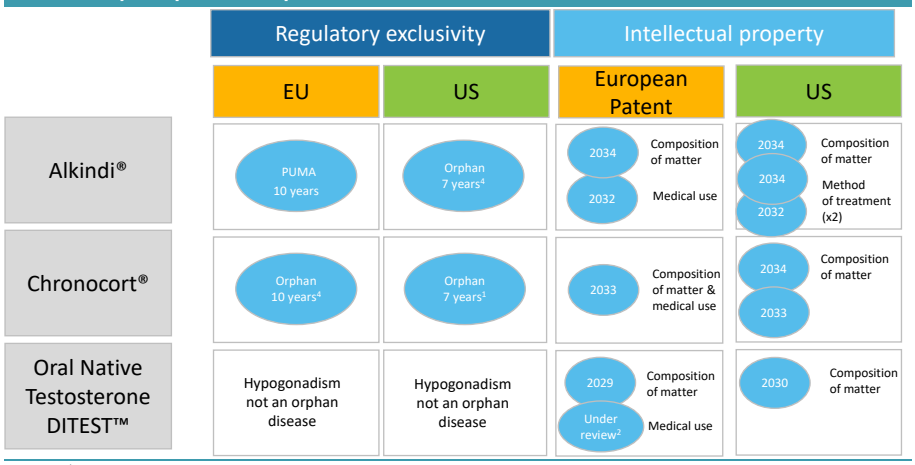
Major shareholders



Source: Company reports

Appendix

Summary of product protection



[1]*Conditional and subject to grant of market authorisation (and that Diurnal is the first sponsor to obtain market authorisation for the relevant product) and on demonstrating significant benefit*
[2]*GB patent application 2001514.5*
Source: Diurnal 2020 results presentation

Summary of key commercial relationships

Country	Partner	Marketing & Distribution Agreement	Anticipated First Revenues	Patents Granted	Annual Addressable Market
US	eTon PHARMACEUTICALS	✓[2]	2021	✓	**$1,143m**[3] (including AI indication expansion)
Japan	TBA	TBA	TBC	✓	**$397m**[4] (including AI indication expansion)
Australia & New Zealand	emerge health	✓	2021	✓	**$10.7m**[3] (CAH and paediatric AI only)
Israel[1]	MEDISON	✓	2021	✓	**$6.1m**[3] (CAH and paediatric AI only)

[1]*Including the Palestinian Authority*
[2]*Alkindi® only*
[3]*Company estimates for Chronocort® based on a price of $6,138 per patient p.a., Eton Pharmaceuticals estimates for Alkindi® Sprinkle*
[4]*Datamonitor Report (2015) and price of $6,138 per patient p.a.*
Source: Diurnal 2020 results presentation

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