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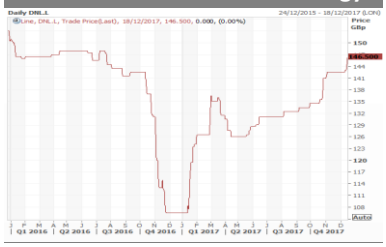
Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	DNL
Price (p)	146
12m High (p)	146
12m Low (p)	105
Shares (m)	52.2
Mkt Cap (£m)	70.4
EV (£m)	64.7
Free Float*	17%
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 positive opinion from the CHMP in Europe, with first sales expected in 2Q'18; while Chronocort is in Phase III trials.

Company information

CEO	Martin Whitaker
CFO	Richard Bungay
Chairman	Peter Allen
	+44 (0) 29 2068 2069
	www.diurnal.co.uk

Key shareholders

Directors	3.3%
IP Group	45.6%
Finance Wales	22.1%
Invesco	12.5%
Oceanwood Capital	8.1%

Diary

Feb-18	Alkindi EC approval
Mch-18	Interims
2Q 2018	Alkindi EC launch

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Diurnal Group

Alkindi®: On route to Europe

Diurnal is a clinical stage specialty pharmaceutical company focused on diseases of the endocrine system. Its two lead candidates are targeted at rare diseases with unmet medical need, with the aim of building a long-term 'Adrenal Franchise'. Following successful completion of a Phase III trial, Alkindi® (previously known as Infacort®) has received a positive opinion from the CHMP, recommending the granting of market authorisation for replacement therapy in adrenal insufficiency for children from birth up to 18 years of age. The European Commission is expected to grant market approval in February, allowing first sales in 2Q 2018.

- **Strategy**: Diurnal's strategic goal is to create a valuable 'Adrenal Franchise' that can treat patients with chronic cortisol deficiency diseases from birth through to old age. Once Infacort and Chronocort are established in EU and the US, the long-term vision is to expand the product offering to other related conditions.

- **CHMP positive opinion:** On 14th Dec 2017, and based on the solid Phase III trial results, the committee for Medicinal Products for Human Use (CHMP) provided a positive opinion, recommending the European Commission to grant marketing authorisation for Alkindi. The final rubber stamp is expected in February 2018.

- **Launch:** Infacort will be marketed under the tradename Alkindi for neonates and children up to 18 years of age. In anticipation of marketing approval and authorisation of the PUMA dossier, Diurnal has been establishing its commercial infrastructure in Europe, with first market launch now expected in 2Q 2018.

- **Risks:** While there is a risk with all drugs in development that they might fail clinical trials or not be approved by the regulators, Diurnal was considered to have unusually low risk because its products are formulation variants of well-established drugs. This stance has been validated by the positive CHMP opinion.

- **Investment summary:** Alkindi, a cortisol replacement therapy designed for children and babies, will be Diurnal's first product on the market. It will be followed by Chronocort for adults. The cortisol replacement market is for conditions that need life-long treatments, and has a potential value of $3.5bn. This is not adequately reflected in the valuation – DCF or peer group analysis.

Financial summary and valuation

Year end June (£m)	*2015	2016	2017	2018E	2019E	2020E
Sales	0.00	0.00	0.00	0.13	3.18	15.19
SG&A	-1.00	-1.99	-3.22	-6.00	-7.54	-9.14
R&D	-2.23	-3.89	-8.34	-10.50	-10.00	-7.00
EBITDA	-2.98	-5.87	-11.54	-16.39	-14.67	-2.47
Underlying EBIT	-2.99	-5.88	-11.55	-16.39	-14.67	-2.47
Reported EBIT	-2.99	-6.99	-12.07	-16.93	-15.24	-3.07
Underlying PBT	-3.02	-5.95	-11.64	-16.57	-14.94	-2.83
Statutory PBT	-3.02	-7.06	-12.16	-17.11	-15.51	-3.43
Underlying EPS (p)	-8.49	-12.48	-17.05	-25.15	-22.35	-1.03
Statutory EPS (p)	-8.72	-15.02	-18.04	-26.19	-23.45	-2.18
Net (debt)/cash	6.05	26.88	16.37	2.89	-10.37	-15.35
Capital increases	9.25	24.52	0.05	0.00	0.00	0.00

**Year to July*

Source: Hardman & Co Life Sciences Research

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Alkindi: first product in the market

CHMP positive scientific opinion

Positive CHMP opinion recommending the EC to approve Alkindi...

On 14th December 2017 and based on results from the Phase III trial, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of marketing authorisation for Alkindi (previously known as the development programme Infacort), by the European Commission, for the paediatric treatment of adrenal insufficiency (AI) including congenital adrenal hyperplasia (CAH).

...for use in infants and, unexpectedly, children up to age 18

The committee also recommended that Alkindi can be used in infants and children up to 18 years of age, whereas Diurnal had sought approval for it to be used only up to six years of age. Following this positive CHMP opinion, the final decision on paediatric use marketing authorisation (PUMA), which will provide market exclusivity, is expected in February 2018 from the European Commission.

The full indication is: "**Replacement therapy of adrenal insufficiency in infants, children and adolescents (from birth to < 18 years old)**".

Commercial strategy

Alkindi represents the first licensed hydrocortisone product available for paediatric use

Infacort will now be known and commercialised under the tradename Alkindi, with first launch now anticipated in 2Q 2018. Diurnal will focus initially on the population of children aged between 0 and 6 years. Alkindi is being made available in a child-friendly preparation in capsules containing four different doses in capsules containing four different doses (0.5mg, 1mg, 2mg and 5mg) of granules of hydrocortisone.

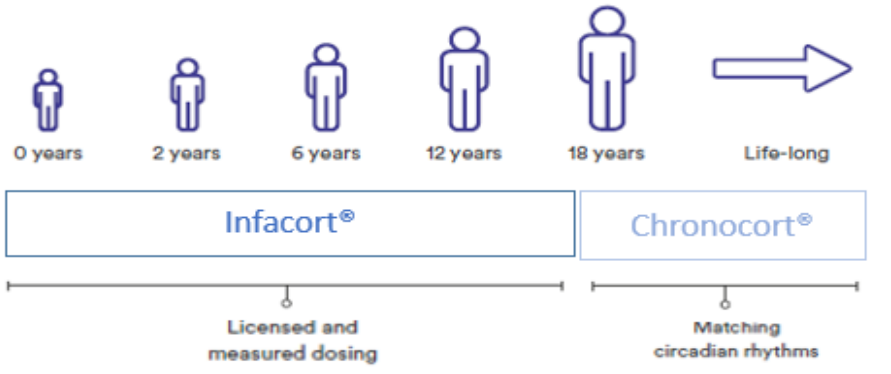
The EC now has 67 days to grant approval

Following the CHMP opinion, the European Commission has 67 days to grant European Market Approval. Diurnal will be the first to license a hydrocortisone product in Europe for paediatric use. It is also the first product that Diurnal brings to the market.

Management has been preparing for commercialisation of Alkindi for several months

Ever since Diurnal completed successfully the Phase III study and submitted the regulatory dossier, management has been building a commercial capability. Everything is already in place to launch Alkindi shortly after the EC approval. Diurnal will be commercialising Alkindi in Europe by itself, thereby retaining full value of the product, and intends to use the same infrastructure for its subsequent hydrocortisone product for adults, Chronocort.

Building a long-life "Adrenal Franchise"



Source: Adapted from Diurnal

European regulatory process

Diurnal used the centralised procedure which allows a single application, single evaluation and single market authorisation throughout the 28 countries of the EU. The applicant is required to submit a dossier of scientific information supporting the efficacy, quality and safety of the product to the CHMP. The Committee then appoints two rapporteurs to evaluate the dossier and report back to the CHMP.

Identical product information is to be provides in all 23 European languages:

- Summary of Product Characterisation (SPC), which define the conditions of use of the product (i.e. indications, warnings, shelf-life, etc.)
- Package Leaflet (information for the patient)
- Package Labelling (information on the packaging)

Submission and assessment of the dossier for marketing authorisation follows strict rules and timelines, as indicated in the following table:

Steps involved in obtaining the European Market Authorisation

Steps	Timeline	Description	
Submission of eligible request	18-7 months before submission of MMA	To find out whether a product can be evaluated under the centralised procedure	✓
Notification of intention to submit an application	7 months before submission of MMA	Notification to the EMA of the intended submission date	✓
Appointment of rapporteurs	7 months before submission of MMA	The Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC) appoints rapporteurs to conduct the scientific assessment.	✓
Pre-submission meetings	6-7 months before submission of MMA	Pre-submission meetings with the EMA to obtain procedural and regulatory advices from the Agency	✓
Submission and validation of the application	First day of assessment	Electronic submission of the application	✓
Scientific evaluation	Up to 210 active days of assessment	The CHMP evaluates the application. The PRAC provides input on aspects related to risk management. Both committees have the possibility to come back to the company with further questions	✓
CHMP scientific opinion	End of assessment	After the evaluation, the CHMP must issue a scientific opinion on whether the medicine may be authorised or not. The EMA sends this opinion to the European Commission, which issues the marketing authorisation.	✓
European Commission decision	Within 67 days of receipt of CHMP opinion	Commission decisions are published in the Community Register of medicinal products for human use and EMA publishes a European Public Assessment Report (EPAR)	

Source: European Medicines Agency, Hardman & Co Life Sciences Research

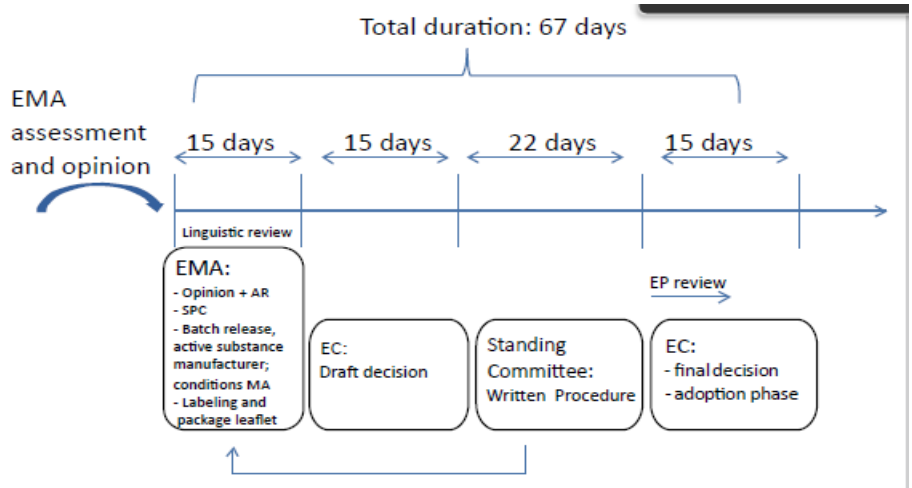
Next steps

European Market Authorisation

Marketing authorisation is binding across all member states

The European Commission now has up to 67 days to grant Alkindi European Marketing Authorisation that will be legally binding in all European member states. Typically, scientific opinions of the CHMP are adopted by consensus. If a consensus is not possible, the rules require an absolute majority of the member states.

The 67 day Decision Making Process (DMP)



Source: M. Kurz Pharmaceut Reg Affaires 2012, 1:3

All product labelling will be identical in all member state languages

During the 67 day period, member states check all translations of the product description, label and packaging and Diurnal will have to provide any modifications that are requested. The opinion of the CHMP and any annexes, translated in all European languages, are then sent to the European Commission and the applicant. It is also during this period that Diurnal will have to provide the EMA with a full colour mock-up of the outer packaging for Alkindi. It is the European Commission and not the EMA that is accountable for the authorisation.

Following transmission of the EMA opinion, the Commission generates within 15 days a draft decision which is forwarded to the 'Standing Committee' that has 22 days to provide a written procedure. After receipt of feedback from member states, the Commission has another 15 days for approval. In parallel the European Parliament has seven days to accomplish its own review.

Pricing

Once marketing authorisation has been granted, decisions about price and reimbursement take place with each member state. The potential role and use of the medicine will be assessed in the context of the national health system of that country.

Our forecasts are based on a price range of $6,100-7,000 across all markets

Although no indication has been given on Alkindi pricing, our forecasts assume that Diurnal will use Plenadren, a once daily formulation of hydrocortisone from Shire (SHP.L) as a benchmark ($7,000 / $6,100 p.a. depending of the market).

Reimbursement code

Both Alkindi® and Chronocort® Phase III programmes include follow-on studies designed to assess the longer-term impact of these therapies on important clinical measures such as quality of life. Diurnal has engaged specialist market access consultants to ensure expected benefits are well-understood by payers.

Commercial partner

Together with Ashfield Healthcare, Diurnal has built up a team of 10 commercial people to market Alkindi. During the year, Ashfield has been focused in establishing a Europe wide network of medical liaison staff. A sales force of 20-30 sales staff (at peak) is sufficient as patients are usually centralised in specialist endocrinology centres.

Commercial opportunity

First licensed product for use in AI in Europe

Alkindi will become the first and only licenced product for paediatric use for adrenal insufficiency available in Europe. With the PUMA dossier already validated by the EMA extending market exclusivity for ten years, Diurnal is expected to start revenues in 2Q 2018. With this in mind, and the fact that it received very positive appraisal from professional, patients, parents and carers, it would be expected to take market share relatively quickly.

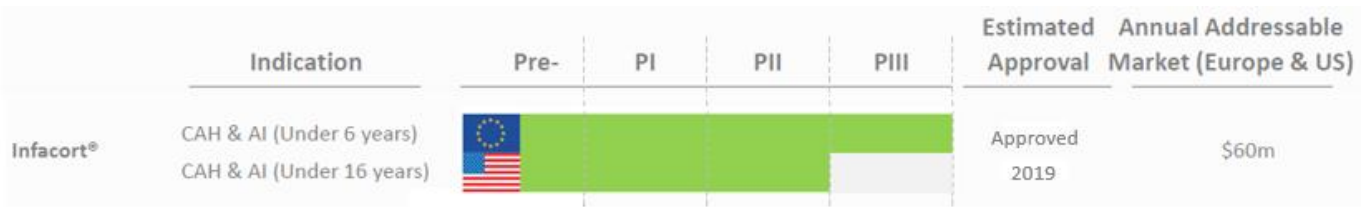
The next territory will be Israel...

Following commercialisation in Europe, Alkindi will be launched next in Israel through a marketing and distribution agreement that Diurnal signed with Medison in March 2017. Medison will use the European dossier, but the product still needs to undergo full regulatory review in Israel. Submission will be in 2018 with approval expected in 2019. Medison provides a vast spectrum of integrated services for companies looking to enter the Israeli healthcare market, and more specifically the niche indications.

With the US dependent on completion of Phase III trials

Approval and launch in the US is not expected before late 2019 and is dependent on successful completion of the US Phase III trial programme.

Alkindi – launch timelines



Source: Diurnal

Commercial infrastructure

Establishing European supply chain and commercial infrastructure

Diurnal will retain the full value of Alkindi through direct commercialisation

Diurnal will retain the full value of Alkindi through direct commercialisation in Europe with relevant partners:

- **Manufacturing:** Already established (since 2010) with specialist GMP supplier, Glatt GmbH, to produce solid pharmaceutical dosage formulations based on multi-particulate (granule) systems
- **Packaging:** Agreement with Sharp Packaging for its expertise in supply chain management
- **Sales & marketing:** Together with Ashfield Healthcare, Diurnal has built up the European sales and medical infrastructure team, employing ten persons, including a European network of medical liaison staff and key account managers

Both Ashfield and Sharp are part of the UDG Healthcare group (UDG.L), a global provider of outsourced commercialisation services to the pharmaceutical industry.

The commercial infrastructure will be used for subsequent products

This infrastructure will also be adopted for Chronocort. Ultimately, with the commercial organisation in place, Diurnal becomes a more attractive partner for companies looking to out-licence products for commercialisation in Europe or for any acquired asset in the endocrine field.

Market exclusivity

Orphan Drug designation

Alkindi was granted Orphan Drug designation for paediatric AI in the US (2015), which is expected to provide commercial exclusivity effective from the date of its market authorisation, providing Diurnal marketing exclusivity for seven years.

Paediatric Use of Marketing Authorisation (PUMA)

PUMA is a commercial European scheme targeting the paediatric sector...

PUMA is a type of marketing authorisation covering indications and appropriate formulations for the paediatric population. The development of a PUMA corresponds to a fast route to approval. It must follow a Paediatric Investigation Plan (PIP) agreed up-front with the paediatric committee of the European Medicines Agency.

- Already authorised
- No longer covered by a supplementary protection certificate or a patent
- Exclusively developed for use in children

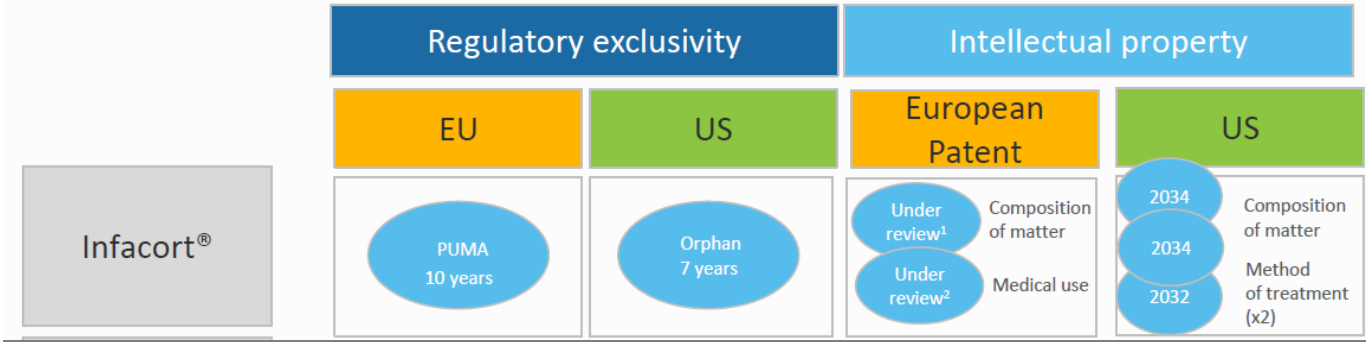
Diurnal has a PIP in place in respect of Alkindi. The PIP covers the paediatric population from newborns through to infants and children up to 18 years of age. A successful PUMA application for Alkindi will provide Diurnal with clear marketing advantages.

... giving 8 years of data exclusivity and 10 years of market exclusivity

- Ten years of market exclusivity

An application for a PUMA must contain the results of studies performed, and information collected, in compliance with the agreed PIP. Therefore, if the relevant studies are not conducted in accordance with the agreed PIP, a PUMA is unlikely to be obtained. Management intends to secure exclusivity for Alkindi in Europe by applying for a PUMA immediately following receipt of regulatory approval.

Diurnal – Commercial exclusivity



[1]Granted GB patent number: 2527233,[2] CAH and AI; Granted GB patent number 2509663
Source: Diurnal

Sales forecasts

Rationale

Given that Alkindi is designed for the paediatric sector where there is no licensed therapeutic for AI available in Europe or the US, and in view of the positive clinical outcomes from the Phase III trial, coupled with a supportive parents' and carers' surveys, we believe that Alkindi will be in a strong position to gain market share relatively quickly.

Population

In our previous report – '*Get the rhythm*' (dated 27th October 2016), we described the pricing policy, with Diurnal expected to align the price of Alkindi with that of Plenadren, licensed for adult adrenal insufficiency only (ca. $6,100/$7,000 annual cost depending on which market). In addition, the addressable market for paediatric adrenal insufficiency in CAH and Addison's disease was also described.

Addressable markets

	Europe	Israel	US	Total
Annual price of drug (25mg)	**$6,100**	**$7,000**	**$6,800**	
Prevalence				
Paediatric CAH	4,200	1,000	7,400	11,600
Paediatric Addison's disease	2,625		1,600	4,225
Market ($m)				
Paediatric CAH	25.6	7.0	50.3	75.9
Paediatric Addison's disease	16.0		10.8	26.8
Total market ($m)	**41.6**	**7.0**	**61.1**	**109.7**

Source: Hardman & Co Life Sciences Research

Alkindi sales model

Our forecasts for Alkindi are based around the following core assumptions:

- 0.77% population growth in the US[1] and 0.26% population growth in Europe[2]
- Approval of Alkindi in February 2018, followed by first sales in 2Q 2018 in Europe
- Alkindi receiving market authorisation in 2019 and first sales in 2020 in the US
- Average wholesaler discounts of 18.5% in Europe and Israel, and 30% in the US

Alkindi will be first launched in Germany and then rolled out across Europe over approximatively 12 months, reflecting local pricing discussions. Launch in Israel is expected in 2019 following regulatory approval. Applying these assumptions, our sales forecasts for Alkindi in Europe, Israel and the US are as follows:

Alkindi: sales model

	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Europe												
Addressable market	41.8	42.0	42.1	42.2	42.3	42.4	42.5	42.6	42.7	42.8	42.9	43.0
Market share	0.05%	6%	15%	23%	35%	42%	50%	53%	55%	57%	59%	60%
Sales ($m)	0.21	2.52	6.31	9.70	14.80	17.80	21.24	22.58	23.49	24.40	25.33	25.82
United States												
Addressable market	62.1	62.6	63.1	63.6	64.1	64.6	65.1	65.6	66.1	66.6	67.1	67.6
Market share			5%	15%	25%	33%	45%	50%	52%	54%	56%	58%
Sales ($m)			3.16	9.54	16.02	21.31	29.28	32.79	34.36	35.96	37.58	39.22
Israel												
Addressable market	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0
Market share		2%	10%	18%	25%	35%	45%	50%	53%	56%	59%	62%
Sales ($m)		0.14	0.70	1.26	1.75	2.45	3.15	3.50	3.71	3.85	3.99	0.14
Total in-market sales ($m)	0.21	2.66	9.88	19.65	31.14	39.67	51.07	55.95	58.51	61.02	63.55	65.68
Net sales* ($m)	0.17	2.17	7.72	15.01	23.70	30.09	38.56	42.16	44.08	45.96	47.86	49.42
Net sales (£m)	**0.13**	**1.60**	**5.72**	**11.12**	**17.56**	**22.29**	**28.56**	**31.23**	**32.65**	**34.04**	**35.45**	**36.61**

**After average wholesaler discounts*
GBP/US$: 1.35
Source: Hardman & Co Life Sciences Research

[1] http://www.worldmeters.info/worldpopulation/us-population
[2] http://ec.europa.eu/eurostat

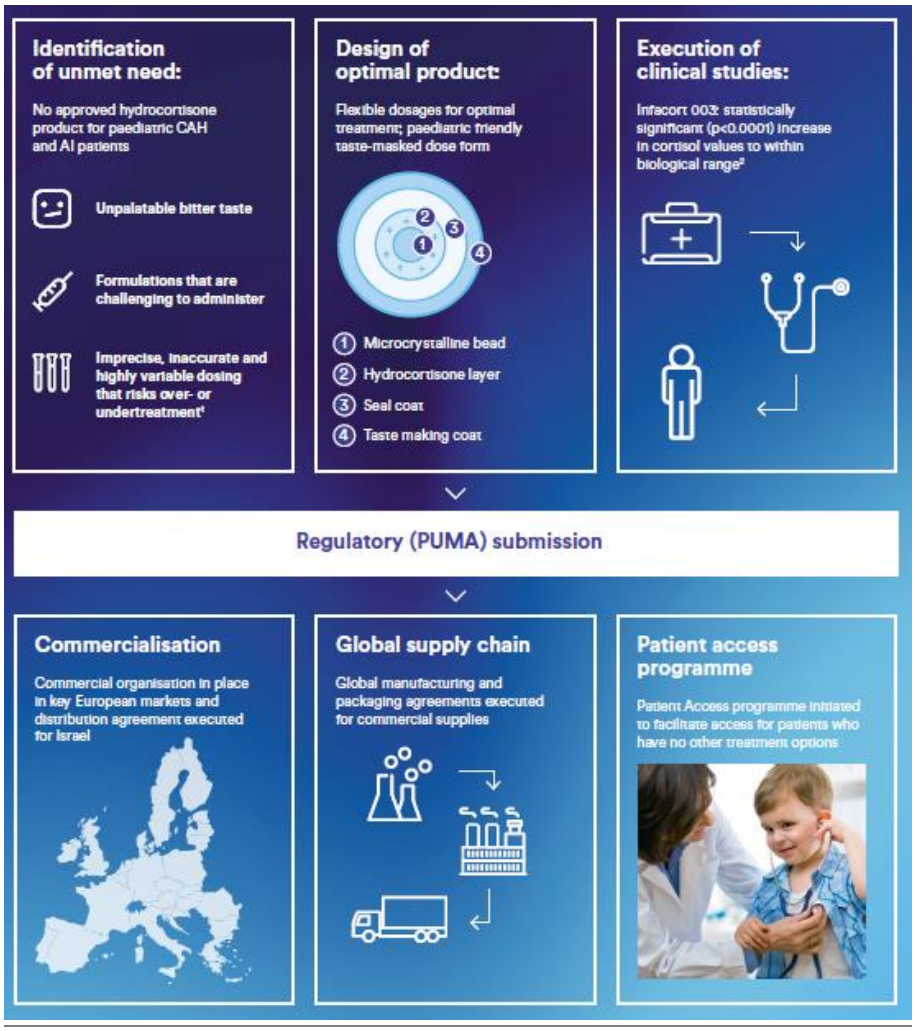
Alkindi – Key facts

Alkindi is an immediate release hydrocortisone (the synthetic version of cortisol) preparation for the control of Adrenal Insufficiency (AI), including Congenital Adrenal Hyperplasia (CAH) in children and infants. To conform with local compliance requirements, Alkindi is targeting:

- **Europe** – new-borns and infants up to 18 years of age, although the initial focus will be on children aged up to six years
- **US** – new-borns, infants and children up to the age of sixteen

To date, there is no child-friendly hydrocortisone replacement product for the above age groups in either Europe or the US. Alkindi represents the first-in-class licenced product. The goal with Alkindi is to deliver improved compliance, improved disease control and a reduced side effect profile due to incorrect dosing.

Alkindi: from concept to commercialisation



Source: Diurnal

Presentation

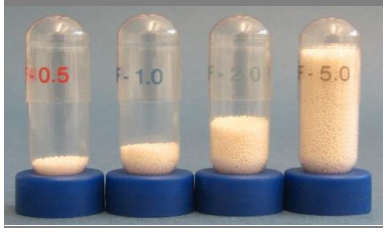
Multi-layered, and multi-particulate formulation...

Alkindi, like Diurnal's Chronocort product, uses the multi-particulate manufacturing technology with its multi-layered, multi-particulate formulation with four essential components:

...in four dose levels

- **Core** – inert microcrystalline bead needed for manufacturing
- **Inner layer** – comprising the active ingredient: hydrocortisone
- **Second layer** – which acts as a seal
- **Outer layer** – corresponding to a taste masking coat

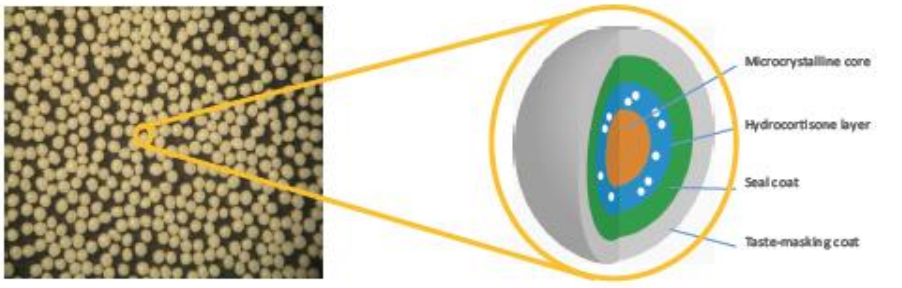
Alkindi – four dose levels



Source: Diurnal:

Manufacturing partner Glatt has all the processes in place to produce commercial batches. Alkindi will be available in capsules containing four different doses of multi-particulates – 0.5mg, 1mg, 2mg and 5mg – again providing endocrinologists with flexibility to individualise the dose according to a patient's needs, which is even more important when treating infants and babies. The capsules can be opened allowing the drug to be mixed/sprinkled with baby/infant food.

Alkindi® presentation



Source: Diurnal

Advantages of Alkindi

Diurnal developed Alkindi to fill a space where there is not an approved licensed product in paediatric adrenal insufficiency conditions.

Accuracy in dosing

Alkindi allows a high accuracy of dosing...

Current practice for paediatric use is for pharmacists to grind hydrocortisone tablets into a fine powder to titrate the dose according to a baby's/infant's weight. The aliquot of powder is then put into a capsule or sachet for administration/mixing with food. The potential for mistakes and weight inaccuracy is inherent with such techniques, leading to poor disease control. The availability of four different doses provides the maximum accuracy and flexibility.

Stability

...with a long shelf-life...

Stability studies on Alkindi are in progress. The shelf-life already exceeds two years, which represents superiority over existing non-licensed hydrocortisone products. Diurnal is still investigating the potential to extend the shelf-life further.

Child friendly preparation

...to aid compliance in children

A key characteristic of Alkindi is for the presentation to have an additional taste-masking outer layer, which aims to minimise the bitter taste of hydrocortisone. This makes it very child-friendly for regular administration.

Financials & investment case

No material changes have been made to forecasts since our previous report '*Ready to press the button*' (14th September 2017).

- **R&D:** Increased investment in R&D reflects the six clinical studies currently on-going; overlap of European and US trials has resulted in an increase in R&D forecasts for the next two years
- **SG&A** – Investment is being made in marketing infrastructure in readiness for the launch of Alkindi in 2018
- **Net cash/(debt):** At 30th June 2017, Diurnal had net cash of £16.4m. Our forecasts suggest that this will be sufficient to take the company through to the middle of calendar 2018 by which time, Alkindi will have been de-risked

Summary financials

Year end March (£000)	*2015	2016	2017	2018E	2019E	2020E
Profit & Loss						
Sales	0.00	0.00	0.00	0.13	3.18	15.19
COGS	0.00	0.00	0.00	-0.01	-0.32	-1.52
SG&A	-1.00	-1.99	-3.22	-6.00	-7.54	-9.14
R&D	-2.23	-3.89	-8.34	-10.50	-10.00	-7.00
Underlying EBIT	-2.99	-5.88	-11.55	-16.39	-14.67	-2.47
Share based costs	0.00	-0.49	-0.52	-0.54	-0.57	-0.60
Exceptional items	0.00	-0.62	0.00	0.00	0.00	0.00
Statutory EBIT	**-2.99**	**-6.99**	**-12.07**	**-16.93**	**-15.24**	**-3.07**
U/L pre-tax profit	-3.02	-5.95	-11.64	-16.57	-14.94	-2.83
Tax liability/credit	0.00	0.49	2.73	3.44	3.27	2.29
Weighted average (m)	**34.61**	**43.75**	**52.24**	**52.21**	**52.21**	**52.21**
Underlying basic EPS (p)	-8.49	-12.48	-17.05	-25.15	-22.35	-1.03
Balance sheet						
Share capital	0.00	0.00	0.00	0.00	0.00	0.00
Reserves	-9.31	23.32	14.46	0.79	-11.46	-12.60
Loans/Debt	0.02	0.00	0.00	0.00	0.00	0.00
less: Cash	6.07	30.11	19.88	6.68	-6.28	-10.93
Invested capital	**-0.01**	**-0.94**	**0.71**	**0.51**	**1.53**	**5.37**
Cashflow						
Trading profit	-2.99	-5.88	-11.55	-16.39	-14.67	-2.47
Working capital	0.02	0.95	1.09	0.12	-1.62	-4.91
Company op cashflow	**-2.96**	**-5.55**	**-10.72**	**-16.27**	**-16.30**	**-7.38**
Capital expenditure	-0.01	0.00	-0.02	-0.02	-0.02	-0.02
Free cashflow	**-2.88**	**-5.02**	**-10.55**	**-13.20**	**-12.96**	**-4.65**
Share issues	9.25	24.52	0.05	0.00	0.00	0.00
Change in net debt	**6.37**	**20.83**	**-10.51**	**-13.48**	**-13.26**	**-4.98**
Opening net cash	-0.34	6.05	26.88	16.37	2.89	-10.37
Closing net cash	**6.05**	**26.88**	**16.37**	**2.89**	**-10.37**	**-15.35**

**Year to July*

Source: Hardman & Co Life Sciences Research

Valuation

Discounted cashflow

The best approach to valuing biopharmaceutical companies is to prepare detailed discounted cashflow analyses of key products through to patent expiry, and then to risk-adjust the NPV based upon industry standards for the probability of the product reaching the market.

A tried and tested DCF model...

On the basis that Diurnal's strategy is to be a fully-integrated specialist pharmaceutical company, with its own sales force in key territories, a DCF has been prepared based on the following key assumptions:

...that is based on clearly stated assumptions...

- Infacort will develop market shares in EU and US of 27-35% five years' from first launch
- Chronocort will develop market shares in EU and US of 20-25% five years' from first launch for both CAH and AI

...and adjusted for the probability of products reaching the market based on industry standards

- Sales and cashflow forecasts are for the duration of the marketing exclusivity period in each territory after which generic versions could emerge, eliminating any terminal value – this approach may be considered conservative
- WACC is at the cost of equity – the way this type of company is funded – which is 10%
- The risk adjustment – probability of the product reaching the market – for Infacort is 100% and 60% in Europe and the US respectively; and for Chronocort is 60% for both territories. The weighted average is 67%
- No account has been taken of potential future products e.g. sex hormones

Diurnal – DCF valuation summary

WACC	NPV	Risk-adjusted NPV	Risk-adj NPV per share
8%	£398m	£267m	510p
9%	£357m	£239m	457p
10%	**£320m**	**£215m**	**410p**
11%	£287m	£193m	368p
12%	£258m	£173m	330p

Source: Hardman & Co Life Sciences Research

The risk-adjusted NPV of Diurnal is £208m, or 399p per share...

...suggesting that there is plenty of upside potential for shareholders

Based on our clearly stated assumptions, the net present value of the cashflows that could be generated from Diurnal's first two products alone equate to £320m. Risk-adjustment to take account of their different stages of development in different territories reduced this to £215m, or 410p per share. This model allows a very fast assessment of the likely effect on the share price following the announcement of clinical results and also suggests that there is plenty of upside for shareholders.

Peer group valuation

There are many specialty pharmaceutical companies with a very diverse range of market capitalisations. For our comparative valuation analysis, a group of quoted specialty pharma companies that are working in the field of endocrinology – but not working in diabetes/insulin – have been selected, to provide a guide about the relative valuation of Diurnal. Most of these companies are also at a similar stage of development as Diurnal, although the high valuation of Corcept (CORT.OQ) is likely due to the fact that it has a product on the market generating annual sales of ca.$160m. However, this also provides an indication of valuation uplift potential when Diurnal's products are launched.

- **Corcept** – Korlym (mifepristone) launched in 2012 for patients suffering Cushing's syndrome associated with hyperglycaemia. Looking to extend its use into prostate, ovarian and breast cancers, alcohol dependence and anxiety and stress disorders
- **Ascendis** – Trials with TransCon formulation technology to extend the release properties of growth hormone for use in hypoparathyroidism
- **Versartis** – Development of somavartan for growth hormone deficiency in both paediatrics (Phase III) and adults (Phase II). However, the stock has blown up following failure in a Phase III trial recently and is now trading below cash
- **Viking –** Developing therapeutics for patients suffering from metabolic and endocrine disorders –lead product VK5211 is in Phase II clinical trials

Peer group valuations

Company	Ascendis Pharmaceuticals	Corcept Therapeutics	Diurnal	Viking Therapeutics	Versartis
Ticker	**ASND**	**CORT**	**DNL**	**VKTX**	**VSAR**
Local currency (lc)	$	$	£	$	$
Share price	37.0	16.4	143.5	3.9	2.0
Shares in issue (m)	36.4	114.1	52.3	28.5	35.8
Market cap (lc)	1,345.7	1,871.6	75.1	111.1	71.6
Mkt cap (£m)	**1,792.5**	**2,493.0**	**75.1**	**148.0**	**95.4**
Cash	242.7	75.2	13.9	9.9	118.7
Debt	0.0	0.0	-3.5	-5.2	-40.0
EV (lc)	1,103.0	1,796.4	64.7	106.5	-7.1
EV (£m)	**828.1**	**1,348.7**	**64.7**	**79.9**	**-5.3**
Relative EV	12.8	20.8	-	1.2	-0.1

Prices taken at close of business on 15th December 2017
Source: Hardman & Co Life Sciences Research

Notes

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