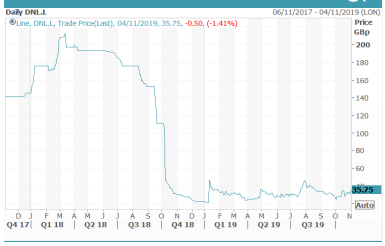
Pharmaceuticals & Biotechnology



Source: Refinitiv

Market data	
EPIC/TKR	**DNL**
Price (p)	**35.0**
12m High (p)	46.5
12m Low (p)	21.0
Shares (m)	84.5
Mkt Cap (£m)	29.6
EV (£m)	20.4
Free Float*	20%
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, with first sales started in May 2018; Chronocort has completed the largest and only Phase III trial globally in CAH.

Company information

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

Key shareholders

Directors	3.0%
IP Group	40.7%
Finance Wales	13.6%
Polar Capital	7.8%
Richard Griffiths	5.9%
Oceanwood Capital	3.7%

Diary

4Q'19	Alkindi US NDA submission
4Q'19	Chronocort EMA MAA

Analysts

Martin Hall	020 7194 7632
	mh@hardmanandco.com
Dorothea Hill	020 7194 7626
	dmh@hardmanandco.com
Grégoire Pavé	020 7194 7628
	gp@hardmanandco.com

DIURNAL GROUP

Approaching a number of near-term milestones

Diurnal (DNL) is a commercial-stage specialty pharmaceutical company focused on diseases of the endocrine system. Its two lead products are targeting rare conditions where medical need is currently unmet, with the aim of building a long-term 'Adrenal Franchise'. The first product, Alkindi®, is being rolled out through key EU markets, and sales have exceeded the £1.0m mark. Despite unexpected Phase III results, positive feedback from the EMA has cleared the path for regulatory submission of Chronocort for adult CAH in Europe before the end of 2019. It has also allowed DNL to revise the primary endpoint in the protocol for the US Chronocort Phase III trial.

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

- **Results:** The focus during 2019 has been to build up the launch of Alkindi in Europe and establish commercial partners in other key territories. Sales during 2019 were in line with forecasts, at £1.0m. Events around Chronocort caused some volatility in R&D spend, which left net cash of £9.1m at 30 June 2019.

- **Chronocort:** Following the surprising results of the European Phase III study with Chronocort, DNL met with the EMA and is now planning to submit an MAA in 4Q'19. The US Phase III trial in CAH will be amended following the European outcome and is expected to start once a partner is on board.

- **Risks:** Concerns about the US prospects for Chronocort have been allayed by the positive EMA outcome and the opportunity to revise its US Phase III protocol. However, this has added extra time into the US development process and delayed the point at which DNL is expected to become cashflow-positive.

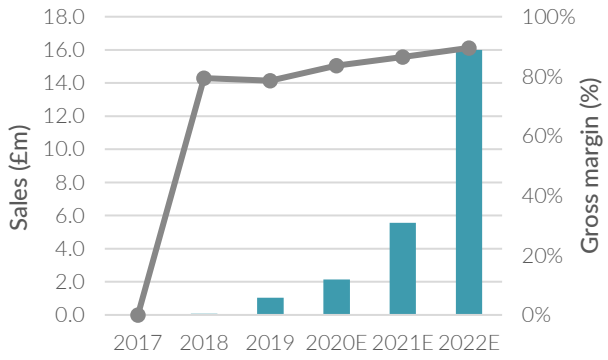
- **Investment summary:** Alkindi, a cortisol replacement therapy designed for children under 18 years of age, is DNL's first product on the market. It is expected to be followed by Chronocort for adults – a larger market – which now has a clear pathway for regulatory approval in both Europe and the US. Despite this, the share price is still languishing well below valuations determined by peer group and DCF (202p) analyses, due possibly to the need for more capital during 2020.

Financial summary and valuation

Year-end Jun (£m)	2017	2018	2019	2020E	2021E	2022E
Sales	0.00	0.07	1.04	2.14	5.56	15.99
SG&A	-3.23	-6.21	-5.83	-7.52	-9.22	-10.92
R&D	-8.34	-10.02	-8.69	-9.43	-8.96	-11.20
EBITDA	-12.07	-16.97	-14.50	-16.00	-14.25	-8.73
Underlying EBIT	-12.08	-16.98	-14.53	-16.02	-14.27	-8.76
Reported EBIT	-12.08	-16.98	-14.53	-16.02	-14.27	-8.76
Underlying PBT	-12.16	-17.11	-14.40	-15.98	-14.27	-8.83
Statutory PBT	-12.16	-16.91	-14.40	-15.98	-14.27	-8.83
Underlying EPS (p)	-18.04	-27.16	-14.54	-12.88	-11.27	-5.69
Statutory EPS (p)	-18.04	-26.78	-19.70	-12.88	-11.27	-5.69
Net (debt)/cash	16.37	17.28	9.15	0.29	-13.82	-22.46
Equity issues	0.05	13.40	5.53	5.57	0.00	0.00

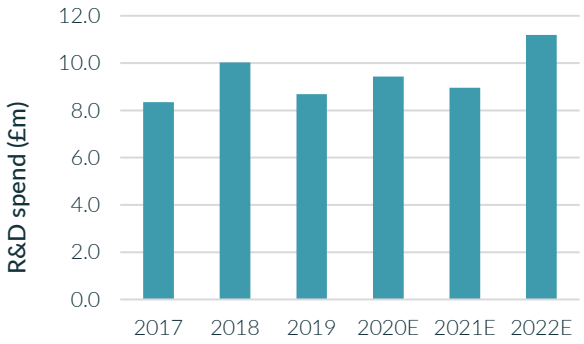
Source: Hardman & Co Life Sciences Research

Sales and gross margin



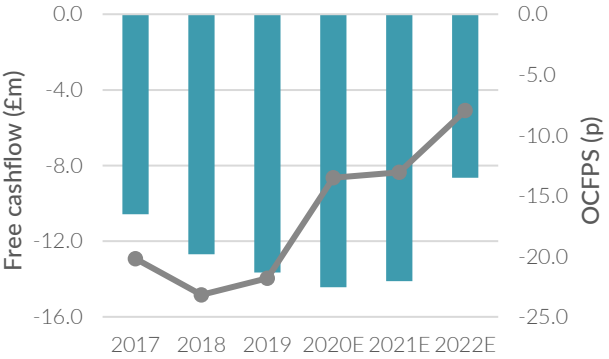
- Sales of Alkindi began in 2Q'18
- Alkindi sales exceeded £1.0m in 2019, after just two country launches
- Gross margin expected to stabilise at 90% in near term
- First sales of Chronocort anticipated to start around end-2021 in Europe

R&D investment



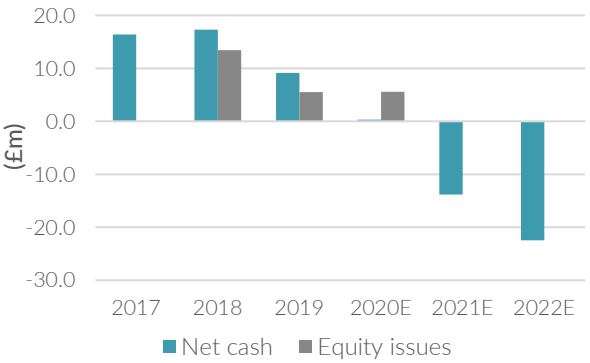
- Preparatory works for US Phase III trial (£2.3m) accounted for 2019 R&D fall
- R&D costs expected to remain constant in following years due to ongoing US Phase III trial in CAH
- US Phase II in AI with Chronocort now anticipated to start once a partner is on board

Free cashflow and OCFPS



- Cashflow driven by R&D investment and corporate overheads
- European subsidiary established and sales force recruited through Ashfield for commercial infrastructure
- Monthly average cashburn at ca.£0.75m for 2020

Net cash and equity issues



- At 31 June 2019, net cash was £9.15m
- Placing and Open offer raised of £5.9m gross (£5.5m net) in June 2019
- In 2018, outstanding convertible loan and accrued interest (total ca.£3.5m) were converted into shares concomitant with a Placing.
- Based on current forecasts, DNL will likely need to raise further cash before end of fiscal 2021

Source: Company data, Hardman & Co Life Sciences Research

2019 results – advancing the pipeline

Key features

Operational highlights

- **Alkindi – Europe:** Following the launch of Alkindi as a cortisol replacement therapy in Adrenal Insufficiency (AI) from birth to 18 years of age in Germany in May 2018, Alkindi is being rolled out across other European countries. The limiting step here is generally the negotiation of price/reimbursement.
- **Alkindi – US:** In the US, DNL has now successfully completed all the studies required for its New Drug Application (NDA), expected in 4Q'19. Partnering discussions have been initiated in the US.
- **Alkindi – RoW:** Concomitantly, through its specialist partners, market authorisations in other key territories have been submitted.
- **Chronocort – Europe:** Despite not meeting the primary endpoint in the European Phase III trial, DNL has received confirmation of the regulatory pathway that will permit a Market Authorisation Application (MAA) for CAH, which is expected to be filed in 4Q'19.
- **Chronocort – US:** Following the European Phase III outcome, management prudently put the US trial on hold. A new design has been proposed, and the study is now expected to commence with a partner.
- **Pipeline:** The oral testosterone replacement product has completed the Phase I/II proof-of-concept trial. Read-out is expected during 4Q'19. DNL anticipates engaging with a partner to run and fund the subsequent trial.

Commercial highlights

- **Alkindi:** This drug is now available in the UK, Germany, Austria, Sweden and Denmark, with pricing agreed in Italy, Iceland and Norway.
- **Sales infrastructure:** The commercial infrastructure and supply chain are in place for Alkindi throughout Europe, with Ashfield Healthcare building up a team of commercial staff. The infrastructure will be used also for subsequent products, such as Chronocort.
- **Distribution:** Outside its core territories, DNL continues to expand its commercial infrastructure in countries that recognise the EU market authorisation dossier (so far, Israel, Australia and New Zealand). Also, DNL is entering into local distribution agreements with specialist partners, such as Frost Pharma for the Nordic regions.

Financial highlights

- **Sales:** Net sales of £1.04m were recorded for Alkindi in fiscal 2019, derived largely from Germany and the UK; the result was broadly in line with our forecast. Timing is difficult to predict, being dependent on pricing discussions on a country-by-country basis. The initial gross margin, at 79%, is expected to stabilise at ca.90% in the near term.
- **SG&A:** Underlying administration costs decreased 6% to -£5.8m, from -£6.2m, reflecting tight cost control and the slower-than-expected launch roll-out of Alkindi while pricing negotiations are ongoing.
- **R&D:** Spend in 2019, at -£8.69m, was lower than in 2018 (£-10.0m), and lower than we had forecast (£-10.0m), caused by the pause in preparatory work for the US Phase III trial and completion of the European Phase III trial for Chronocort.

- **Placing:** DNL undertook a Placing and Open Offer of new Ordinary shares at 26p per share in June 2019, raising gross new capital of £5.9m (£5.5m net).
- **Net cash/(debt):** At 30 June 2019, the gross cash on the balance sheet was £9.2m (£17.3m), which was about -£0.7m lower than we had expected, due to the increased working capital requirements often seen with growth companies.

Diurnal – 2019 Results, actual vs. expectations

Year-end Jun (£m)	2018 actual	2019 actual	Growth %	2019 forecast	Delta Δ
Sales	0.07	1.04	nm	1.14	-0.10
COGS	-0.02	-0.22	nm	-0.17	-0.05
Gross margin	79.5%	78.5%	-	85%	-
R&D spend	-10.02	-8.69	-13%	-10.0	+1.31
Administration costs	-6.21	-5.83	-6%	-5.50	-0.38
Underlying EBIT	**-16.98**	**-14.53**	**-14%**	**-15.38**	**+0.78**
Net cash/(debt)	17.28	9.15	-	9.80	-0.65

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

Diurnal – development timetable in Europe and the US

[1] *Subject to confirmation from the FDA*
[2] *Subject to NIH Grant, further funding or partnering*
Source: Diurnal 2019 results presentation, September 2019

2019-20 milestones

Key value inflections point for 2019-20

Milestones	Date	Status
Meeting with FDA to confirm NDA submission pathway for Alkindi	1Q'19	✓
Scientific Advice with EMA to confirm regulatory submission path for Chronocort	2Q'19	✓
DITEST Phase I/II readout	4Q'19	
Chronocort European regulatory submission (CAH)	4Q'19	
Alkindi US NDA submission (AI and CAH)	4Q'19	
Conclude US partnering discussion for Alkindi (Chronocort)	1H'20	
Potential approval of Alkindi in the US	End-2020	
Potential approval of Chronocort in Europe	Early-2021	

Source: Diurnal, Hardman & Co Life Sciences Research

Alkindi

First full year of sales in Europe

Alkindi being rolled out across Europe

In 2019, the first full year on the market for Alkindi, sales reached over £1m. Despite being a centralised authorisation process for the EU, the roll-out of Alkindi has to be a staged process, influenced by the timetable for agreeing pricing with the relevant authorities in each country. This is normal practice for drugs approved in Europe. Although Germany was the first-launch territory, pricing discussions took some time to reach a conclusion, with the price agreed only recently, at which point endocrinologists knew the cost of prescribing Alkindi. On the other hand, since approval in September 2018 in the UK, pricing discussions have gone smoothly, with sales accounting for 29% of the total in fiscal 2019.

Alkindi customer analysis

Source: Diurnal 2019 results presentation, Hardman & Co Life Sciences Research

To date, Alkindi has been launched in Germany (May 2018), the UK (September 2018), Austria (April 2019), Sweden (July 2019) and Denmark (July 2019), and pricing has been approved in the UK, Germany, Italy, Austria, Denmark, Iceland, Norway and Sweden. Further launches are expected before the end of calendar 2019, including, in the Nordic region, through DNL's distribution partner, Frost Pharma (formerly Anthrop Pharma). In addition, DNL has received a positive Scottish Medicines Consortium (SMC) pricing & reimbursement decision, allowing the roll-out of sales of Alkindi in Scotland and elsewhere in the UK, which tends to follow the SMC's decision.

Overall, the roll-out of Alkindi launches has been slower than expected due to external factors, such as slow pricing/reimbursement discussions and Brexit, as well as the implementation of new regulations (Falsified Medicines Directive), which require a unique bar code for each package. Despite these factors, Alkindi sales in 2019 remained largely in line with our forecasts.

Brexit plan

DNL has developed its product supply chain to minimise the impact of Brexit, should the UK depart from the EU with or without an agreement:

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

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

FDA submission for Alkindi before end-2019

US update

Meanwhile, DNL has confirmed its intention to file its NDA with the FDA for Alkindi in paediatric AI and CAH by 4Q'19. Approval is expected to take approximately 12 months. No further studies are required, and the European dossier will be used, together with two additional studies, both successfully completed.

In parallel with the NDA submission, DNL will seek confirmation of Orphan Drug Status for Alkindi in paediatric AI. The company will need to provide evidence of significant clinical benefit of Alkindi over existing therapies.

To maximise the commercial opportunity, DNL does not intend to sell Alkindi directly in the US, but through a licensing partner, and discussions with potential partners have been initiated.

Rest of the World

In other territories, commercialisation will be through local distributors, with knowledge of either endocrine or niche markets, who will be responsible for dealing with the local regulatory authorities. Such deals also cover DNL's other products.

Israel

DNL signed a marketing and distribution agreement with Medison Pharma in 2018, to make Alkindi and Chronocort available in Israel. The Ministry of Health in Israel has confirmed receipt of the Alkindi submission and that it has been validated. Market authorisation is expected to take a year, and first sales are therefore expected during 1H'20. With around 1,000 patients affected, the market opportunity for Alkindi and Chronocort is estimated at $6.3m.

Australia and New Zealand

DNL has licensed (February 2018) exclusive rights to sell Alkindi and Chronocort in Australia and New Zealand to Emerge Health, a specialist hospital pharma company. Emerge submitted an application for market authorisation in July 2019 to the Australian Therapeutic Goods Administration, with first sales expected towards the end of 2020. Around 1,750 patients are affected by paediatric AI and adult CAH, giving a market estimated to be worth $10.2m.

Nordic regions

Exclusive rights for Alkindi in the Nordic regions – covering Sweden, Norway, Denmark, Finland and Iceland – have been out-licensed to Frost Pharma. With an estimated 490 paediatric patients in this region, the market is valued at $3.1m.

Japan

First patents for Alkindi and Chronocort have been granted by the Japanese Patent Office. DNL 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.

Marketing and distribution agreements in place

Country	Partner	Marketing and distribution agreement	First sales	Patents granted	Addressable market[2]
Israel[1]	Medison Pharma	Yes	2020	Yes	$6.3m
Australia & New Zealand	Emerge Health	Yes	2020	Yes	$10.2m
Nordic regions	Frost Pharma	Yes	2019	Yes	$3.1m
US	TBA	TBA	2021	Yes	$132m (plus indication expansion)
Japan	TBA	TBA	TBC	Yes	$415m

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

Chronocort

Post the Phase III European trial

Preparing for EMA submission

No further trials needed…

…paving the way for MAA submission in 4Q'19

Despite not meeting the complex primary endpoint of superior control over a period of 24 hours, compared with conventional glucocorticoid therapy in the pivotal Phase III trial with Chronocort in adult CAH patients, DNL met with representatives of the EMA to discuss a way forward. Formal Scientific Advice following the meeting was positive, with the EMA confirming the clinical and regulatory pathway. At its 2019 results meeting, DNL confirmed its intention to submit an MAA for Chronocort in CAH in Europe in 4Q'19, with approval potentially a year later or in early 2021.

The EMA representatives understood the statistical issue with the Phase III data, as well as the evidence of better control of biomarkers and improved quality of life using Chronocort. Importantly, feedback confirmed that no new data were needed for the purpose of a regulatory submission.

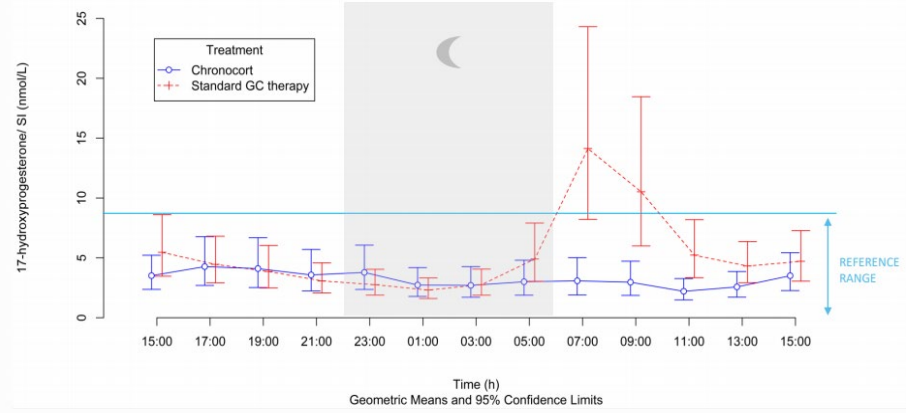
As part of the MAA, DNL intends to extend the use of Chronocort to adolescent CAH patients, in line with its objective of a long-life adrenal franchise strategy. Also, DNL will apply for Orphan Drug Status in Europe.

Advantages of Chronocort

Despite not meeting its primary endpoint, Chronocort bears several significant advantages compared with standard-of-care

Full analysis of the data highlighted several crucial advantages that Chronocort exposes compared with standard-of-care:

Chronocort Phase III trial results



Source: Diurnal 2019 results presentation, Hardman & Co Life Sciences Research

- Chronocort achieved androgen control of both 17-OHP and another androgen marker, androstenedione (A4), at a lower dose (30mg) compared with standard treatments (35mg).
- Crucially, Chronocort achieved the desired level of 17-OHP in the critical early-morning period – a level that is usually too high in patients with standard-of-care (increased cortisol levels address morning fatigue).
- There was no adrenal crisis with Chronocort (an event requiring hospitalisation for several days) vs. three events in patients on standard-of-care.
- There were significantly lower overall 17-OHP levels over the 24-hour period, as measured by the area under the curve (see graph above).
- There were less variable biomarker levels on Chronocort.

- Chronocort was well tolerated and provided the natural overnight cortisol release, unlike standard therapy.
- There were fewer "sick days" in patients receiving Chronocort (during sickness, the cortisol level naturally increases): 26 days vs. 36 days with standard-of care.
- Additional unexpected benefits we seen with Chronocort, such as less fatigue and the return of menstrual cycles in female patients; also note that one patient was pregnant while receiving the drug.

Extension study

Data from Phase III safety extension study with Chronocort helped discussions with EMA

Following completion of the Phase III study, DNL has been conducting an open-label safety extension study [DIUR-006, NCT03062280] for patients wishing to continue on Chronocort or electing to switch from their current glucocorticoid therapy (standard-of-care) to Chronocort. To date, a total of 91 patients have been enrolled. The main aspect of the trial is to assess the long-term safety and tolerability of Chronocort, with the study expected to run until regulatory approval. DNL has indicated that there has been a low drop-out rate from the extension study (less than 10%).

In an interim analysis (April 2019), DNL stated that a number of patients had been on Chronocort for more than 30 months and were all still continuing with the treatment. This analysis indicated additional benefits of Chronocort, such as:

- 17-OHP and A4 androgen control maintained over the 24-month period;
- further steroid dose reduction over the period;
- weight and body-mass index (BMI) maintained during the period; and
- metabolic parameters unchanged.

DNL will continue to assess interim data from the long-term Chronocort study, which will provide additional information to determine whether the effect can be maintained and whether there will be additional clinical benefits.

US Phase III trial in CAH

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

The outcome of the EMA Scientific Advice meeting was important in guiding amendments to the US Phase III trial protocol, and means that DNL can now resume all the regulatory and preparatory work. 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 US Phase III study will be run with a partner, and DNL has indicated that it is in advanced discussions with a suitable specialist pharma company. However, it does still have the option to run the trial by itself, although this would require additional capital.

Chronocort in AI patients

DNL also intends to start a US Phase II trial in order to address the large AI market. This trial is expected to be conducted at some of the same sites as the Phase III CAH trial, and DNL will investigate different options to finance it, such as grant funding, partnering or further capital. As such, the trial could start around the end of 2019.

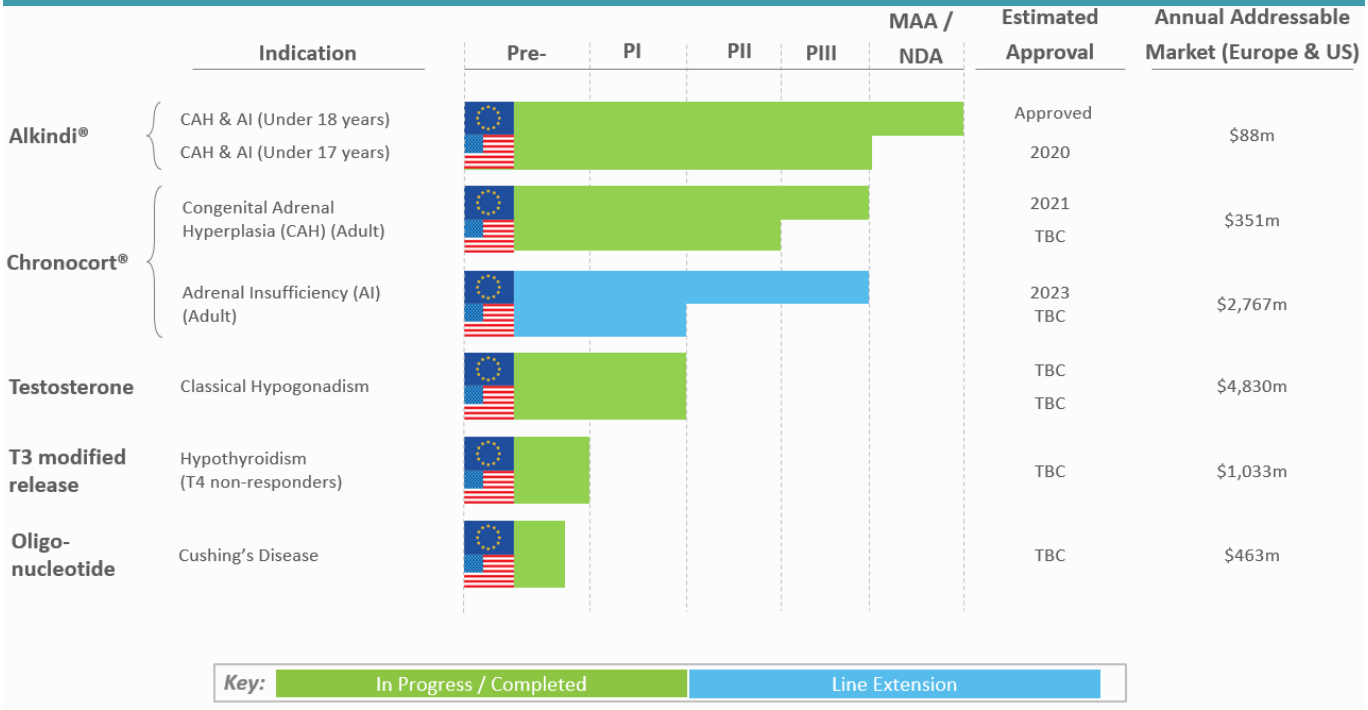
Updated pipeline

Building the endocrine pipeline

DNL's vision is "to become a world-leading endocrinology speciality pharma company". It aims to maximise its commercial infrastructure in the niche field of endocrinology, which is dominated 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.

In addition, DNL has been investigating opportunities for alternative capital for the early-stage programmes, such as grant funding. DNL has applied for various grants, and it has already received positive feedback, due to the unmet needs that the company is aiming to address.

Diurnal – R&D pipeline



Source: Diurnal 2019 results presentation

In the meantime, DNL is evaluating products for additional endocrine conditions

European Phase I/II in hypogonadism completed

The Phase I/II proof-of-concept trial with DITEST, a new oral formulation of native testosterone for the treatment of male hypogonadism, is now completed. The study was designed to evaluate the pharmacokinetic data in 12 patients with primary and secondary hypogonadism. The study consisted of two parts:

- the first part of the trial was about safety and tolerability of DITEST in 12 patients; and
- the second part involved a higher dose of DITEST in both fasted and fed states.

Final trial results are expected to be communicated during 4Q'19 and, depending on positive outcomes, DNL will have discussions with potential partners about taking the product forward.

Hypothyroidism

Early development of a modified-release T3 (triiodothyronine) product continues to progress. It is believed that up to 20% of the hypothyroidism population does not respond to pro-hormone T4 therapy, which is the current standard-of-care. DNL sees a considerable opportunity for this innovative product.

Potential treatment for Cushing's disease

DNL is reviewing its options with an oligonucleotide silencing RNA (siRNA) acting on the pituitary gland for a potential treatment for Cushing's disease, a condition characterised by an excess of cortisone secretion. *In vitro* studies, assessing the stability of the molecule in different formulations, have shown that the molecule is robust and efficacious. DNL owns the Orphan Drug Designation for this molecule in Europe.

Financial summary

Profit & Loss

- **Sales:** Sales of Alkindi in its first full year were just over £1.0m. Growth in sales is dependent on two factors, both of which are difficult to predict: the timing of reimbursement discussions in remaining European countries and the cycle of patients returning for clinic appointments (typically three- to six-month cycle).
- **Gross margin:** The gross margin in 2019 was 78.5%. DNL is aiming to improve the gross margin over the longer term. This will be achieved through the combination of a 36-month shelf life and increased product demand, allowing DNL to increase the manufacturing batch size with both Glatt and Delpharm.
- **SG&A:** Administration costs were reduced following the unexpected Phase III result with Chronocort. Herein, marketing costs will increase as a consequence of the launch roll-out of Alkindi, while general administration costs are likely to remain stable.
- **R&D:** The outcome of the Phase III study with Chronocort prompted a pause in R&D investment. Now that the regulatory pathway has been confirmed, activities will resume for the Phase III trial in CAH patients and the Phase II trial in AI patients. Costs could be shared in the event that they are run with partners, which would significantly reduce the cost shown in our model.

Profit & Loss account						
Year-end Jun (£m)	**2017**	**2018**	**2019**	**2020E**	**2021E**	**2022E**
Sales	0.00	0.07	1.04	2.14	5.56	15.99
COGS	0.00	-0.02	-0.22	-0.35	-0.75	-1.67
SG&A	-3.23	-6.21	-5.83	-7.52	-9.22	-10.92
Share-based costs	-0.52	-0.81	-0.83	-0.87	-0.91	-0.96
R&D	-8.34	-10.02	-8.69	-9.43	-8.96	-11.20
EBITDA	-12.07	-16.97	-14.50	-16.00	-14.25	-8.73
Depreciation	-0.01	-0.01	-0.02	-0.02	-0.02	-0.02
Licensing/Royalties	0.01	0.00	0.00	0.00	0.00	0.00
Underlying EBIT	**-12.08**	**-16.98**	**-14.53**	**-16.02**	**-14.27**	**-8.76**
Exceptional items	0.00	0.00	0.00	0.00	0.00	0.00
Statutory EBIT	-12.08	-16.98	-14.53	-16.02	-14.27	-8.76
Net interest	-0.09	-0.13	0.13	0.05	0.00	-0.07
Underlying PBT	**-12.16**	**-17.11**	**-14.40**	**-15.98**	**-14.27**	**-8.83**
Reported PBT	-12.16	-16.91	-14.40	-15.98	-14.27	-8.83
Tax liability/credit	2.73	2.28	2.11	2.29	2.17	2.72
Tax rate	-22%	-13%	-15%	-14%	-15%	-31%
Underlying net income	**-9.43**	**-14.83**	**-12.29**	**-13.69**	**-12.10**	**-6.11**
Statutory net income	-9.43	-14.62	-12.29	-13.69	-12.10	-6.11
Ordinary 5p shares:						
Period-end (m)	52.32	61.34	84.53	107.33	107.33	107.33
Weighted average (m)	52.24	54.60	62.39	106.27	107.33	107.33
Fully-diluted (m)	56.66	59.42	66.85	110.74	111.80	111.80
Underlying basic EPS (p)	**-18.0**	**-27.2**	**-14.5**	**-12.9**	**-11.3**	**-5.7**
Statutory basic EPS (p)	-18.0	-26.8	-19.7	-12.9	-11.3	-5.7
Underlying fully-dil. EPS (p)	-16.6	-24.9	-18.4	-12.4	-10.8	-5.5
Statutory fully-dil. EPS (p)	-16.6	-24.6	-18.4	-12.4	-10.8	-5.5
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Hardman & Co Life Sciences Research

Balance sheet

- **Inventory:** As expected, the stock levels of Alkindi have been increased in preparation for upcoming country launches.
- **Working capital:** As is usual during the growth phase of a company, there is an increase in the capital tied up with receivables and payables. This will unwind over a period of time, as shown in the reduction in debtor days and creditor days.
- **Net cash/(debt):** At 30 June 2018, DNL had gross cash of £9.1m, and no debt. Based on current forecasts, we estimate DNL to have sufficient cash through to the end of calendar 2020, when further cash will be needed. This could come in one, or a combination, of several forms. Notably, DNL is contemplating the option of finding a partner to run the US Phase III trial in CAH and the global Phase II trial in AI, each of which could have a positive impact on its cash position.

Balance sheet						
at 31 Jun (£m)	2017	2018	2019	2020E	2021E	2022E
Shareholders' funds	17.08	16.88	10.94	2.83	-9.27	-15.38
Cumulated goodwill	0.00	0.00	0.00	0.00	0.00	0.00
Total equity	17.08	16.88	10.94	2.83	-9.27	-15.38
Share capital	2.62	3.07	4.23	4.23	4.23	4.23
Reserves	14.46	13.81	6.72	-1.40	-13.50	-19.61
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	3.51	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	8.88	17.28	9.15	0.29	-13.82	-22.46
less: Deposits	11.00	0.00	0.00	0.00	0.00	0.00
Invested capital	**0.71**	**-0.40**	**1.80**	**2.54**	**4.55**	**7.08**
Fixed assets	0.02	0.03	0.03	0.04	0.06	0.08
Intangible assets	0.00	0.02	0.05	0.05	0.05	0.05
Inventories	0.00	0.12	0.67	1.38	3.58	5.15
Trade debtors	*0.00*	*0.08*	*0.51*	*1.07*	*1.39*	*2.66*
Other debtors	*4.03*	*5.02*	*3.05*	*0.90*	*0.85*	*0.81*
Tax credit/liability	*0.00*	*0.00*	*0.00*	*2.20*	*2.23*	*2.44*
Trade creditors	*-1.72*	*-3.32*	*-1.15*	*-1.35*	*-1.75*	*-2.05*
Other creditors	*-1.62*	*-2.35*	*-1.37*	*-1.75*	*-1.86*	*-2.07*
Debtors less creditors	0.68	-0.57	1.04	1.07	0.87	1.81
Invested capital	**0.71**	**-0.40**	**1.80**	**2.54**	**4.55**	**7.08**
Net cash/(debt)	**16.37**	**17.28**	**9.15**	**0.29**	**-13.82**	**-22.46**
Stock days	-	615	235	175	163	100
Debtor days	-	385	178	135	81	46
Creditor days	-	nm	1,866	1,288	754	414

Source: Hardman & Co Life Sciences Research

Cashflow

- **Underlying EBIT:** The P&L is the main driver of cashflow.
- **Working capital:** The build-up of inventories, debtors and creditors is consistent with the product launch and growth phase of a company.
- **Placing:** In June 2019, DNL completed a £5.9m (gross)/£5.5m (net) fundraise via a Placing and Open Offer. This boosted the period-end cash position.
- **Capital increase:** Based on our forecasts, in order to support the commercialisation of products and the clinical trial programme, the company will need to raise more capital before the end of the 2020 financial year. However, management is seeking co-development/commercial partners in some territories, which could result in upfront licensing payments, and which would have a direct bearing on the timing and quantum of money that would need to be raised.

Cashflow						
Year-end Jun (£m)	2017	2018	2019	2020E	2021E	2022E
Underlying EBIT	-12.08	-16.98	-14.53	-16.02	-14.27	-8.76
Depreciation	0.01	0.01	0.02	0.02	0.02	0.02
Share-based costs	0.00	-0.12	-0.55	-0.71	-2.20	-1.57
Inventories	*0.00*	*-0.12*	*-0.55*	*-0.56*	*-0.32*	*-1.28*
Receivables	*0.00*	*-0.12*	*-0.55*	*-0.20*	*-0.40*	*-0.30*
Payables	*-0.77*	*-1.54*	*1.36*	*-1.47*	*-2.91*	*-3.14*
Change in working capital	1.09	0.66	-2.33	-1.47	-2.91	-3.14
Other	-0.27	0.00	0.00	0.00	0.00	0.00
Company op. cashflow	**-10.74**	**-15.50**	**-16.01**	**-16.61**	**-16.26**	**-10.92**
Net interest	0.19	0.11	0.13	0.05	0.00	-0.07
Lease payments	0.00	0.00	0.00	0.00	0.00	0.00
Tax paid/received	0.00	2.74	2.28	2.20	2.23	2.44
Operational cashflow	**-10.55**	**-12.66**	**-13.60**	**-14.36**	**-14.02**	**-8.55**
Capital expenditure	-0.02	-0.02	-0.03	-0.03	-0.04	-0.04
Free cashflow	-10.57	-12.69	-13.66	-14.43	-14.11	-8.64
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	**-10.57**	**-12.69**	**-13.66**	**-14.43**	**-14.11**	**-8.64**
Share repurchases	0.00	0.00	0.00	0.00	0.00	0.00
Share issues	0.05	13.40	5.53	5.57	0.00	0.00
Change in net debt	**-10.51**	**0.91**	**-8.14**	**-8.86**	**-14.11**	**-8.64**
OCFPS (p)	-20.2	-23.2	-21.8	-13.5	-13.1	-8.0
Opening net cash	26.88	16.37	17.28	9.15	0.29	-13.82
Closing net cash	**16.37**	**17.28**	**9.15**	**0.29**	**-13.82**	**-22.46**

Source: Hardman & Co Life Sciences Research

Valuation

DCF

DCF valuation of 202p per share

The consequence of the Chronocort trial outcome is minimal in the bigger picture, as it has delayed both the EMA MAA submission and the start of the US Phase III trial only by about six months. Hence, there has not been a material change to our DCF valuation based on our clearly-stated assumptions in our *research note*, published on 25 April 2019. The net present value of the cashflows that could be generated from DNL's first two products equates to £305m. Risk-adjustment to take account of the different stages of development in different territories reduces this to £171m, or 202p per share.

Diurnal – DCF valuation summary

WACC	NPV (£m)	Risk-adjusted NPV (£m)	Risk-adjusted NPV per share (p)
8%	388	217	257
9%	344	193	228
10%	**305**	**171**	**202**
11%	271	152	180
12%	241	135	160

Source: Hardman & Co Life Sciences Research

Peer group comparisons

Valuation uplift potential for DNL 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 DNL. This gives an indication of the valuation uplift potential for DNL as it makes further progress in the US. The peer group comparative valuations are shown in the following table. Since our last publication, Corcept has seen an appreciation of its EV by 22%, while the EVs of Ascendis, Millendo and Viking have fallen by 5%, 68% and 45%, respectively, due largely to the difficult biotech market.

Over the same period, DNL's EV has appreciated by 108%.

Comparative valuation

Company	Ascendis	Corcept.	Diurnal	Millendo	Viking
Ticker	ASND	CORT	DNL	MLND	VKTX
Local currency	$	$	£/p	$	$
Share price	97.5	14.5	35.0	7.4	6.7
Shares in issue (m)	47.2	113.7	84.5	13.4	72.2
Market cap. (lc, m)	4,601.1	1,648.5	29.6	99.5	485.3
Market cap. (£m)	3,566.7	1,277.9	29.6	77.1	376.2
Cash (lc, m)	767.1	201.5	9.1	55.3	292.6
Debt (lc, m)	0.0	0.0	0.0	-0.5	0.0
EV (lc, m)	3,834.0	1,447.0	20.4	44.7	192.6
EV (£m)	2,972.1	1,121.7	20.4	34.7	149.3
Relative EV (x)	**145.4**	**54.9**	**-**	**1.7**	**7.3**
2020E sales (£m)	0.0	286.0	2.1	0.0	0.0
EV/sales (x)	-	5.1	10.2	-	-

lc = local currency
Share prices and currencies taken at close of business on 1 November 2019
Source: Hardman & Co Life Sciences Research

As seen many times before with UK small-cap biotech companies, US peers 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 DNL's products become further de-risked.

Disclaimer

Hardman & Co provides professional independent research services and all information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable. However, no guarantee, warranty or representation, express or implied, can be given by Hardman & Co as to the accuracy, adequacy or completeness of the information contained in this research and they are not responsible for any errors or omissions or results obtained from use of such information. Neither Hardman & Co, nor any affiliates, officers, directors or employees accept any liability or responsibility in respect of the information which is subject to change without notice and may only be correct at the stated date of their issue, except in the case of gross negligence, fraud or wilful misconduct. In no event will Hardman & Co, its affiliates or any such parties be liable to you for any direct, special, indirect, consequential, incidental damages or any other damages of any kind even if Hardman & Co has been advised of the possibility thereof.

This research has been prepared purely for information purposes, and nothing in this report should be construed as an offer, or the solicitation of an offer, to buy or sell any security, product, service or investment. The research reflects the objective views of the analyst(s) named on the front page and does not constitute investment advice. However, the companies or legal entities covered in this research may pay us a fixed fee in order for this research to be made available. A full list of companies or legal entities that have paid us for coverage within the past 12 months can be viewed at http://www.hardmanandco.com/legals/research-disclosures. Hardman may provide other investment banking services to the companies or legal entities mentioned in this report.

Hardman & Co has a personal dealing policy which restricts staff and consultants' dealing in shares, bonds or other related instruments of companies or legal entities which pay Hardman & Co for any services, including research. No Hardman & Co staff, consultants or officers are employed or engaged by the companies or legal entities covered by this document in any capacity other than through Hardman & Co.

Hardman & Co does not buy or sell shares, either for their own account or for other parties and neither do they undertake investment business. We may provide investment banking services to corporate clients. Hardman & Co does not make recommendations. Accordingly, they do not publish records of their past recommendations. Where a Fair Value price is given in a research note, such as a DCF or peer comparison, this is the theoretical result of a study of a range of possible outcomes, and not a forecast of a likely share price. Hardman & Co may publish further notes on these securities, companies and legal entities but has no scheduled commitment and may cease to follow these securities, companies and legal entities without notice.

The information provided in this document is not intended for distribution to, or use by, any person or entity in any jurisdiction or country where such distribution or use would be contrary to law or regulation or which would subject Hardman & Co or its affiliates to any registration requirement within such jurisdiction or country.

Some or all alternative investments may not be suitable for certain investors. Investments in small and mid-cap corporations and foreign entities are speculative and involve a high degree of risk. An investor could lose all or a substantial amount of his or her investment. Investments may be leveraged and performance may be volatile; they may have high fees and expenses that reduce returns. Securities or legal entities mentioned in this document may not be suitable or appropriate for all investors. Where this document refers to a particular tax treatment, the tax treatment will depend on each investor's particular circumstances and may be subject to future change. Each investor's particular needs, investment objectives and financial situation were not taken into account in the preparation of this document and the material contained herein. Each investor must make his or her own independent decisions and obtain their own independent advice regarding any information, projects, securities, tax treatment or financial instruments mentioned herein. The fact that Hardman & Co has made available through this document various information constitutes neither a recommendation to enter into a particular transaction nor a representation that any financial instrument is suitable or appropriate for you. Each investor should consider whether an investment strategy of the purchase or sale of any product or security is appropriate for them in the light of their investment needs, objectives and financial circumstances.

This document constitutes a 'financial promotion' for the purposes of section 21 Financial Services and Markets Act 2000 (United Kingdom) ('FSMA') and accordingly has been approved by Capital Markets Strategy Ltd which is authorised and regulated by the Financial Conduct Authority (FCA).

No part of this document may be reproduced, stored in a retrieval system or transmitted in any form or by any means, mechanical, photocopying, recording or otherwise, without prior permission from Hardman & Co. By accepting this document, the recipient agrees to be bound by the limitations set out in this notice. This notice shall be governed and construed in accordance with English law. Hardman Research Ltd, trading as Hardman & Co, is an appointed representative of Capital Markets Strategy Ltd and is authorised and regulated by the FCA under registration number 600843. Hardman Research Ltd is registered at Companies House with number 8256259.

(Disclaimer Version 8 – Effective from August 2018

Status of Hardman & Co's research under MiFID II

Some professional investors, who are subject to the new MiFID II rules from 3rd January, may be unclear about the status of Hardman & Co research and, specifically, whether it can be accepted without a commercial arrangement. Hardman & Co's research is paid for by the companies, legal entities and issuers about which we write and, as such, falls within the scope of 'minor non-monetary benefits', as defined in the Markets in Financial Instruments Directive II.

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

The fact that Hardman & Co is commissioned to write the research is disclosed in the disclaimer, and the research is widely available.

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

In addition, it should be noted that MiFID II's main aim is to ensure transparency in the relationship between fund managers and brokers/suppliers, and eliminate what is termed 'inducement', whereby free research is provided to fund managers to encourage them to deal with the broker. Hardman & Co is not inducing the reader of our research to trade through us, since we do not deal in any security or legal entity)

research@hardmanandco.com

35 New Broad Street
London
EC2M 1NH

+44(0)20 7194 7622

www.hardmanandco.com