



28 March 2019

Diurnal Group plc
("Diurnal" or the "Company")

Interim Results for the Six Months Ended 31 December 2018

Strong launches for Alkindi® in Germany and UK with further launches planned for 2019

Company on track for two major regulatory filings during 2019

Continued progress in emerging early-stage pipeline

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces its results for the six months ended 31 December 2018 (the "Period").

Operational highlights (during the Period and post the Period end)

- **Alkindi®** (hydrocortisone granules in capsules for opening)
 - Launch of Alkindi® in the UK as the first specifically developed and licensed replacement therapy of paediatric adrenal insufficiency and positive Scottish Medicines Consortium pricing and reimbursement decision
 - Confirmation of the current clinical and regulatory path for Alkindi® with the US FDA, facilitating NDA submission in Q4 2019
 - Partnering discussions for Alkindi® in the US initiated following confirmation of regulatory path
- **Chronocort®** (modified release hydrocortisone)
 - Completion of European Phase 3 study in congenital adrenal hyperplasia, the largest ever treatment study in this disease, and subsequent announcement of headline data:
 - Study missed primary endpoint of superiority of Chronocort® to conventional therapy in control of androgens (17-OHP) over the 24-hour period
 - Chronocort achieved significantly better control of androgens (17-OHP) in the period 07:00-15:00
 - Chronocort® achieved 24-hour control on a lower overall dose of glucocorticoid with fewer patients requiring rescue therapy (sick day rules)
 - Scientific Advice sought from European Medicines Agency with a view to filing a Marketing Authorisation Application in Q4 2019

Financial overview

- Alkindi® revenues of £186k (H1 2017/18: £nil) following initial launches, in Germany and UK, in line with Board's expectations; continued progress post-Period end with sales for the two months ended 28 February 2019 of £190k
- Operating loss of £9.7m (H1 2017/18: £7.7m) reflecting increased investment in clinical development activities
- Held-to-maturity financial assets, cash and cash equivalents at 31 December 2018 of £6.9m (31 December 2017: £14.0m); 30 June 2018 of £17.3m

Martin Whitaker, PhD, Chief Executive Officer of Diurnal, commented:

"The Company has made excellent progress with Alkindi® with sales performance in line with the Board's expectations, following successful launches in the UK and Germany, and with continued growth after the Period end. Further Alkindi® launches are planned for 2019 in Europe. We have also clarified the US regulatory path for Alkindi®, facilitating the Company's first New Drug Application to the US Food and Drug Administration in Q4 2019.

Despite the initially disappointing top-line analysis of data from the Chronocort® European Phase 3 study in CAH, following further in depth analysis of the study results we continue to believe that Chronocort® represents a valuable treatment option for patients based on multiple important clinical parameters. We have requested

Scientific Advice from the EMA in order to clarify the regulatory path for a potential Marketing Authorisation Application (MAA) and we expect to receive this advice in Q2 2019. If the EMA agrees that our existing clinical data could support a regulatory submission, Diurnal anticipates filing an MAA for Chronocort® in Q4 2019.”

In the Interim Results:

- “H1” refers to the six-month period ended 31 December
- “m” and “k” represent million and thousand, respectively
- “Group” is the Company and its subsidiary undertakings, Diurnal Limited and Diurnal Europe B.V.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014 (MAR).

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Notes to Editors

About Diurnal Group plc

Founded in 2004, Diurnal is a UK-based specialty pharma company developing high quality products for the global market for the life-long treatment of chronic endocrine conditions, including Congenital Adrenal Hyperplasia and Adrenal Insufficiency. Its expertise and innovative research activities focus on circadian-based endocrinology to yield novel product candidates in the rare and chronic endocrine disease arena.

For further information about Diurnal, please visit www.diurnal.co.uk

Forward looking statements

Certain information contained in this announcement, including any information as to the Group’s strategy, plans or future financial or operating performance, constitutes “forward-looking statements”. These forward-looking statements may be identified by the use of forward-looking terminology, including the terms “believes”, “estimates”, “anticipates”, “projects”, “expects”, “intends”, “aims”, “plans”, “predicts”, “may”, “will”, “seeks” “could” “targets” “assumes” “positioned” or “should” or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward-looking statements include all matters that are not historical facts. They appear in a number of places throughout this announcement and include statements regarding the intentions, beliefs or current expectations of the Directors concerning, among other things, the Group’s results of operations, financial condition, prospects, growth, strategies and the industries in which the Group operates. The directors of the Company believe that the expectations reflected in these statements are reasonable but may be affected by a number of variables which could cause actual results or trends to differ materially. Each forward-looking statement speaks only as of the date of the particular statement.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future or are beyond the Group’s control. Forward-looking statements are not guarantees of future performance. Even if the Group’s actual results of operations, financial condition and the development of the industries in which the Group operates are consistent with the forward-looking statements contained in this document, those results or developments may not be indicative of results or developments in subsequent periods.

Chief Executive Review

The primary focus for the Company remains on Chronocort® and Alkindi®, our two lead products, which are potentially valuable treatment options for the orphan diseases congenital adrenal hyperplasia (CAH) and paediatric adrenal insufficiency (AI), a combined market opportunity in the US and Europe of approximately \$500 million. During the Period, Alkindi® has made significant commercial progress with initial country launches in Europe. Despite the initially disappointing top-line analysis of data from the Chronocort® European Phase 3 trial during the Period, Diurnal believes the overall data package is compelling with respect to the drug as a potential treatment for CAH. If the EMA agrees that the existing clinical data is sufficient to support a regulatory submission, the Company expects to file a Marketing Authorisation Application (MAA) for Chronocort® in Q4 2019.

Alkindi® Europe: continued commercial roll-out to drive revenue growth

Alkindi® is the first product specifically designed for young children suffering from paediatric AI, and the related condition CAH. Alkindi® is licensed in Europe, effective, safe and easy to administer. Given the specialist prescribing base, and to retain the maximum commercial value of the product, Diurnal is commercialising Alkindi® itself in larger European markets, focusing its marketing efforts initially on patients aged 0-6 years where the unmet need is highest. Diurnal will assess the most effective means of accessing smaller markets for Alkindi® and will either use in-house resource or engage a distribution partner.

Diurnal launched Alkindi® in the UK in September 2018, its second launch following introduction in Germany in May 2018. During the Period, Diurnal has continued to make positive progress in both territories, including pricing discussions, notably with a positive Scottish Medicines Consortium pricing and reimbursement decision in October 2018. Diurnal believes that the health economic arguments supporting Alkindi® are robust and support the proposed pricing in key markets. Alkindi® has continued to make strong progress after the end of the Period, with continued sales growth in the UK and Germany.

The roll-out of Alkindi® beyond Germany and the UK during the Period has been slightly slower than anticipated, due in part to the unpredictability of timeliness of pricing discussions, which are conducted on a country-by-country basis, and in part to external factors impacting the supply chain: namely, activities required to prepare for the UK's departure from the EU, including the establishment of a subsidiary company within the EU and securing the required licenses and authorisations; and the implementation of Falsified Medicines Directive in early 2019, which requires changes to packaging to facilitate tracking of individual packs of medicines. Nevertheless, the Group expects a series of country launches during the remainder of 2019 that will continue to provide strong revenue growth for Alkindi®.

After the end of the Period, the Company entered into a marketing and distribution agreement with Anthrop Pharma (Anthrop), a specialist pharmaceutical company focused on the sales and marketing of niche, high-quality paediatric medicines to the hospital sector in the Nordic region. The agreement covers the commercialisation of Alkindi® in Sweden, Denmark, Norway, Finland and Iceland. Diurnal believes that Anthrop's local expertise will accelerate the commercial traction of Alkindi® in these territories, whilst enabling the Group to focus its resources on the larger European markets.

Diurnal has continued to develop a robust product supply chain during the Period, in particular to minimise disruption to the Group's operations should the UK depart from the EU without a transitional arrangement. The Group's supply chain remains located entirely within the EU, with primary manufacturing of Alkindi® capsules in Germany, packaging in France, and distribution in the Netherlands. Diurnal's wholly-owned subsidiary, Diurnal Europe B.V., holds the Alkindi® EU marketing authorisation and will hold other required authorisations and licenses following the UK's departure from the EU. After the end of the Period, Diurnal additionally established a satellite distribution facility in the UK, to ensure continuity of supply for the UK market.

The Company believes that its European commercial infrastructure is a valuable asset that can ensure it not only retains the maximum commercial value of its in-house products in major European territories, but also makes Diurnal an attractive partner for companies seeking to commercialise endocrinology focused products in Europe. Diurnal continues to assess such business development opportunities where they are additive to its business model.

Alkindi® US: clear path to regulatory submission

During the Period, Diurnal successfully completed the Alkindi® US reference drug bioequivalence study to support its planned New Drug Application (NDA) application in the US. In addition, the Group also completed the Alkindi® safety evaluation and tolerability extension study in Europe, which will provide valuable long-term exposure data in support of market access in the US.

Following the successful completion of these studies, Diurnal has discussed the proposed NDA package with the US Food and Drug Administration (FDA), who confirmed Diurnal's planned regulatory path for Alkindi® in the US. Reflecting this, Diurnal plans to submit an NDA for Alkindi® during Q4 2019, with potential for approval in late 2020.

As highlighted previously, Diurnal intends to seek a licensing partner for its late-stage cortisol deficiency pipeline in the US and, following the recent FDA feedback, has now initiated partnering discussions for Alkindi® in the US.

Chronocort®: defining the regulatory path in Europe and US

Diurnal's second product candidate, Chronocort®, provides a drug release profile that the Company believes better mimics the body's natural cortisol circadian rhythm, which current therapy is unable to replicate, and is designed to improve disease treatment for adults with CAH, as measured by androgen control.

During the Period, the Group completed its European pivotal Phase 3 clinical trial of Chronocort® for the treatment of CAH in adults, with a total of 122 patients enrolled across 11 clinical sites, the largest interventional study conducted to date in this patient population. Patients completing treatment in this study had the option to enrol into a long-term safety extension study, assessing the impact of treatment with Chronocort® over an extended period, regardless of whether the patients were initially treated with Chronocort® or standard-of-care. A significant proportion of patients eligible to enter the follow-on study did so, and patient drop-out rates from this study have been very low to date.

In October 2018, Diurnal announced that, whilst Chronocort® had been able to demonstrate 24-hour control of androgens in its European Phase 3 trial in CAH, it did not meet the primary endpoint of superior control compared to conventional glucocorticoid therapy. Subsequently, Diurnal has performed a detailed analysis of the study data, identifying important differences between Chronocort® and the control arm of the trial based upon a number of important clinical parameters. Diurnal has also analysed interim data from the ongoing safety extension study; notably, a number of patients on the safety extension trial have now been treated for at least 12 months and show sustained benefit from extended Chronocort® treatment, consistent with feedback from the study investigators in this open-label trial. Based on these findings, Diurnal continues to believe that Chronocort® represents a valuable treatment option for patients and has requested Scientific Advice from the EMA, expected to be received in Q2 2019, in order to clarify the regulatory path for a potential MAA. If the EMA agrees that the existing clinical data set supports a regulatory submission, Diurnal expects to file an MAA for Chronocort® in Q4 2019.

The Group intends to use its commercial organisation and supply chain developed for Alkindi® for the planned future launch of Chronocort® in Europe. In addition, the pricing work undertaken for Alkindi® has provided insights into the cortisol deficiency market that will be extremely valuable when developing health economic arguments for Chronocort®.

Following discussion with the FDA, Diurnal designed a Phase 3 registration package for Chronocort® in the US designed to recruit up to 150 patients with CAH, randomised to either receive Chronocort® twice-daily or standard-of-care. Based upon the headline results from the European Phase 3 study, Diurnal has paused this study whilst it reviews the European data package and the Scientific Advice from the EMA, with a view to optimising the design of the US study based on this new information. Diurnal believes that the preparatory work undertaken prior to this pause, including identification of key clinical sites, will substantially accelerate the updated clinical trial once the protocol has been revised and agreed with the FDA.

During the Period, Diurnal also developed a Phase 2 study design to assess the utility of Chronocort® in AI, which represents a sizeable commercial opportunity (potentially \$0.9bn in the US alone) and with a highly favourable competitive landscape in the US. Following the Chronocort® European Phase 3 study results, the AI study was paused in order to preserve cash whilst seeking Scientific Advice from the EMA. Diurnal believes that this study is ready to commence, either in-house or with the support of a US partner.

In the longer term, Diurnal intends to explore the development of Chronocort® for adolescent CAH patients, providing the potential for life-long treatment, with patients commencing treatment with Alkindi® and transitioning to Chronocort®. Reflecting this strategy, the Company plans to request further Scientific Advice from the EMA for the development of Chronocort® in younger patients after filing the MAA for adult CAH.

Strong patent protection for product portfolio

Diurnal's pipeline of product candidates for cortisol deficiency are protected by an extensive patent portfolio, benefitting from granted or pending patents in key jurisdictions, along with strong protection through orphan drug designations. Shortly after the end of the Period, a second US patent was granted for Chronocort®, further

strengthening the in-house patent portfolio. The FDA has granted Chronocort® orphan drug designation in the treatment of both CAH and AI and has granted Alkindi® orphan drug designation in the treatment of paediatric AI. In Europe, the PUMA for Alkindi® affords ten years of market exclusivity, whilst Chronocort® benefits from the orphan drug designations for CAH and AI. These orphan drug designations mean Alkindi® and Chronocort® have the potential to be granted market and data exclusivity on approval in the US and Europe.

Maximising late-stage pipeline value

During the Period, Diurnal has continued to refine its strategy to optimise market access for its products. Outside of key European markets and the US, the Company aims to maximise revenues from Alkindi® and Chronocort® by entering into distribution agreements. The Company seeks to access territories where there is the potential for a price which reflects the innovation for its products and which can use the European or US regulatory dossiers as the basis for local regulatory submissions. This approach is exemplified by its agreements with Emerge Health for the marketing of Alkindi® and Chronocort® in Australia and New Zealand, and Medison for the marketing of Alkindi® and Chronocort® in Israel. Shortly after the end of the Period, Medison confirmed that the MAA for Alkindi® in Israel had been accepted for filing. Diurnal expects Emerge Health to submit Alkindi® for approval during 2019.

Following the grant of the Group's first patents for Alkindi® and Chronocort® in Japan during 2018, Diurnal is continuing to assess its strategy for entry into this important market with a local partner. Japan is an attractive market for Diurnal's late-stage cortisol deficiency pipeline, with a well-developed pharmaceutical market, including orphan drug designation and a large population, with the market for CAH and AI estimated at \$415 million.

Building an earlier-stage pipeline

Whilst Diurnal's current primary focus is on bringing its late-stage cortisol deficiency pipeline to the market in Europe and the US and to expand these products into new indications, the Group's long-term plan is to expand into endocrine disease areas, such as those associated with the thyroid, gonads and pituitary. During the Period, Diurnal has been focused on applying for grants to assist the development of its early-stage pipeline whilst focusing resources on its late-stage pipeline. Feedback from these grant applications have been positive and highlight the significant unmet needs Diurnal is aiming to address.

Diurnal's early-stage pipeline products include a modified-release T3 replacement therapy for patients with hypothyroidism who do not respond to current standard-of-care (a potential market of \$1bn in the US and Europe), a native oral testosterone for the treatment of male hypogonadism (a greater than \$5bn market opportunity), which completed a Phase 1/2 clinical study in male patients with hypogonadism during the Period, and its novel siRNA therapy for Cushing's disease (a ca. \$480m market opportunity), a condition characterised by an excess of cortisol. In addition, Diurnal regularly assesses third party products for chronic endocrine disorders that fit within its strategic vision.

Outlook

If the EMA agrees that further clinical studies are not required to support an MAA for Chronocort®, Diurnal anticipates submitting a regulatory dossier during Q4 2019. If approved by the EMA, the drug will join Alkindi®, enlarging the Company's commercial cortisol replacement therapy franchise. This should further enable Diurnal to build a strong and profitable European business through penetration of the combined addressable market for the treatment of CAH and paediatric AI which is estimated by the Company to be worth \$360m in Europe alone.

Diurnal also expects additional progress for Alkindi®, with further country launches scheduled during 2019 to accelerate growth of revenues, along with a planned NDA submission in the US during Q4 2019. Diurnal has received strong interest in Alkindi® and Chronocort® for the US and will continue to progress licensing discussions, including the potential for co-development of Chronocort® in the US, both in CAH and AI. The US remains an important market for Diurnal's late-stage pipeline focused on cortisol deficiency, with a combined market size for the treatment of CAH and paediatric AI estimated at \$132m, and a future expansion opportunity in adult AI, which represents a \$0.9bn market opportunity in the US.

Financial Review

Revenues

The Group launched Alkindi® in Germany in May 2018 and in the UK in September 2018, with further European launches planned for 2019. Total revenues recorded for the Period were £186k (H1 2017/18: £nil), which is net of provisions for stock placed into the wholesale distribution chain on a sale-or-return basis. In the period from launch to 31 December 2018, Alkindi® has generated sales in excess of £250k, reflecting a strong take-up of the product in line with the Board's expectations. This strong growth has continued post-Period end, with sales for the eight months ended 28 February 2019 reaching £376k.

The roll-out of Alkindi® beyond Germany and the UK has been impacted to a small degree by the unpredictability of timeliness of pricing discussions, which are conducted on a country-by-country basis, by activities required to prepare for the UK's departure from the EU (including the establishment of a subsidiary company within the EU and securing the required licenses and authorisations) and the impact of the Falsified Medicines Directive, which requires each pack of pharmaceuticals to have a unique identifying code. Nevertheless, the Group expects a series of country launches during the remainder of 2019 that will continue to provide strong revenue growth for Alkindi®.

Research and Development (R&D) expenses

R&D expenditure for the Period was £7.6m (H1 2017/18: £4.7m). Expenditure increased significantly in the Period as the Group undertook activities to initiate a Chronocort® US Phase 3 trial in CAH and a US Phase 2 trial in AI, in addition to completion of the Chronocort® Phase 3 registration trial in Europe and the transition of patients completing this study into the European long-term follow-on study. Following the Chronocort® European Phase 3 trial read-out in October 2018, the US clinical studies were put on hold, in order to re-assess the study designs and also to extend the cash runway beyond the planned Scientific Advice from EMA. Consequently, R&D expenses are expected to be significantly lower in the second half of the financial year.

R&D costs are net of capitalised development costs for Alkindi® in Europe of £17k, which are recorded as an intangible asset on the balance sheet and will be amortised over the duration of the regulatory protection afforded by the Paediatric Use Medicine Authorisation (PUMA) until February 2028.

Administrative expenses

Administrative expenses for the Period were £2.2m (H1 2017/18: £3.0m). Expenses in the Period reflected a credit of £0.6m relating to the provision for Employers' National Insurance contribution on share option exercises, reflecting the fall in the share price following the announcement of the Chronocort® Phase 3 clinical trial headline data, and also include a foreign exchange gain of £0.1m on the Group's holding of US Dollars. The prior Period included non-recurring pre-commercialisation expenses for Alkindi® in anticipation of its first commercial launch.

Following the Chronocort® European Phase 3 trial read-out in October 2018, a number of cost-saving measures were implemented, including headcount reductions and a restructuring of the commercial team engaged by Ashfield Healthcare. The impact of these cost saving measures was limited during the Period but is expected to reduce administrative expenses in the second half of the financial year.

Operating loss

Operating loss for the Period increased to £9.7m (H1 2017/18: £7.7m), reflecting the increased Research and Development expenses outlined above.

Financial income and expense

Financial income in the Period was £73k (H1 2017/18: £40k), reflecting the Group's holding of US Dollars, in order to hedge the costs of the planned US clinical studies, which attracted a significantly higher interest rate than the Group's Sterling deposits. Financial expense for the prior Period of £146k (H1 2015/16: £134k) largely comprised the non-cash financial expense of the convertible loan, which was retired at the time of the Group's fundraising in April 2018.

Loss on ordinary activities before tax

Loss before tax for the Period was £9.6m (H1 2017/18: £7.8m).

Tax

The current year includes an estimate of the R&D tax credit attributable to the six months ended 31 December 2018. The Group received £2,285k from HMRC in respect of the R&D tax credit claim for the year ended 30 June 2018 after the end of the Period. The Group has not recognised any deferred tax assets in respect of trading losses arising in the Period.

Earnings per share

Loss per share increased to 13.4 pence (H1 2017/18: 12.7 pence), reflecting the higher operating expenses outlined above.

Cash flow

Net cash used in operating activities was £10.5m (H1 2017/18: £5.9m), driven by the planned increase in Research and Development expenses during the Period, in addition to the settlement of trade payable and accrued expenses relating to the Chronocort® European Phase 3 CAH study and US Phase 3 CAH and AI studies during the Period.

Balance sheet

Total assets decreased to £12.1m (31 December 2017: £18.1m), primarily reflecting the operating cash outflows. Cash and cash equivalents at 31 December 2018 were £6.9m (31 December 2017: £4.7m) and held-to-maturity financial assets were £nil (31 December 2017: £9.3m), reflecting change in the Group's treasury arrangements during H1 2018 such that all its cash deposits are now immediately accessible and, consequently, are classified as cash and cash equivalents. Total liabilities decreased to £2.9m (31 December 2017: £7.3m), reflecting the early conversion of the convertible loan during H1 2017 along with the timing of payment of certain clinical trial expenses as noted above. Net assets were £9.2m (31 December 2017: £10.8m).

Financial outlook

Following the cost reduction measures outlined above, Diurnal expects its cash resources to last until at least Q4 2019 based upon current planned expenditure. As highlighted in the Operational Review, Diurnal believes that clarification of the regulatory path for Chronocort® in Europe is the key step in the implementation of the Group's strategic plans. In addition, the Group is encouraged by US interest in its late-stage pipeline, which provides an opportunity to generate non-dilutive income, including potential for signature fees, milestone payments and development cost funding.

Principal risks and uncertainties

Diurnal considers strategic, operational and financial risks and identifies actions to mitigate these risks. The principal risks and uncertainties are set out in the Group's Annual Report and Accounts for the year ended 30 June 2018, available on the website www.diurnal.co.uk. There are no changes to these principal risks since the issue of the Annual Report and Accounts.

Consolidated income statement
for the six months ended 31 December 2018

| | | Unaudited | Unaudited | Audited |
|---|-------------|--------------------|--------------------|--------------------|
| | | 6 months | 6 months | 12 months |
| | | ended | ended | ended |
| | | 31 Dec 2018 | 31 Dec 2017 | 30 Jun 2018 |
| | Note | £000 | £000 | £000 |
| Sales | | 186 | - | 73 |
| Cost of sales | | (33) | - | (15) |
| Gross profit | | <u>153</u> | <u>-</u> | <u>58</u> |
| Research and development expenditure | | (7,622) | (4,713) | (10,024) |
| Administrative expenses | | (2,196) | (3,000) | (6,813) |
| Other operating income | | - | - | - |
| Operating loss | | <u>(9,665)</u> | <u>(7,713)</u> | <u>(16,779)</u> |
| Financial income | | 73 | 40 | 95 |
| Financial expense | | - | (146) | (221) |
| Loss before tax | | <u>(9,592)</u> | <u>(7,819)</u> | <u>(16,905)</u> |
| Taxation | 7 | 1,383 | 1,149 | 2,282 |
| Loss for the period | | <u>(8,209)</u> | <u>(6,670)</u> | <u>(14,623)</u> |
| Basic and diluted loss per share (pence per share) | 6 | <u>(13.4)</u> | <u>(12.7)</u> | <u>(26.8)</u> |

All activities relate to continuing operations.

The Notes form part of this condensed financial information.

Consolidated statement of comprehensive income
for the six months ended 31 December 2018

| | | Unaudited | Unaudited | Audited |
|----------------------------|--|--------------------|--------------------|--------------------|
| | | 6 months | 6 months | 12 months |
| | | ended | ended | ended |
| | | 31 Dec 2018 | 31 Dec 2017 | 30 Jun 2018 |
| | | £000 | £000 | £000 |
| Loss for the period | | <u>(8,209)</u> | <u>(6,670)</u> | <u>(14,623)</u> |

The Notes form part of this condensed financial information.

Consolidated balance sheet
as at 31 December 2018

| | Note | Unaudited As at 31 Dec 2018 £000 | Unaudited As at 31 Dec 2017 £000 | Audited As at 30 Jun 2018 £000 |
|-----------------------------------|------|---|---|---|
| Non-current assets | | | | |
| Intangible assets | | 31 | 3 | 16 |
| Property, plant and equipment | | 41 | 27 | 26 |
| | | <u>72</u> | <u>30</u> | <u>42</u> |
| Current assets | | | | |
| Inventories | | 259 | - | 123 |
| Trade and other receivables | 8 | 4,867 | 4,049 | 5,093 |
| Held to maturity financial assets | | - | 9,250 | - |
| Cash and cash equivalents | | 6,863 | 4,745 | 17,284 |
| | | <u>11,989</u> | <u>18,044</u> | <u>22,500</u> |
| Total assets | | <u>12,061</u> | <u>18,074</u> | <u>22,542</u> |
| Current liabilities | | | | |
| Trade and other payables | 9 | (2,908) | (3,624) | (5,661) |
| | | <u>(2,908)</u> | <u>(3,624)</u> | <u>(5,661)</u> |
| Non-current liabilities | | | | |
| Loans and borrowings | 10 | - | (3,657) | - |
| | | <u>-</u> | <u>(3,657)</u> | <u>-</u> |
| Total liabilities | | <u>(2,908)</u> | <u>(7,281)</u> | <u>(5,661)</u> |
| Net assets | | <u>9,153</u> | <u>10,793</u> | <u>16,881</u> |
| Equity | | | | |
| Share capital | | 3,086 | 2,628 | 3,067 |
| Share premium | | 37,800 | 23,686 | 37,769 |
| Consolidation reserve | | (2,943) | (2,943) | (2,943) |
| Other reserve | | - | 1,458 | - |
| Retained losses | | (28,790) | (14,036) | (21,012) |
| Total equity | | <u>9,153</u> | <u>10,793</u> | <u>16,881</u> |

The Notes form part of this condensed financial information.

Consolidated statement of changes in equity
for the six months ended 31 December 2018

| | Unaudited Share capital £000 | Unaudited Share premium £000 | Unaudited Consolidation reserve £000 | Unaudited Other reserve £000 | Unaudited Retained losses £000 | Unaudited Total £000 |
|---|---------------------------------------|---------------------------------------|---|---------------------------------------|---|----------------------------|
| Balance at 30 June 2017 | 2,616 | 23,675 | (2,943) | 1,458 | (7,730) | 17,076 |
| Loss for the period and Total comprehensive loss for the period | - | - | - | - | (6,670) | (6,670) |
| Equity settled share-based payment transactions | - | - | - | - | 368 | 368 |
| Issue of shares for cash | 12 | 11 | - | - | (4) | 19 |
| Total transactions with owners recorded directly in equity | 12 | 11 | - | - | 364 | 387 |
| Balance at 31 December 2017 | 2,628 | 23,686 | (2,943) | 1,458 | (14,036) | 10,793 |
| Loss for the period and Total comprehensive loss for the period | - | - | - | - | (7,953) | (7,953) |
| Equity settled share-based payment transactions | - | - | - | - | 440 | 440 |
| Issue of shares for cash | 277 | 10,224 | - | - | - | 10,501 |
| Costs charged against share premium | - | (630) | - | - | - | (630) |
| Issue of share capital on conversion of loan | 162 | 4,489 | - | (921) | - | 3,730 |
| Equity component of convertible loan | - | - | - | (537) | 537 | - |
| Total transactions with owners recorded directly in equity | 439 | 14,083 | - | (1,458) | 977 | 14,041 |
| Balance at 30 June 2018 | 3,067 | 37,769 | (2,943) | - | (21,012) | 16,881 |
| Loss for the period and Total comprehensive loss for the period | - | - | - | - | (8,209) | (8,209) |
| Equity settled share-based payment transactions | - | - | - | - | 442 | 442 |
| Issue of shares for cash | 19 | 42 | - | - | (11) | 50 |
| Costs charged against share premium | - | (11) | - | - | - | (11) |
| Total transactions with owners recorded directly in equity | 19 | 31 | - | - | 431 | 481 |
| Balance at 31 December 2018 | 3,086 | 37,800 | (2,943) | - | (28,790) | 9,153 |

Loss for the period is the only constituent of total comprehensive loss for each period so the period amounts are shown in the same line in the consolidated statement of changes in equity.

Consolidated statement of cash flows
for the six months ended 31 December 2018

| | Unaudited 6 months ended 31 Dec 2018 £000 | Unaudited 6 months ended 31 Dec 2017 £000 | Audited 12 months ended 30 Jun 2018 £000 |
|--|---|---|--|
| Cash flows from operating activities | | | |
| Loss for the period | (8,209) | (6,670) | (14,623) |
| <i>Adjustments for:</i> | | | |
| Depreciation, amortisation and impairment | 10 | 6 | 14 |
| Share-based payment | 430 | 368 | 808 |
| Net foreign exchange (gain)/loss | (79) | 3 | (203) |
| Financial income | (73) | (40) | (95) |
| Finance expenses | - | 146 | 221 |
| Taxation | (1,383) | (1,149) | (2,282) |
| Increase in inventories | (135) | - | (123) |
| Decrease / (increase) in trade and other receivables | 1,660 | 213 | (1,535) |
| (Decrease) / increase in trade and other payables | (2,753) | 284 | 2,320 |
| Cash used in operations | <u>(10,532)</u> | <u>(6,839)</u> | <u>(15,498)</u> |
| Interest paid | - | - | (2) |
| Tax received | - | 911 | 2,737 |
| Net cash used in operating activities | <u>(10,532)</u> | <u>(5,928)</u> | <u>(12,763)</u> |
| Cash flows from investing activities | | | |
| Additions of property, plant and equipment | (24) | (14) | (19) |
| Capitalisation of research and development | (17) | - | (15) |
| Purchases of held to maturity financial assets | - | (5,500) | (5,500) |
| Disposals of held to maturity financial assets | - | 7,250 | 16,500 |
| Interest received | 73 | 40 | 107 |
| Net cash from investing activities | <u>32</u> | <u>1,776</u> | <u>11,073</u> |
| Cash flows from financing activities | | | |
| Net proceeds from issue of share capital | - | 19 | 9,890 |
| Net cash from financing activities | <u>-</u> | <u>19</u> | <u>9,890</u> |
| Net (decrease)/increase in cash and cash equivalents | (10,500) | (4,133) | 8,200 |
| Cash and cash equivalents at the start of the period | 17,284 | 8,881 | 8,881 |
| Effects of exchange rate changes on cash and cash equivalents | 79 | (3) | 203 |
| Cash and cash equivalents at the end of the period | <u>6,863</u> | <u>4,745</u> | <u>17,284</u> |

Notes to the consolidated financial statements

1 General information

Diurnal Group plc ('the Company') and its subsidiaries (together 'the Group') are a commercial stage specialty pharmaceutical business targeting patient needs in chronic endocrine (hormonal) diseases which the Group believes are currently not met satisfactorily by existing treatments. It has identified a number of specialist endocrinology market opportunities in Europe, the US and worldwide that are together estimated to be substantial commercial opportunities.

The Company is a public limited company incorporated and domiciled in the United Kingdom. Its registered number is 09846650. The address of its registered office is Cardiff Medicentre, Heath Park, Cardiff, CF14 4UJ and its primary and sole listing is on the Alternative Investments Market (AIM) of the London Stock Exchange.

2 Basis of preparation

As permitted these unaudited consolidated interim financial statements have been prepared and approved by the Directors in accordance with UK AIM rules and the IAS 34 'Interim financial reporting' as adopted by the European Union. They should be read in conjunction with audited consolidated financial statements for the year ended 30 June 2018, which were prepared in accordance with IFRS as adopted by the European Union.

The financial information contained in these interim financial statements has been prepared under the historical cost convention, and on a going concern basis. The interim financial information for the six months ended 31 December 2018 and for the six months ended 31 December 2017 contained within this interim report do not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006. The figures for the year ended 30 June 2018 have been extracted from the audited statutory accounts which were approved by the Board of Directors on 19 September 2018 and delivered to the Registrar of Companies. The report of the auditors on those accounts was unqualified and did not contain statements under 498 (2) or (3) of the Companies Act 2006, though it did include a reference to a matter to which the auditor drew attention by way of emphasis without qualifying their report in relation to going concern.

3 Going concern

The Group is subject to a number of risks that are characteristic of development and commercialisation of novel therapeutic agents due to the complex nature of the industry. These risks include, amongst others, uncertainties inherent to clinical trials, regulatory approvals of pipeline programmes, and the outcome of pricing and reimbursement discussions. Ultimately, the attainment of a strong and profitable commercial business and the future viability of the Group are contingent on future uncertain events such as the ability to obtain adequate financing to conduct the Group's development and commercialisation activities, and the ability to successfully partner pipeline programmes to obtain non-dilutive financing to achieve a level of funding that is adequate to support the Group's cost structure and to finance its operations. The Group's failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

The Group has historically experienced net losses and significant cash outflows from cash used in operating activities, which reflect the development and early commercialisation stage of the portfolio. As at 31 December 2018, the Group had total equity of £9.2m, which included an accumulated deficit of £28.8m. The Group incurred a net loss for the 6 months ended 31 December 2018 of £8.2m and used cash in operating activities of £10.5m for the same period. As at 31 December 2018, the Group had cash and cash equivalents of £6.9m.

The Directors have prepared cash flow forecasts and considered the cash flow requirement for the Group for the next 15 months. These forecasts show that to continue funding development and commercialisation, further financing is likely to be required over the course of the next 12 months. This requirement for additional financing represents a material uncertainty that may cast significant doubt upon the Group's and parent company's ability to continue as a going concern.

If the Directors conclude that such financing is unlikely to be available within the required timeframe, options available to the company include licensing or selling one or more of the pipeline programmes and delaying expenditure, particularly in respect of the development programmes, thereby extending the cash runway.

Based on the above, the Directors believe it remains appropriate to prepare the financial statements for the six months ended 31 December 2018 on a going concern basis. However, these circumstances represent a material uncertainty that may cast significant doubt upon the company's ability to continue as a going concern and, therefore to continue realising its assets and discharging its liabilities in the normal course of business. The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate.

4 Accounting policies

These consolidated interim financial statements for the six months ended 31 December 2018 include the results of Diurnal Group plc and its wholly-owned subsidiaries, Diurnal Limited and Diurnal Europe B.V. The unaudited results for the period have been prepared on the basis of accounting policies adopted in the audited accounts for the year ended 30 June 2018 and expected to be adopted in the financial year ending 30 June 2019.

Where new IFRS standards amendments or interpretations became effective in the six months to the 31 December 2018, there has been no material impact on the net assets or results of the Group.

5 Segmental information

The Board regularly reviews the Group's performance and balance sheet position for its operations and receives financial information for the Group in order to assess performance and make strategic decisions about the allocation of resources. The following analysis by segment is presented in accordance with IFRS 8 on the basis of those segments whose operating results are regularly reviewed by Board. A brief description of the segments of the business is as follows:

- Alkindi® - development and supply of the Group's Alkindi® product
- Chronocort® - development of the Group's Chronocort® product
- Central and early-stage - all other activities, including development of the Group's early-stage pipeline products

| | Unaudited | | | | Unaudited | | | |
|---------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | Alkindi® | Chronocort® | Central and early-stage | Total | Alkindi® | Chronocort® | Central and early-stage | Total |
| | 6 months ended 31 Dec 2018 | 6 months ended 31 Dec 2018 | 6 months ended 31 Dec 2018 | 6 months ended 31 Dec 2018 | 6 months ended 31 Dec 2017 | 6 months ended 31 Dec 2017 | 6 months ended 31 Dec 2017 | 6 months ended 31 Dec 2017 |
| | £000 | £000 | £000 | £000 | £000 | £000 | £000 | £000 |
| Revenue | 186 | - | - | 186 | - | - | - | - |
| Operating loss | (1,416) | (4,840) | (3,409) | (9,665) | (1,349) | (2,923) | (3,441) | (7,713) |
| Financial income | - | - | 73 | 73 | - | - | 40 | 40 |
| Financial expense | - | - | - | - | - | - | (146) | (146) |
| Taxation | - | - | 1,383 | 1,383 | - | - | 1,149 | 1,149 |
| Loss for the period | (1,416) | (4,840) | (1,953) | (8,209) | (1,349) | (2,923) | (2,398) | (6,670) |

| | Audited | | | Total |
|-------------------|-----------------------------------|-----------------------------------|-----------------------------------|----------|
| | Alkindi® | Chronocort® | Central and early-stage | |
| | 12 months ended 30 Jun 2018 | 12 months ended 30 Jun 2018 | 12 months ended 30 Jun 2018 | |
| | £000 | £000 | £000 | |
| Revenue | 73 | - | - | 73 |
| Operating loss | (2,685) | (6,210) | (7,884) | (16,779) |
| Financial income | - | - | 95 | 95 |
| Financial expense | - | - | (221) | (221) |
| Taxation | - | - | 2,282 | 2,282 |
| Loss for the year | (2,685) | (6,210) | (5,728) | (14,623) |

The revenue analysis below is based on the country of registration of the fee-paying party:

| | Unaudited 6 months ended 31 Dec 2018 £000 | Unaudited 6 months ended 31 Dec 2017 £000 | Audited 12 months ended 30 Jun 2018 £000 |
|--------|---|---|--|
| Europe | 186 | - | 73 |

The Group's customers are wholesalers in the markets in which it has launched Alkindi®, namely the UK and Germany. An analysis of revenue by customer is set out in the table below:

| | Unaudited 6 months ended 31 Dec 2018 £000 | Unaudited 6 months ended 31 Dec 2017 £000 | Audited 12 months ended 30 Jun 2018 £000 |
|-----------------|---|---|--|
| Customer A | 63 | - | 55 |
| Customer B | 103 | - | 17 |
| Other customers | 20 | - | 1 |
| | 186 | - | 73 |

Segment assets and liabilities are as follows:

| | Unaudited | | | Total | Unaudited | | | Total |
|---|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| | Alkindi® | Chronocort® | Central and early-stage | | Alkindi® | Chronocort® | Central and early-stage | |
| | As at 31 Dec 2018 £000 | As at 31 Dec 2018 £000 | As at 31 Dec 2018 £000 | As at 31 Dec 2018 £000 | As at 31 Dec 2017 £000 | As at 31 Dec 2017 £000 | As at 31 Dec 2017 £000 | As at 31 Dec 2017 £000 |
| Segment assets | 468 | 165 | 11,428 | 12,061 | 8 | 287 | 17,779 | 18,074 |
| Segment liabilities | (447) | (1,556) | (905) | (2,908) | (739) | (1,474) | (5,068) | (7,281) |
| Total net (liabilities) / assets | 21 | (1,391) | 10,523 | 9,153 | (731) | (1,187) | 12,711 | 10,793 |
| Depreciation, amortisation and impairment | 2 | 1 | 7 | 10 | - | 1 | 5 | 6 |
| Capital expenditure | 12 | - | 12 | 24 | - | - | 14 | 14 |
| Capitalised development costs | 17 | - | - | 17 | - | - | - | - |

| | Audited | | | Total |
|---|------------------------------|------------------------------|------------------------------|----------------|
| | Alkindi® | Chronocort® | Central and early-stage | |
| | As at 30 Jun 2018 £000 | As at 30 Jun 2018 £000 | As at 30 Jun 2018 £000 | |
| Segment assets | 315 | 1,642 | 20,585 | 22,542 |
| Segment liabilities | (842) | (2,967) | (1,852) | (5,661) |
| Total net (liabilities) / assets | <u>(527)</u> | <u>(1,325)</u> | <u>18,733</u> | 16,881 |
| Depreciation, amortisation and impairment | 1 | 1 | 12 | 14 |
| Capital expenditure | - | - | 19 | 19 |
| Capitalised development costs | <u>15</u> | <u>-</u> | <u>-</u> | 15 |

All material segmental non-current assets are located in the UK.

6 Loss per share

| | Unaudited 6 months ended 31 Dec 2018 | Unaudited 6 months ended 31 Dec 2017 | Audited 12 months ended 30 Jun 2018 |
|--|---|---|--|
| Loss for the period (£000) | (8,209) | (6,670) | (14,623) |
| Weighted average number of shares (000) | 61,430 | 52,430 | 54,596 |
| Basic and diluted loss per share (pence per share) | <u>(13.4)</u> | <u>(12.7)</u> | <u>(26.8)</u> |

The diluted loss per share is identical to the basic loss per share in all periods, as potential dilutive shares are not treated as dilutive since they would reduce the loss per share.

7 Taxation

| | Unaudited 6 months ended 31 Dec 2018 £000 | Unaudited 6 months ended 31 Dec 2017 £000 | Audited 12 months ended 30 Jun 2018 £000 |
|---|---|---|--|
| Current tax: | | | |
| - UK corporation tax on losses of period | - | - | - |
| - Research and development tax credit receivable for the current period | (1,380) | (1,149) | (2,275) |
| - Prior period adjustment in respect of research and development tax credit | (3) | - | (7) |
| Deferred tax: | | | |
| - Origination and reversal of temporary differences | - | - | - |
| Tax on loss on ordinary activities | <u>(1,383)</u> | <u>(1,149)</u> | <u>(2,282)</u> |

The Group is entitled to claim tax credits in the United Kingdom under the UK research and development (R&D) small or medium-sized enterprise (SME) scheme, which provides additional taxation relief for qualifying expenditure on R&D activities and includes an option to surrender a portion of tax losses arising from qualifying activities in return for a cash payment from HM Revenue & Customs (HMRC). With effect from the year ended 30 June 2017, the Group reflects R&D tax credits on an accruals basis since it has established a track record of agreeing claims with HMRC.

The Group's claim for R&D tax credits for the year ended 30 June 2018 was finalised at £2,278k and submitted to HMRC during the Period, with the cash payment subsequently being received after the end of the Period.

8 Trade and other receivables

| | Unaudited As at 31 Dec 2018 £000 | Unaudited As at 31 Dec 2017 £000 | Audited As at 30 Jun 2018 £000 |
|---|---|---|---|
| Trade receivables | 109 | - | 77 |
| VAT recoverable | 510 | 362 | 732 |
| Prepayments | 531 | 720 | 1,904 |
| Other debtors | 58 | - | 105 |
| Research and development tax credit claims receivable | 3,659 | 2,967 | 2,275 |
| | <u>4,867</u> | <u>4,049</u> | <u>5,093</u> |

9 Trade and other payables

| | Unaudited As at 31 Dec 2018 £000 | Unaudited As at 31 Dec 2017 £000 | Audited As at 30 Jun 2018 £000 |
|-------------------------------|---|---|---|
| Trade payables | 1,191 | 1,434 | 3,159 |
| Other payables | 27 | - | 9 |
| Other tax and social security | 106 | 65 | 72 |
| Accrued expenses | 1,584 | 2,125 | 2,421 |
| | <u>2,908</u> | <u>3,624</u> | <u>5,661</u> |

10 Loans and borrowings

| | Unaudited As at 31 Dec 2018 £000 | Unaudited As at 31 Dec 2017 £000 | Audited As at 30 Jun 2018 £000 |
|---|---|---|---|
| Non-current loans and borrowings | | | |
| Convertible loans | - | 3,657 | - |
| | <u>-</u> | <u>3,657</u> | <u>-</u> |

IP Group convertible loan

On 24 December 2015 the Company received £4.7m from IP2IPO Limited, a wholly owned subsidiary of IP Group plc, under a convertible loan agreement. The convertible loan facility is interest free and unsecured. The convertible loan note is a compound financial instrument containing a host financial liability and an equity component as there is a contractual obligation to deliver a fixed number of shares at the IPO price if the loan note is converted.

At the time of the Group's fundraising in April 2018, IP2IPO Limited exercised its option to convert the loan into equity at the IPO price of 144 pence per share. The effective interest required under accounting standards to charge the transaction costs and equity element of the loan to the income statement over the term of the loan was accrued for the period up to the date of conversion of the loan. Upon conversion of the loan, 3,229,575 new ordinary shares were issued, with the difference between the value of shares issued and accrued loan amount of £921k being debited from other reserves. The shortfall of £537k between the redemption value of

the loan at maturity and the accrued value at the date of conversion was transferred from other reserves to accumulated losses.

At 31 December 2017, the amount outstanding comprised:

| | Unaudited As at 30 Dec 2017 £000 |
|---|---|
| Loan amount brought forward | 3,511 |
| Accrued interest | 146 |
| Liability component at period end | <u>3,657</u> |
| Less amount included in current liabilities | - |
| Included in non-current liabilities | <u>3,657</u> |