24 September 2019

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

Results for the year ended 30 June 2019

Building on the successful launch of Alkindi®

Further key clinical and regulatory milestones expected in the next 12 months

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces its audited results for the year ended 30 June 2019.

Operational highlights

Alkindi®

- Successful launch of Alkindi® in the UK as the first specifically developed and licensed replacement therapy for paediatric adrenal insufficiency
- Alkindi® pricing agreed in Germany, Italy, Austria, Sweden, Norway, Denmark and Iceland
- Confirmation of the current clinical and regulatory path for Alkindi® in the US with the US Food and Drug Administration, facilitating a New Drug Application (NDA) submission in Q4 2019
- Progress in the rest of world with Alkindi® Marketing Authorisation Application (MAA) submission in Israel and grant of Orphan Drug Designation in Australia

Chronocort®

- MAA submission is on track for Q4 2019: confirmation of the current clinical and regulatory path for Chronocort® by the European Medicines Agency (EMA) following completion of European Phase 3 study
    - Pivotal study in congenital adrenal hyperplasia, the largest ever interventional study in this disease completed
        - 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 the same or lower overall dose of glucocorticoid with fewer patients requiring rescue therapy (sick day rules)
    - Scientific Advice from the EMA confirmed no additional clinical studies required

Financial overview

- Alkindi® revenues reached over £1 million during the financial year
- Successful completion of a £5.9 million Placing and Open Offer with institutional and private investors to fund further development of Diurnal's late-stage pipeline and commercial roll-out
- Reduced operating loss of £14.5m (2018: £16.8m), reflecting completion of the Chronocort European Phase 3 study, implementation of cost-saving measures and increase in revenues
- Cash and cash equivalents at 30 June 2019 of £9.1m (30 June 2018: £17.3m)
- Net cash used in operating activities was £13.7m (2018: £12.8m), in line with the Board's expectations

Post-period highlights

- Successful launch of Alkindi® in Sweden and Denmark
- Submission of MAA for Alkindi® in Australia following the grant of Orphan Drug Designation
- Investment in enhanced capsuling capability for Alkindi® and Chronocort® agreed with manufacturing partner, Glatt Pharmaceutical Services

Martin Whitaker, CEO of Diurnal, commented:
"Diurnal continues to execute on delivering its vision of becoming a world leading endocrinology specialty pharma company. During the year, we made substantial operational and commercial progress, overcoming significant challenges, and remain in a strong position.

"Alkindi®, our first commercialised product, demonstrated strong market uptake, which we believe validates our strategy of focusing on the treatment of underserved chronic endocrine diseases, as well as our expertise in developing, registering and commercialising high-quality products. Importantly, we have also built a valuable sales infrastructure in Europe for Alkindi®, which we can use to commercialise future products including Chronocort®. As further testament to the expert team at Diurnal, we are pleased that following our detailed analysis of data from our Phase 3 clinical programme of Chronocort® in Europe and our discussion with the EMA, the product remains on track for submission of an MAA in Q4 2019.

"Additionally, as we look ahead, we expect further country launches in Europe for Alkindi® during H2 2019, along with a planned NDA submission of the product in the US during Q4 2019. Diurnal has received strong interest in Alkindi® and Chronocort® for the US and we are progressing with licensing discussions."

This announcement contains insider information for the purposes of Article 7 of Regulatory (EU) No596/2014.

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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.

Chairman's Statement

Diurnal has ended a challenging year in a strong position as the Group continues to move towards its vision of becoming a world-leading endocrinology specialty pharma company. The strong market uptake of Alkindi® is a validation of both the Group's strategy of focusing on the treatment of chronic endocrine diseases and of its expertise in developing, registering and commercialising high-quality products. Similarly, following the surprising initial headline data from the Phase 3 trial, the progress made towards ensuring the Chronocort® European commercial launch remains on track is testament to the resilience and resourcefulness of our staff and we look forward to the Marketing Authorisation Application (MAA) submission which remains on track for Q4 2019. I am particularly encouraged by the strong support we continue to receive from physicians and patient groups who provide valuable input into the development of our products, and from our investors who have continued to support the Group during this critical period in its development.

A focused strategy

Diurnal is focused on the in-house commercialisation of Alkindi® and Chronocort® in key European territories where it is able to optimise market access in a cost-effective manner. For markets outside of these core territories, Diurnal's strategy is to engage with partners who have extensive local knowledge, a strong commitment to our products, and who are able to rapidly gain market access to help patients.

The launch of Alkindi® has provided Diurnal the opportunity to become a fully-integrated organisation with the capabilities to successfully design, develop and commercialise innovative products that address key unmet patient needs in chronic endocrine diseases. The Group will realise significant synergies through the use of the same commercial infrastructure and supply chain for Chronocort® in Europe, following the anticipated marketing authorisation submission in late 2019 and subsequent regulatory approval. Chronocort® will also benefit significantly from the Group's experience in obtaining regulatory and pricing approval for Alkindi®.

Chronocort® presents the opportunity of a 'platform product', with potential to expand beyond the treatment of congenital adrenal hyperplasia (CAH) into adrenal insufficiency (AI), which is approximately five times the size of the CAH market, as well as other potential indications in inflammatory diseases. By leveraging its late-stage portfolio in this way, Diurnal believes it can build a highly cash-generative business, providing the capability to invest both in its own innovative product portfolio, as well as seeking new opportunities from external sources, to drive long-term growth for shareholders.

Diurnal continues to believe its focus on rare and orphan diseases in the endocrine space provides the opportunity to develop high-quality, differentiated products that address the burden of living with these diseases and demonstrate clear clinical benefits, both to physicians and payers, as shown by the success of Alkindi® following its launch in May 2018.

Delivering our late-stage pipeline

Diurnal has continued to make significant progress with its innovative products for the treatment of cortisol deficiency, Alkindi® for paediatric patients and Chronocort®.

Diurnal's belief in the clinical benefits for Alkindi® has been borne out in the market, with pricing now agreed in a number of European territories in line with the Group's aspirations. The Group achieved revenues in excess of £1 million during the year, reflecting a highly successful launch of Alkindi®.

An important event during the year was the completion of the Chronocort® European Phase 3 study in October 2018. Despite Chronocort® controlling patients' condition more effectively than in its successful Phase 2 trial, it failed to meet the complex primary efficacy endpoint. Nevertheless, it is clear to Diurnal that Chronocort® is a safe and effective treatment that is able to deliver real benefits to patients; this was corroborated in a successful meeting with the European Medicines Agency (EMA), which confirmed the current regulatory path. As a consequence, a European MAA will be submitted in Q4 2019 without the need for additional clinical trials.

Following the unexpected headline result from the Chronocort® European Phase 3 programme, the Group deemed it prudent to pause the Chronocort® US development programme, in order to incorporate key learnings from the European study. The US protocol has now been redesigned and is ready for recommencement of development, which is likely to be in conjunction with a partner.

Outside of these territories, Diurnal's partners in Israel and Australia have continued to make excellent progress. The Group will continue to seek opportunities to maximise the value of Alkindi® by seeking partners

in other territories, particularly those which can accept the European regulatory dossier and which will support pricing in line with the clinical benefits offered by the product.

Financial stability

Diurnal successfully completed a £5.9 million placing and open offer in June 2019, which will facilitate the submission of marketing authorisation applications for Chronocort® in Europe and Alkindi® in the US, as well as the continued build-out of the commercial infrastructure to support the expected growth in Alkindi® revenues over the coming years. Diurnal has managed costs carefully during the year and believes that it is well placed to raise the further funds required to reach sustainable profitability. I would like to thank our existing and new shareholders for their support as Diurnal aims to provide much-needed, high-quality treatment options to patients with chronic endocrine diseases.

Strong governance and risk management

The Group has continued to operate a strong system of internal controls and appropriate risk management systems throughout the year. The identification and management of risks is embedded in the senior management team and is overseen by the Board, which enables the Group to pre-empt and effectively manage issues across the business.

A key focus during the year has been Diurnal's preparations for the UK's planned departure from the European Union. Diurnal's commercial supply chain is located entirely within the EU in order to minimise any cross-border trading impacts on the commercialisation of Alkindi® across Europe. The Group's wholly owned subsidiary in the Netherlands is now fully equipped to commercialise products within the EU on an ongoing basis. It is a testament to Diurnal's quality approach and systems that it was able to obtain the necessary licences and approvals on a timely basis, to avoid disruption of the business.

People and culture

I would like to thank our employees for their continued support and hard work in driving the Group's progress towards commercialising its first products, in particular given the challenges in the current year and the complexities of transitioning from a development organisation to a fully-integrated company. Few UK companies have successfully taken their own product from concept to commercialisation and the fact our key milestones have been met during a period of intense activity and change demonstrates the strength of the Diurnal team. I am pleased that, throughout this period of rapid growth and development, Diurnal has managed to retain an entrepreneurial culture, both in its direct employees and also in the highly skilled contractors and consultants who support the business.

I would also like to thank my fellow Board members for the progress made this year in overseeing a strategy that will ensure continued and sustainable growth from our pipeline.

Key milestones expected next year

The next 12 months are expected to see further significant progress in Diurnal, with two major regulatory filings anticipated within the first half of our next financial year and continued launches of Alkindi® in key European markets. The Group also expects to report progress in finding a partner for its late-stage products in the US and other markets globally. The Group remains mindful of external growth opportunities and continues to assess endocrinology assets that fit within its disease focus.

Looking forward, I am optimistic that the Group's novel late-stage pipeline products are well positioned to deliver Diurnal's ambition of becoming a world-leading, endocrinology-focused specialty pharma company, delivering significant value for our shareholders.

Peter Allen
Chairman
23 September 2019

Operational Review

The Group's primary focus remains on progressing Chronocort® and Alkindi®, our two lead products, which are potentially valuable treatment options with a combined opportunity in the US and Europe of over $400 million for congenital adrenal hyperplasia (CAH) and paediatric adrenal insufficiency (AI), underserved orphan diseases resulting from cortisol deficiency. During the year, Alkindi® has made significant commercial progress following first country launches in the UK and Germany.

Despite the initially disappointing top-line analysis of data from the Chronocort® European Phase 3 clinical trial during Q3 2018, Diurnal believes the overall data package is compelling with respect to the drug as a potential treatment for CAH. Following a positive Scientific Advice meeting with the European Medicines Agency (EMA) in Q2 2019, the Group expects to file a marketing authorisation application (MAA) for Chronocort®, using the existing clinical data, in Q4 2019. With the operational progress made over the past year, Diurnal believes it can become one of the few UK biotechnology companies to successfully take multiple products from concept to commercialisation.

Late-stage pipeline: targeting patient needs in diseases of cortisol deficiency

Diurnal's late stage development pipeline is targeting disorders of the adrenal axis with two novel formulations of hydrocortisone.

CAH is an orphan condition caused by the deficiency of adrenal enzymes, most commonly 21-hydroxylase, which is required to produce cortisol, an essential hormone in regulating metabolism and the response to stress. The block in the cortisol production pathway causes the over-production of male steroid hormones (androgens), which are precursors to cortisol. The condition presents at birth and affects both sexes. The cortisol deficiency and over-production of male sex hormones can lead to increased mortality, infertility and severe development defects, including ambiguous genitalia, premature sexual development and short stature. Sufferers, even if treated, remain at risk of death through an adrenal crisis. The condition is estimated to affect approximately 41,000 patients in Europe and 16,000 patients in the US, with approximately 405,000 patients in the rest of the world.

AI is a condition characterised by deficiency in cortisol often acquired during a persons' lifetime. The primary symptom of AI is chronic fatigue and patients are at risk of adrenal crisis and death if they do not have adequate cortisol replacement. AI is either primary or secondary, with primary AI resulting from diseases intrinsic to the adrenal gland and secondary AI resulting from pituitary diseases where there is a failure of the pituitary gland to stimulate the adrenal gland. The condition is estimated to affect approximately 297,000 patients in Europe and 154,000 patients in the US, with approximately three million patients in the rest of the world.

Paediatric AI (including CAH) has been identified as an orphan disease in the US, where there are estimated to be approximately 4,100 sufferers under the age of 17, and in Europe, where there are estimated to be around 10,000 suffers under the age 18. Untreated, the disease is associated with significant morbidity and increased mortality.

Alkindi® Europe: strong market uptake driving 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 and has been proven to be 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®, either through the use of in-house resources or distribution partners.

Diurnal launched Alkindi® in the UK in September 2018, its second launch following introduction in Germany in May 2018. During the year, Diurnal has continued to make good progress in both territories, including pricing discussions, notably with a positive Scottish Medicines Consortium pricing and reimbursement decision in October 2018 and agreement of the price in Germany. Alkindi® achieved revenues of over £1 million during the financial year, a key milestone for the Group, and has continued to make strong progress, with continued revenue growth to date in H2 2019.

The roll-out of Alkindi® beyond Germany and the UK has continued during the year, with pricing agreed in Italy, Sweden, Denmark, Austria, Norway and Iceland. Diurnal believes that the health economic arguments supporting Alkindi® are robust and support pricing submissions in the remaining key European markets. The Group expects a series of country launches during the remainder of 2019 that will continue to provide strong

revenue growth for Alkindi®, including the launch in the Nordic region shortly after the end of the financial year by its distribution partner Frost Pharma (formerly Anthrop Pharma).

Diurnal has continued to develop a robust product supply chain during the year; 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 Wholesaler Dealer Licence required to market Alkindi® in the EU should the UK depart from the EU.

The Group 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. As a result, Diurnal continues to assess such business development opportunities where they are additive to its business model.

Alkindi® US: regulatory submission planned for 2019

During the year, Diurnal successfully completed the Alkindi® US reference drug bioequivalence study to support its planned New Drug Application (NDA) submission in the US. In addition, the Group 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 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. In parallel with the NDA submission, Diurnal will apply for Orphan Drug Status for Alkindi® in paediatric AI, which requires Diurnal to demonstrate significant clinical benefit for Alkindi® compared to existing therapies. Diurnal intends to seek a licensing partner for its late-stage products in the US and, following the positive FDA feedback, has now initiated partnering discussions for Alkindi®.

Chronocort®: clear regulatory path in Europe and US

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

During the year, 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 retention rate in this study has been high to date.

In October 2018, Diurnal announced that, whilst Chronocort® had been able to demonstrate 24-hour control of androgens in the Phase 3 trial, it did not meet the primary endpoint of superior control throughout the 24 hour period compared to conventional glucocorticoid therapy. Subsequently, Diurnal 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 clinical parameters. Diurnal also analysed interim data from the ongoing safety extension study; notably, a number of patients on the safety extension trial have been treated for at least 30 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 held a Scientific Advice meeting with the EMA in Q2 2019, which confirmed the existing clinical and regulatory path for Chronocort® Diurnal, therefore, expects to file an MAA for Chronocort® in Q4 2019. As part of the MAA submission, Diurnal intends to file for the use of Chronocort® for adolescent CAH patients, providing the potential for seamless life-long treatment, with patients commencing treatment with Alkindi® and transitioning to Chronocort®. In parallel with the MAA submission, Diurnal will apply for Orphan Drug Status for Chronocort® in CAH, which requires Diurnal to demonstrate significant clinical benefit for Chronocort® compared to existing therapies. Diurnal has also undertaken the necessary arrangements with the UK's Medicines and Healthcare products Regulatory Agency (MHRA) for a potential separate UK regulatory submission, should the UK depart from the EU without a transitional arrangement.

Assuming the EMA approves Chronocort® for the treatment of CAH, Diurnal subsequently intends to submit a line extension in Europe for the treatment of AI, a much larger market opportunity, using existing clinical data, once the current Orphan Drug Designation for the product Plenadren® in the treatment of AI has expired.

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 discussions with the FDA during 2018, Diurnal designed a Phase 3 registration package for Chronocort® in the US, which would 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 paused this study while it reviewed the European data package. The design of the US study has now been optimised based on this new information. The study is expected to recommence once the Group has identified a development and commercialisation partner for Chronocort® in the US. Diurnal believes that the preparatory work undertaken for this study, including identification of key clinical sites, will substantially accelerate its recommencement once a US partner has been secured.

During the year, Diurnal also developed a Phase 2 study design to assess the utility of Chronocort® in AI, which represents a sizeable commercial opportunity in the US (potentially close to a $1bn market opportunity) with a highly favourable competitive landscape. Following the Chronocort® European Phase 3 study results, the AI study was paused in order to preserve cash. Subject to funding, Diurnal believes that this study is ready to commence, either in-house or with the support of a US partner.

Maximising late-stage pipeline value

During the year, Diurnal continued to optimise market access for its products outside of Europe and the US, where the Group aims to maximise revenues from Alkindi® and Chronocort® by entering into distribution and/or licensing agreements. The Group 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 Diurnal's 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. During the year, Medison confirmed that the MAA for Alkindi® had been accepted for filing by the Israeli Ministry of Health and Emerge Health successfully obtained Orphan Drug Designation from the Therapeutic Goods Administration (TGA) in Australia. Just after the year end, Emerge Health successfully submitted an MAA for Alkindi® in Australia with approval anticipated around the middle of 2020.

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 a well-developed pharmaceutical market, with orphan drug designation and a large population, and is therefore an attractive market estimated at $397 million for Diurnal's late-stage products for CAH and AI.

Diurnal is also assessing the potential for the commercialisation of Alkindi® in China, where it recently received notification of the grant of its patent for the product. The Chinese health authorities have recently prioritised the treatment of chronic paediatric diseases and China represents a large market opportunity for paediatric AI (including CAH), with patient numbers estimated to be at least twice the size of the European market.

Early stage pipeline: targeting needs in endocrine diseases

Diurnal aspires to be a significant participant in the endocrinology field with a pipeline of therapies targeting multiple endocrine disorders where patient and clinical needs are underserved. Whilst Diurnal's primary focus is currently on bringing its late-stage cortisol deficiency pipeline to the market in Europe and the US and to expand these products into new indications and geographies, the Group's long-term plan is to expand into further endocrine disease areas, such as those associated with the thyroid, gonads and pituitary.

During the year, Diurnal has been focused on applying for government grants to assist the development of its early-stage pipeline whilst focusing resources on its late-stage pipeline. Feedback from these grant applications has been positive and highlight the significant unmet needs Diurnal is aiming to address.

During the year, Diurnal completed dosing of a Phase 1 proof-of-concept clinical study with DITEST™, its native oral testosterone therapy for the treatment of male hypogonadism (a market opportunity of close to $5bn). In this study, carried out in 24 hypogonadal men, the performance of DITEST™ has been assessed in terms of oral absorption of testosterone with or without a high fat meal and levels of by-products of metabolism, compared to oral modified testosterone undecanoate. The study is scheduled to read out during Q4 2019 and, if successful, Diurnal plans to enter partnering discussions for DITEST™ in order to maximise the value of this innovative treatment.

Diurnal's other 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) and its novel siRNA therapy for Cushing's disease (a market opportunity of close to $0.5bn), a condition characterised by an excess of cortisol. In addition, Diurnal regularly assesses third party products for endocrine disorders that fit within its strategic vision.

Further strengthening of in-market exclusivity

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.

During the year, a second US patent was granted for Chronocort® and a second patent for Alkindi® was granted in Japan. These granted patents provide in-market protection for both Alkindi® and Chronocort® to 2034. The Group expects to continue to expand patent coverage for its products in the future, further strengthening its in-house patent portfolio.

Diurnal's late-stage products are targeting rare and orphan diseases and therefore, in addition to the strong and expanding patent portfolio, have the benefit of additional regulatory protection in key markets. 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, providing seven years of market exclusivity in the US assuming Orphan Drug Status is granted upon the expected approval of these products. In Europe, the paediatric use marketing authorisation (PUMA) for Alkindi® affords ten years of data and market exclusivity, whilst Chronocort® benefits from separate Orphan Drug Designations for both CAH and AI.

Outlook

Following the positive Scientific Advice meeting with the EMA, Diurnal anticipates submitting an MAA for Chronocort® during Q4 2019. If approved by the EMA, the product will join Alkindi® to enlarge the Group'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 Group to be worth over $300m in Europe alone.

Diurnal also expects additional progress for Alkindi®, with further country launches in Europe scheduled during H2 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 products, with a combined market size for the treatment of CAH and paediatric AI estimated at $125m, and a future expansion opportunity in adult AI, which represents a close to $1bn market opportunity in the US.

The Group is well positioned to build on the approval of its first product Alkindi®, and to become a fast growing, independent, international specialty pharmaceutical company focusing on creating products that address unmet patient needs in endocrinology.

Martin Whitaker
Chief Executive Officer
23 September 2019

Financial review

Revenues and gross margin

The Group launched Alkindi® in Germany in May 2018 and in the UK in September 2018. Total revenues recorded for the year were £1,044k (2018: £73k), which is net of provisions for stock placed into the wholesale distribution chain on a sale-or-return basis.

The roll-out of Alkindi® has been impacted by the unpredictability of timing of pricing discussions, which are conducted on a country-by-country basis, by activities required to prepare for the UK's planned exit 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. Nevertheless, the Group expects a series of country launches during the remainder of 2019 that will continue to provide strong revenue growth for Alkindi® and the Group's supply chain is fully prepared for the UK's departure from the EU.

Gross margin for the year was 79% (2018: 79%). As Alkindi® sales volumes grow, the Group expects to be able to realise margin improvements through manufacturing efficiencies.

Operating expenses

Research and development (R&D) expenditure for the year was £8.7m (2018: £10.0m). Expenditure increased significantly in the first half of the year as the Group undertook activities to initiate the Chronocort® US Phase 3 trial, in addition to completing the Chronocort® Phase 3 registration trial in Europe and transitioning 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. Consequently, R&D expenses were significantly lower in the second half of the financial year.

R&D expenditure in the consolidated income statement is net of capitalised development costs for Alkindi® of £37k (2018: £15k). The Group continues to expense development costs relating to the separate development programme for Alkindi® in the US, and for Chronocort® development.

Administrative expenses for the year were £6.7m (2018: £6.8m). Expenses in the year included a credit of £0.6m relating to the release of a provision for Employers' National Insurance contributions on share option exercises, reflecting the fall in the share price following the announcement of the Chronocort® Phase 3 clinical trial headline data in October 2018. Following the Chronocort® European Phase 3 trial read-out in October 2018, a number of cost-saving measures were implemented. The impact of these cost-saving measures offset continued investment in the launch of Alkindi® across Europe.

Operating loss

Operating loss for the year reduced to £14.5m (2018: £16.8m), reflecting the cost-saving measures outlined above and increased revenues.

Financial income and expense

Financial income in the year was £130k (2018: £95k) despite lower average cash balances compared to the previous year, largely reflecting the Group's decision to hold a portion of its cash balances in US Dollars which benefited from a higher interest rate.

Financial expense for the prior year of £221k largely comprised the non-cash financial expense of the convertible loan, which was converted into shares at the time of the Group's fundraising in April 2018.

Loss on ordinary activities before tax

Loss before tax for the period was £14.4m (2018: £16.9m).

Tax

The current year includes the estimated research and development tax credit claim in respect of the year ended 30 June 2019 of £2,105k, which has not yet been submitted to HMRC, along with an additional £3k in respect of the year ended 30 June 2018 following submission and payment of the claim. The Group has not recognised any deferred tax assets in respect of trading losses arising in either the current financial year or accumulated losses in previous financial years.

Earnings per share

Basic loss per share was 19.7 pence (2018: 26.8 pence).

Cash flow

Net cash used in operating activities was £13.7m (2018: £12.8m). The operating cash outflow was significantly reduced in the second half of the year, reflecting the placing Chronocort® US development on hold and the cost-saving measures outlined above.

Net cash from investing activities was £0.1m (2018: net cash from investing activities £11.1m). The prior year balance reflects the movement of all longer-dated held to maturity financial assets to short-dated cash and cash equivalents resulting from the change in the Group's treasury arrangements during the year: all its cash deposits are now immediately accessible and, consequently, are classified as cash and cash equivalents.

Net cash from financing activities during the year was £5.5m, reflecting the net proceeds of the placing and open offer completed in June 2019. Net cash from financing activities in the prior year of £9.9m reflects the net proceeds of the placing completed in April 2018.

Balance sheet

Total assets decreased to £13.5m (2018: £22.5m), largely reflecting the utilisation of cash in operating activities highlighted above, partly offset by the placing and open offer completed in June 2019.

Following the approval of the Alkindi® PUMA in February 2018, the Group is now recognising stocks of raw materials, components, work-in-progress and finished goods relating to its commercial supplies of Alkindi® on the balance sheet. Total stock at the year-end increased substantially to £672k (2018: £123k), largely reflecting manufacturing batches in progress to support the planned country launches for Alkindi® in the second half of 2019.

The Group also has trade receivables arising from the sale of Alkindi® to wholesalers and distribution partners; at the year end, trade receivables amounted to £510k (2018: £77k). Trade receivables are expected to reduce significantly as a proportion of revenues in future, once initial extended credit terms revert to normal credit terms.

Cash and cash equivalents were £9.1m (2018: £17.3m). Total liabilities decreased to £2.5m (2018: £5.7m), reflecting the reduced level of operating activities in the second half of the financial year noted above.

Financial outlook

Following the cost reduction measures outlined above and the net proceeds from the placing and open offer completed in June 2019, Diurnal expects its cash resources to last until at least Q2 2020 based upon current planned expenditure which is focused on submission of marketing authorisation applications for Chronocort® in Europe and Alkindi® in the US and continued development of the European commercial organisation and roll-out of Alkindi® together with ongoing licensing disussions. Diurnal believes that submission of the marketing authorisation applications, planned for Q4 2019, are key steps in the implementation of the Group's strategic plans that will support further financing activities. 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.

Richard Bungay
Chief Financial Officer
23 September 2019

Consolidated income statement
for the year ended 30 June 2019

	Note	Year ended 30 June 2019 £000	Year ended 30 June 2018 £000
Revenue		1,044	73
Cost of sales		(224)	(15)
Gross profit		820	58
Research and development expenditure		(8,690)	(10,024)
Administrative expenses		(6,656)	(6,813)
Other operating income		-	-
Operating loss		(14,526)	(16,779)
Financial income	5	130	95
Financial expense	6	-	(221)
Loss before tax		(14,396)	(16,905)
Taxation	7	2,108	2,282
Loss for the year		(12,288)	(14,623)
Basic and diluted loss per share (pence per share)	8	(19.7)	(26.8)

All activities relate to continuing operations.

Consolidated statement of comprehensive income
for the year ended 30 June 2019

	Year ended 30 June 2019 £000	Year ended 30 June 2018 £000
Loss for the year and total comprehensive loss for the year	(12,288)	(14,623)

Consolidated balance sheet
as at 30 June 2019

	Note	2019 £000	2018 £000
Non-current assets			
Intangible assets		49	16
Property, plant and equipment		33	26
		82	42
Current assets			
Inventories	9	672	123
Research and development tax credit claims receivable	7	2,105	2,275
Trade and other receivables	10	1,457	2,818
Cash and cash equivalents	11	9,147	17,284
		13,381	22,500
Total assets		13,463	22,542
Current liabilities			
Trade and other payables	12	(2,503)	(5,661)
		(2,503)	(5,661)
Non-current liabilities			
Trade and other payables		(16)	-
		(16)	-
Total liabilities		(2,519)	(5,661)
Net assets		10,944	16,881
Equity			
Share capital	13	4,226	3,067
Share premium		42,153	37,769
Group reconstruction reserve		(2,943)	(2,943)
Other reserve		-	-
Accumulated losses		(32,492)	(21,012)
Total equity		10,944	16,881

Consolidated statement of changes in equity
for the year ended 30 June 2019

	Share capital £000	Share premium £000	Group reconstruction reserve £000	Other reserve £000	Accumulated losses £000	Total £000
Balance at 30 June 2017	**2,616**	**23,675**	**(2,943)**	**1,458**	**(7,730)**	**17,076**
Loss for the year and total comprehensive loss for the year	-	-	-	-	(14,623)	(14,623)
Equity settled share-based payment transactions	-	-	-	-	808	808
Issue of shares for cash	289	10,235	-	-	(4)	10,520
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	451	14,094	-	(1,458)	1,341	14,428
Balance at 30 June 2018	**3,067**	**37,769**	**(2,943)**	**-**	**(21,012)**	**16,881**
Loss for the year and total comprehensive loss for the year	-	-	-	-	(12,288)	(12,288)
Equity settled share-based payment transactions	-	-	-	-	825	825
Issue of shares for cash	1,159	4,790	-	-	(17)	5,932
Costs charged against share premium	-	(406)	-	-	-	(406)
Total transactions with owners recorded directly in equity	1,159	4,384	-	-	808	6,351
Balance at 30 June 2019	**4,226**	**42,153**	**(2,943)**	**-**	**(32,492)**	**10,944**

Consolidated cash flow statement
for the year ended 30 June 2019

	Note	Year ended 30 June 2019 £000	Year ended 30 June 2018 £000
Cash flows from operating activities			
Loss for the year		(12,288)	(14,623)
Adjustments for:			
Depreciation, amortisation and impairment		22	14
Share-based payment		825	808
Net foreign exchange gain		(10)	(203)
Financial income	5	(130)	(95)
Finance expenses	6	-	221
Taxation	7	(2,108)	(2,282)
Increase in inventories		(549)	(123)
Decrease / (increase) in trade and other receivables		1,361	(1,535)
(Decrease) / Increase in trade and other payables		(3,143)	2,320
Cash used in operations		(16,020)	(15,498)
Interest paid		-	(2)
Tax received	7	2,279	2,737
Net cash used in operating activities		(13,741)	(12,763)
Cash flows from investing activities			
Additions of property, plant and equipment		(25)	(19)
Capitalisation of research and development expenditure		(37)	(15)
Purchases of held to maturity financial assets		-	(5,500)
Disposal of held to maturity financial assets		-	16,500
Interest received		130	107
Net cash from investing activities		68	11,073
Cash flows from financing activities			
Net proceeds from issue of share capital		5,526	9,890
Net cash from financing activities		5,526	9,890
Net (decrease) / increase in cash and cash equivalents		(8,147)	8,200
Cash and cash equivalents at the start of the year		17,284	8,881
Effect of exchange rate changes on cash and cash equivalents		10	203
Cash and cash equivalents at the end of the year		9,147	17,284

Notes to the consolidated financial statements

1 Corporate information

Diurnal Group plc (the "Company" or the "parent") is a public limited company incorporated and domiciled in the United Kingdom, and registered in England (registered number: 09846650), whose shares are publicly traded. The registered office is located at Cardiff Medicentre, Heath Park, Cardiff CF14 4UJ.

The Group is a clinical stage specialty pharmaceutical business targeting patient needs in chronic endocrine (hormonal) diseases.

2. Basis of preparation

The financial information set out above does not constitute the Group's statutory accounts for the years ended 30 June 2019 or 2018 but is derived from those accounts. Statutory accounts for 2018 have been delivered to the registrar of companies, and those for 2019 will be delivered in due course. The auditor has reported on those accounts; their report for 2019 was unqualified and included a material uncertainty relating to the going concern paragraph which drew attention to a note in those financial statements covering the same matter as disclosed in Note 3 of this announcement. The auditors' report for 2018 was also unqualified and included a material uncertainty relating to the going concern.

The consolidated financial information has been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union, IFRS IC interpretations and the Companies Act 2006. The financial information contained in these financial statements have been prepared under the historical cost convention, and on a going concern basis.

The Group has applied the following standards and amendments for the first time for their annual reporting period commencing 1 July 2018:

- IFRS 9, 'Financial Instruments';
- IFRS 15 'Revenue from Contracts with Customers';
- Classification and Measurement of Share-based Payment Transactions – Amendments to IFRS 2;
- Annual Improvements 2014–2016 cycle;
- Transfers to Investment Property – Amendments to IAS 40; and
- Interpretation 22, 'Foreign Currency Transactions and Advance Consideration'.

The Group had to change its accounting policies following the adoption of IFRS 9 and IFRS 15. All amendments listed above did not have any impact on the amounts recognised in prior periods and are not expected to significantly affect the current or future periods. All other accounting policies used in the financial information are consistent with those used in the prior year.

Certain new accounting standards and interpretations have been published that are not mandatory for 30 June 2019 reporting periods and have not been early adopted by the Group. The Group's assessment of the impact of these new standards and interpretations is set out below.

IFRS 16, 'Leases': IFRS 16 was issued in January 2016. It will result in almost all leases being recognised on the balance sheet by lessees, since the distinction between operating and finance leases is removed. Under the new standard, an asset (that is, the right to use the leased item) and a financial liability to pay rentals are recognised. The only exceptions are short-term and low-value leases.

There are no other standards that are not yet effective and that would be expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

The preparation of financial information in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Although these estimates are based on management's best knowledge of the amount, event or actions, actual events ultimately may differ from those estimates.

3. Going concern

For the year ended 30 June 2019, the Group made an operating loss of £14.5m on revenue of £1.0m and used net cash in operating activities of £13.7m. Cash and cash equivalents at 30 June 2019 were £9.1m.

The Board has considered the applicability of the going concern basis in the preparation of the financial statements. This included the review of internal budgets and financial results and a review of cash flow forecasts for the 12 month period following the date of signing the financial statements. Under current business plans the Group's cash resources will extend to Q2 2020. Based on this, additional funding is expected to be required by the end of Q1 2020 to support the Group's and the Company's going concern status. Dependent upon the funds raised, and the level of income generated from licensing activities, further funding may be required to reach profitability.

The Group completed a £5.9m fundraising with existing and new investors in June 2019. The Directors have a reasonable expectation that the Group will be able to raise further financing, which could come from a variety of sources, to support its ongoing development and commercialisation activities, following the anticipated completion of marketing authorisation applications for Chronocort® in Europe and Alkindi® in the US, both expected in Q4 2019. The Directors also have a reasonable expectation that the Group will be able to generate significant funding through entering into strategic collaborations for the development and commercialisation of its late-stage pipeline outside of Europe. However, there can be no guarantee that the Group will be able to raise sufficient funding from existing and new investors, nor that the Group will be able to secure strategic collaborations for its late-stage pipeline. In the event that the Group does not successfully raise new financing, the Directors consider that the Group would be able to reduce expenditure on its development programmes, potentially extending the Group's cash resources to more than 12 months from the date of signing the financial statements.

Based on the above factors the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, the above factors give rise to a material uncertainty which may cast significant doubt on the Group's and 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. 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 Board considers it appropriate to report 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

Segmental results are calculated on an IFRS basis. All revenue is recognised at a point in time rather than over time.

	Alkindi®	**Chronocort®**	**Central and early-stage**	**Total**
	2019	**2019**	**2019**	**2019**
	£000	**£000**	**£000**	**£000**
Revenue	1,044	-	-	1,044
Operating loss	(1,935)	(5,954)	(6,637)	(14,526)
Financial income	-	-	130	130
Financial expense	-	-	-	-
Taxation	-	-	2,108	2,108
Loss for the year	(1,935)	(5,954)	(4,399)	(12,288)

	Alkindi®	Chronocort®	Central and early-stage	Total
	2018	2018	2018	2018
	£000	£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:

	Year ended 30 June 2019	Year ended 30 June 2018
	£000	£000
UK	300	-
Rest of Europe	744	73
	1,044	73

An analysis of revenue by customer is set out in the table below:

	Year ended 30 June 2019	Year ended 30 June 2018
	£000	£000
Customer A	300	-
Customer B	291	-
Customer C	151	-
Customer D	137	17
Customer E	134	55
Other customers	31	1
	1,044	73

5. Finance income

	Year ended 30 June 2019	Year ended 30 June 2018
	£000	£000
Interest receivable on cash and cash equivalents and term deposits	130	95
Total finance income	130	95

6. Finance expenses

	Year ended 30 June 2019	Year ended 30 June 2018
	£000	£000
Total interest payable on loans	-	221
Total finance expense	-	221

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.

At the time of the 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 financial expense for the year ended 30 June 2018 represents

the accrual of the effective interest required to charge the transaction costs and equity element of the loan to the income statement over the term of the loan for the period up to the date of conversion of the loan.

7. Taxation

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 has reflected R&D tax credits on an accruals basis since it has established a track record of agreeing claims with HMRC. Consequently, the income statement for the year ended 30 June 2018 reflects the R&D tax credit claim for the year ended 30 June 2018, which was received from HMRC in February 2019. The amount in respect of the year ended 30 June 2019 has not yet been agreed with HMRC, although there is no reason to believe that this claim will be rejected.

	Year ended 30 June 2019 £000	**Year ended 30 June 2018 £000**
Current tax:		
- UK corporation tax on losses of year	-	-
- Research and development tax credit receivable for the current year	(2,105)	(2,275)
- Prior year 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	(2,108)	(2,282)

Reconciliation of total tax expense

The tax assessed for the year varies from the small company rate of corporation tax as explained below:

	Year ended 30 June 2019 £000	**Year ended 30 June 2018 £000**
Loss on ordinary activities before tax	(14,396)	(16,905)
Tax at the standard rate of UK corporation tax rate of 19% (2018: 19%)	(2,735)	(3,212)
Effects of:		
Expenses not deductible for tax purposes	35	154
Depreciation in excess of capital allowances	(2)	(2)
Enhanced research and development relief	(906)	(978)
Share-based payments	134	(62)
Prior year adjustment in respect of research and development tax credit	(3)	(7)
Tax losses carried forward	1,369	1,825
Total tax credits for the year	(2,108)	(2,282)

The standard rate of UK corporation tax has been 19% from 1 April 2017, giving rise to an effective rate of tax for the year ended 30 June 2019 of 19% (year ended 30 June 2018: 19%).

8. Loss per share

	Year ended 30 June 2019	Year ended 30 June 2018
Loss for the year (£000)	(12,288)	(14,623)
Weighted average number of shares (000)	62,390	54,596
Basic and diluted loss per share (pence per share)	(19.7)	(26.8)

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

9. Inventories

	2019 £000	2018 £000
Work in progress	521	14
Finished goods	151	109
	672	123

10. Trade and other receivables

	2019 £000	2018 £000
Trade receivables	510	77
VAT recoverable	219	732
Prepayments	482	1,904
Other debtors	246	105
	1,457	2,818

11. Cash and cash equivalents

	2019 £000	2018 £000
Cash at bank and on hand	9,147	17,284

The Group holds its cash and cash equivalents with its clearing bank and in a segregated cash facility providing same day access to its cash. The Group's treasury policy requires that deposits are held with financial institutions having a minimum credit rating of A- (from Moody's S&P or Fitch), that individual counterparty exposure is no more than £5m and that the maximum term is 12 months. The Group's deposits are in line with this policy.

12. Trade and other payables

	2019 £000	2018 £000
Trade payables	1,145	3,159
Other payables	37	9
Other tax and social security	82	72
Accrued expenses	1,255	2,421
	2,519	5,661

The Group accrues for employer National Insurance contributions that may become due on unexercised share-based payments that are not HMRC tax-advantaged. In the current year £16k of the accrual has been

classified as a non-current liability. The comparative amount of £76k has not been reclassified as the amount is not considered material.

13. Share capital

	2019 Number	2019 £000	2018 Number	2018 £000
Ordinary shares of £0.05 each	84,528,382	4,226	61,336,523	3,067