



20 September 2018

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

Results for the year ended 30 June 2018

A transformational year as the Group reports first commercial revenues

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 2018.

Operational highlights

- Grant of a paediatric use marketing authorisation (PUMA) by the European Commission for Alkindi® (hydrocortisone granules in capsules for opening) as replacement therapy of adrenal insufficiency (AI) in infants, children and adolescents (from birth to < 18 years old)
- First launch of Alkindi® in Germany as replacement therapy of paediatric AI
- Completion of patient recruitment for the European Phase III trial of Chronocort® (modified-release hydrocortisone) in congenital adrenal hyperplasia (CAH)
 - Headline data expected during early Q4 2018
- Grant of first US patent for Chronocort® and grant of first Japanese patents for Alkindi® and Chronocort®
- Marketing and distribution agreement with Emerge Health for Alkindi® and Chronocort® in Australia and New Zealand executed

Financial overview

- Successful completion of £10.5m placing with institutional and private investors to fund further development of Diurnal's late-stage pipeline
- First commercial revenues recorded for the period from launch in May 2018
- Operating loss of £16.8m (2016/17: £12.1m) reflecting increased investment in clinical and development activities and build-out of commercial organisation
- Held to maturity financial assets, cash and cash equivalents at 30 June 2018 of £17.3m (30 June 2017: £19.9m)
- Net cash used in operating activities was £12.8m (2016/17: £10.5m), in line with the Board's expectations

Post-period highlights

- Treatment phase of European Phase III trial of Chronocort® in CAH completed

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

"Diurnal has had a transformational year, with the approval of our first product, Alkindi®, and delivery of our first commercial revenues following its launch in Germany in May 2018. We have also made excellent progress with our late-stage pipeline, in particular the completion of recruitment and treatment in our Chronocort® European Phase III study, which is expected to report headline data in Q4 2018, and with the establishment of a clear regulatory path in the US. With a number of key clinical and regulatory milestones due in the next 12 months, we believe that Diurnal is entering a very exciting period as it executes its strategy to become a world-leading, endocrinology focused speciality pharmaceutical company."

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

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About Diurnal

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

During the last financial year, Diurnal continued to deliver against key milestones, culminating in the Group's first commercial product launch in May 2018 and generation of our first product revenues. This puts Diurnal amongst a small group of UK companies that have successfully taken a product from initial concept all the way to commercialisation. It has been possible due to a clear strategy, highly skilled staff, the support of physicians and patient groups, the backing of our investors and not least the patients who take part in our clinical trials.

Delivering on strategy

With the recent launch of Alkindi[®], Diurnal has 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. In the short-term, Diurnal has in place plans to roll out Alkindi[®] across key European markets, whilst maximising the potential for this product elsewhere through entry via local distribution or licensing arrangements. In the medium term, Diurnal plans to use the same infrastructure to commercialise Chronocort[®] in Europe, following the anticipated successful completion of the European Phase III study in congenital adrenal hyperplasia (CAH) and subsequent regulatory approval. Diurnal is also exploring the potential for Chronocort[®] in adrenal insufficiency (AI), a much larger market opportunity, as well as other potential indications. By leveraging its late-stage portfolio in this way, Diurnal believes that it can build a 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's product development pipeline primarily comprises novel formulations of existing pharmaceutical agents, which the Board believes provides a lower development risk profile for investors, while providing substantial upside through successful registration and commercialisation of these products. Development of pharmaceutical products remains challenging across the industry, particularly in relation to evolving regulatory requirements and the pricing of pharmaceutical products. Pricing of novel, innovative products that are based upon existing active ingredients presents a particular pricing challenge. Diurnal believes that by focusing on rare and orphan diseases in the endocrine space, it can gain great insights into the burden of living with these diseases through our interactions with physicians and patient groups, and consequently is able to develop high-quality products that demonstrate clear clinical benefits, both to physicians and payers.

Significant operational progress

During the year, Diurnal has continued to make significant progress with its innovative late-stage pipeline, focused on diseases of cortisol deficiency, meeting key milestones that underpin its future growth plans. In Europe, where Diurnal plans to build an in-house commercialisation capability, Alkindi[®] was approved in February 2018 and patient recruitment was completed in the Chronocort[®] European Phase III trial in the same month. Alkindi[®] was launched in Germany, utilising the highly experienced commercial team that Diurnal has built with Ashfield Healthcare (Ashfield), with further product launches planned over the coming months. In the US, where Diurnal's current plans are to seek a commercialisation partner, significant progress has been made in defining the regulatory path for these products, with Alkindi[®] approaching the end of its Phase III development programme and the Chronocort[®] registration studies scheduled to commence in early Q4 2018. This progress was underpinned by the grant of key Alkindi[®] and Chronocort[®] patents during the year. In these key markets, Diurnal's late-stage pipeline is protected not only by an extensive patent portfolio, but also by strong regulatory designations providing data and market exclusivity on approval.

Outside of these territories, the Group continued to maximise the value of its late-stage development pipeline with the entry into a distribution arrangement for Australia and New Zealand, and the grant of key Alkindi[®] and Chronocort[®] patents in Japan.

Strong financial position

Diurnal's IPO in December 2015, raising £30m before expenses, put it in a strong position to build a platform for growth. The Group further strengthened its financial position through the successful completion of a £10.5m fundraising in April 2018, which has enabled it to pursue the US development of Chronocort[®], with the Phase III registration study in CAH due to commence shortly. Diurnal also 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 make a real difference to patients without effective treatment options for chronic endocrine diseases.

Governance and risk management

As the Group continues its rapid growth, the Board and senior management remain focused on maintaining a strong system of internal controls and appropriate risk management systems, to ensure that this growth is well-

controlled and does not compromise the integrity of the organisation. During the year, the Group formally adopted the QCA Corporate Governance code, although in large part this represents a formalisation of existing governance practices of the Group.

The Board continues to monitor the potential effects of Brexit on the Group's business and, in particular, any impact on the regulatory framework for pharmaceutical product development, approval and commercialisation, as well as potential disruption in movement of goods between the UK and Europe. Diurnal made the decision some time ago to place its commercial supply chain entirely within Europe, in order to minimise any cross-border trading impacts on the commercialisation of Alkindi® across Europe and continues to assess developments closely in the run up to Brexit in March 2019.

People and culture

Throughout the period of rapid growth over the last few years, Diurnal has managed to retain an entrepreneurial culture, both in its direct employees and also in the commercial team built with Ashfield and the highly skilled contractors and consultants who support the business. The Board closely monitors the corporate culture through discussions with the executive management to ensure that it remains consistent with its strategy of being a small, focused specialty pharmaceutical player focused in the endocrine area. I would like to thank our employees for their continued support and hard work in driving the Group's successful commercialisation of its first product, whilst continuing to develop our innovative pipeline products to provide a solid platform for our future growth.

Key milestones expected in the next 12 months

The next 12 months are expected to see further significant progress in Diurnal, with two major regulatory filings anticipated within the next year and continued launches of Alkindi® in key European markets. The next key milestone following the completion of recruitment and treatment in the Chronocort® European Phase III study for CAH is the report of headline data, expected in Q4 2018. Diurnal also plans to investigate the potential of Chronocort® in the larger AI market alongside the US registration study for Chronocort® in CAH. The Group continues discussions with interested parties to access key markets outside of Europe, and also remains mindful of external growth opportunities and continues to assess endocrinology assets that fit within its disease focus. Diurnal also expects to complete a further fundraising during the next year in order to support its growth plans.

I look forward with optimism and believe the Group is increasingly well positioned to achieve its ambition of becoming a world-leading, endocrinology-focused specialty pharma company, delivering significant value for our shareholders.

Peter Allen
Chairman
19 September 2018

Operational Review

This has been a transformational year for the Group, receiving approval for its first product Alkindi®, in Europe, successfully launching Alkindi® in Germany in May 2018 and securing its first commercial sales.

With progress made over the past year, Diurnal believes that it can become one of the few UK biotechnology companies to successfully take multiple products from concept to commercialisation.

In keeping with the Group's strategy set out at IPO, Diurnal believes that developing novel products containing well-characterised active ingredients targeting endocrine conditions with high unmet needs offers a lower risk approach than developing new chemical entities, whilst retaining exclusivity through orphan drug and regulatory routes. Following our achievements in Europe, this approach can now be expanded to other territories worldwide and specifically the initiation of clinical studies in the US following the success fundraising of £10.5 million during the year.

Late-stage pipeline: challenging diseases of cortisol deficiency

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

Congenital adrenal hyperplasia (CAH) is an orphan condition caused by deficiency of adrenal enzymes, most commonly 21-hydroxylase, which is required to produce cortisol. The block in the cortisol production pathway causes the over-production of male steroid hormones (androgens), which are precursors to cortisol. The condition is congenital 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 (precocious) 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 47,000 patients in Europe and 17,000 patients in the US, with approximately 400,000 patients in the rest of the world.

Adrenal insufficiency (AI) is a condition characterised by deficiency in cortisol, an essential hormone in regulating metabolism and the response to stress. The primary symptoms of AI are 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 stimulation of the adrenal gland by the pituitary gland. The condition is estimated to affect approximately 296,000 patients in Europe and 138,000 patients in the US, with approximately 4 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 4,500 sufferers under the age of 16. In Europe there are estimated to be around 10,000 sufferers under the age 18. Untreated, the disease is associated with significant morbidity and increased mortality.

Alkindi®: first approval and commercial revenues in Europe

In December 2017, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended granting a paediatric use marketing authorisation (PUMA) for Alkindi® (hydrocortisone granules in capsules for opening) for the treatment of primary AI. The positive opinion from the CHMP was based on review of data from the Group's pivotal open-label Phase III clinical trial conducted in 24 subjects before their sixth birthday, requiring replacement therapy for AI due to CAH, primary adrenal failure or hypopituitarism. The study successfully met its primary endpoint and no serious adverse events were reported. Based on these data, and a comprehensive market authorisation application dossier from Diurnal, the CHMP recommended the product's use to include paediatric patients up to 18 years of age. This expansion of Alkindi®'s label, beyond the anticipated label of use in children aged up to six years old, provides Diurnal with a much broader commercial opportunity for Alkindi® in Europe. Subsequently, in February 2018 the CHMP opinion was adopted by the European Commission enabling EU-wide marketing authorisation for Alkindi®.

Following the grant of marketing authorisation, decisions about price and reimbursement will take place at the level of each European Member State. As part of the pan-European commercialisation programme for Alkindi®, Diurnal is currently in discussion with various health authorities to ensure timely launches in all major European countries.

The first of these launches occurred during May 2018 in Germany, with the Alkindi® price being in line with the Group's expectations and published in the LAUER-TAXE® (the reference for all German pharmacies, insurers and wholesalers). Given the concentrated endocrinologist prescribing base, and to retain the full value of the product, Diurnal is commercialising Alkindi® itself in major European markets, focusing its marketing efforts

initially on patients aged 0-6 years where the unmet need is highest. Diurnal has established the commercial infrastructure required to support a successful launch of Alkindi® working closely with Ashfield to supplement Diurnal's small, but very experienced in-house commercial team. The Diurnal European-wide team consists of 14 individuals in place in key European territories and fully integrated with Diurnal's in-house team.

Diurnal has now completed implementation of the commercial supply chain with leading global service providers for manufacturing, packaging and distribution that are completely located within the EU.

Chronocort®: targeting effective disease control in adults

Chronocort® is a modified-release preparation of hydrocortisone that has been designed to mimic the circadian rhythm of cortisol when given in a twice-a-day "toothbrush" regimen (last thing at night before sleep and first thing in the morning on waking). The first planned indication for Chronocort® is CAH in adults and the clinical data in patients from a successfully completed Phase II trial demonstrated that Chronocort® was able to control CAH (as determined by control of androgens) in 94% of patients after receiving Chronocort® for six months.

Chronocort® is currently in a Phase III trial in Europe, which during the year successfully completed enrolment of 122 patients with CAH across seven countries and eleven clinical trial sites. Patients being treated for CAH with combinations of generic steroids (standard of care) were enrolled on the trial and randomised to either Chronocort® on a twice-daily regime or continued their standard-of-care regimen. The primary endpoint of the trial is the control of androgens on the same or lower total daily dose of steroid when treated with Chronocort® when compared to standard-of-care treatment. This primary endpoint is identical to the previously successful Phase II clinical trial for Chronocort®. Secondary and exploratory endpoints include an assessment of body mass index, bone turnover and levels of fatigue. The last patient was dosed after the year end and the initial read-out on the primary endpoint is expected during Q4 2018.

An open label safety extension trial of long-term safety, efficacy and tolerability of Chronocort® in patients with CAH, previously enrolled in the Phase III registration trial, is continuing with over 80% of patients rolling over into this trial and, of those patients enrolling, the proportion of patients remaining within the trial has been very high (>90%). This trial is intended to provide further valuable safety data to support the registration and commercialisation of Chronocort®.

Significant progress in defining the regulatory path in the US

The US remains the second most important market for Diurnal's late-stage pipeline, with an estimated 17,000 patients suffering from CAH and an estimated 138,000 sufferers with AI.

During the period, the Group announced that it had entered into an agreement with Worldwide Clinical Trials (Worldwide) to support the US clinical development of Chronocort® in both CAH and AI.

Working with Worldwide, Diurnal will conduct the US Phase III registration trial and follow-on study for Chronocort® for the treatment of CAH. Following recent progress in the Group's discussions with the US Food and Drug Administration (FDA), Diurnal expects to initiate the Phase III study in early Q4 2018. The Phase III study will recruit around 150 patients with CAH, who will be randomised to either receive Chronocort® twice-daily or standard-of-care. Patients in the study will be treated for 12 months, with the primary endpoint of the study being the proportion of patients achieving biochemical control with Chronocort® or standard of care. A number of secondary endpoints including weight, body composition, hirsutism, fatigue and quality of life will be used to determine clinical benefit of Chronocort® over standard of care.

In advance of the start of the US Phase III pivotal trial, Diurnal completed a bioavailability study post period, which demonstrated that subjects dosed with Chronocort® had comparable exposure to hydrocortisone when compared to subjects dosed with immediate-release hydrocortisone. This bioavailability study will form part of the regulatory package to support the registration of Chronocort® for CAH in the US.

In addition, Diurnal is seeking to pave the way for future indication expansion opportunities with Chronocort® through the initiation of a Phase II proof-of-concept study in AI patients. Worldwide will also conduct this Phase II study, which is expected to commence around the end of 2018.

For Alkindi®, during the year, Diurnal successfully completed a food matrix compatibility study, which is supportive of the package of data that the Group believes is required by the FDA for successful registration of the product in the US. This study was a single centre, open label, randomised, single dose crossover study in 18 healthy adult subjects. The primary objective of the study was to evaluate the bioavailability of Alkindi® multi-particulate granules administered as sprinkles onto soft food or yoghurt compared with direct administration to the back of the mouth. The results of the study confirm that the pharmacokinetics of Alkindi®

when sprinkled onto soft food or yoghurt are equivalent to Alkindi® administered directly. There were no adverse events and Alkindi® was well tolerated.

In addition, a second Alkindi® study assessing bioequivalence to adult doses of hydrocortisone was started and fully enrolled during the period. This bioequivalence study is anticipated to read out during Q4 2018 and, together with the food matrix compatibility study, and Alkindi® European data, will be submitted for review to the FDA around the end of 2018 with a view to submitting an NDA in 2019 with approval anticipated during 2020.

Endocrine focused early-stage pipeline

Diurnal aspires to be a significant participant in the endocrinology field with a pipeline of therapies targeting multiple endocrine disorders.

The Group continues the proof-of-concept Phase I/II study with its native oral testosterone product, DITEST™, for the treatment of male hypogonadism. This study is designed to evaluate the pharmacokinetics, safety, tolerability and food effect of DITEST™ in male patients with hypogonadism. The study is expected to complete around the end of 2018.

The Group continues to assess the potency of different formulations of its oligonucleotide (siRNA) therapy, targeted to the pituitary gland, for the potential treatment of Cushing's Disease (cortisol excess).

The Group continues with plans to finalise development of a modified-release T3 (triiodothyronine) for the treatment of hypothyroidism where the needs of up to 25% of patients on existing replacement therapy, T4 (thyroxine), are not being adequately met.

The Group continues to explore other indications that may benefit from Chronocort®, such as inflammatory diseases.

Delivering on the Group's marketing and distribution strategy

Geographic expansion of Alkindi® and Chronocort® outside the Group's stated core markets is an important element of Diurnal's broader commercialisation strategy and further progress was made in this respect during the year.

In February 2018, a marketing and distribution agreement with Emerge Health, a leading, specialised Australian pharmaceutical company focused on the marketing and sales of niche, high quality medicines to the hospital sector, was executed for Alkindi® and Chronocort® in Australia and New Zealand. Under the terms of the agreement, Emerge Health will receive the exclusive rights to market and sell Alkindi® and Chronocort® in Australia and New Zealand. Diurnal will provide Emerge Health with product from its established European supply chain. Diurnal anticipates the market authorisation of Alkindi® in Australia during 2020.

The Group continues to work closely with Medison Pharma Limited, Israel's leading group for the marketing of innovative niche healthcare solutions, with whom Diurnal executed a marketing and distribution agreement in 2017, with anticipated market authorisation of Alkindi® in Israel during 2020.

Diurnal continues to assess opportunities for similar agreements in selected high-value markets which can utilise existing regulatory data sets.

Further strengthening of the in-market exclusivity position

Diurnal continues to protect its product candidates through a robust and extensive patent portfolio.

During the year, the Group received notification of grant of the first of its US Chronocort® patents: a composition of matter patent for the product formulation for use as a treatment for conditions such as AI. The Group also received grant of its first Japanese patents for Alkindi® and Chronocort® and, post-period end, a notice of grant in Japan for a second Alkindi® patent. These granted patents provide in-market protection for Alkindi® to 2034 and for Chronocort® until 2033. The Group expects to continue to expand patent coverage for its products in the future.

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. In Europe, the EMA offers 10 years of exclusivity (eight years' data plus two years' market exclusivity) through a PUMA, which serves as an inducement for pharmaceutical manufacturers to specifically develop therapies for use in the paediatric population. During the year, the grant of the marketing authorisation by the European Commission confirmed that Alkindi® has PUMA status and therefore exclusivity until 2028. Chronocort® already

benefits from granted orphan drug designations in Europe for both CAH and AI, meaning that it has the potential to have 10 years' market exclusivity post-approval. In the US, the FDA has granted Chronocort® orphan drug designation in the treatment of both CAH and AI and granted Alkindi® orphan drug designation in the treatment of paediatric AI, which affords seven years market exclusivity post-approval.

Outlook

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. Together with its other late-stage product, Chronocort®, Diurnal has the opportunity to build a valuable life-long adrenal franchise, providing critical medicines in underserved disease of cortisol deficiency, and believes that it is well-positioned to raise the funding required to support these growth plans. With the European Chronocort® trial now completed and on track to read out during Q4 2018, the Group believes that a recommendation for approval could be forthcoming in 2020. Reflecting a combined cortisol deficiency market size of over 400,000 patients in Europe and US alone, in addition to further opportunities beyond these two territories, the Board believes that the potential for Diurnal is very positive.

Martin Whitaker
Chief Executive Officer
19 September 2018

Financial Review

Revenues

The Group achieved a significant milestone during the year, with the recording of its first commercial revenues, following the launch of Alkindi® in Germany in May 2018. Total revenues recorded for the year were £73k (2017: nil), which is net of provisions for stock placed into the wholesale distribution chain on a sale-or-return basis.

Operating income and expenses

Operating expenses are in a growth phase, reflecting the investment in headcount and business infrastructure to support the transition of the business to a fully integrated speciality pharma organisation with commercialisation capabilities in Europe, alongside increased investment in developing the late-stage clinical pipeline. This continued investment in the business will support its anticipated growth and development in the coming years.

Research and development expenditure for the year was £10.0m (2017: £8.3m). Expenditure on product development and clinical costs increased during the year as the Group progressed towards completion of recruitment for the Chronocort® Phase III registration trial in Europe and transitioned patients completing this study into the long-term follow-on study, as well as commencing studies to support both the Alkindi® and Chronocort® US Phase III programmes and planning activities for the commencement of a Phase II trial for Chronocort® in AI, to be conducted in the US, around the end of 2018.

As previously highlighted in the interim report for the six months ended 31 December 2017, the approval of the Alkindi® paediatric use marketing authorisation (PUMA) in February 2018 was the trigger for the Group to commence capitalisation of development costs for Alkindi® in Europe under IAS38. Costs capitalised during the year amounted to £15k, 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 PUMA until February 2028. The Group will continue to expense development costs relating to the separate development programme for Alkindi® in the US.

Administrative expenses for the year were £6.8m (2017: £3.7m), reflecting a substantial increase in infrastructure and pre-commercialisation expenses in preparation for the first commercial launch of Alkindi®, which was achieved as expected in May 2018. The Alkindi® launch is underpinned by the Group's arrangements with Ashfield, who provide contract staff on a fee-for-service basis. The increased costs reflect the team of medical scientific liaisons (MSLs), key account managers (KAMs) and support staff engaged by Ashfield, with 14 individuals in place at the end of the financial year, along with health economic and market access activities to support pricing discussions with healthcare payers.

Operating loss

Operating loss for the year increased to £16.8m (2017: £12.1m), reflecting the increased operating expenses outlined above.

Financial income and expense

Financial income in the year was £95k (2017: £182k), due to lower average cash balances compared to the previous year. The Group successfully completed a follow-on offering in April 2018, raising £10.5m before expenses; however, these funds only had an impact for the last three months of the year.

Financial expense for the year was £221k (2017: £272k), being the non-cash financial expense of the convertible loan. As part of the recent fundraising, IP Group exercised its option to convert the loan into equity at the IPO price of 144 pence per share. The financial expense for the year represents the accrual of 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 up to the date of conversion of the loan.

Loss on ordinary activities before tax

Loss before tax for the period was £16.9m (2017: £12.2m).

Tax

The current year includes the estimated research and development tax credit claim in respect of the year ended 30 June 2018 of £2,275k, which has not yet been submitted to HMRC, along with an additional £7k in respect of the year ended 30 June 2017, following finalisation and agreement of the claim. The prior year includes the cash received in respect of the R&D tax credit claim for the year ended 30 June 2016 of £911k, which was received in August 2017, along with the R&D tax credit claim for the year ended 30 June 2017 of

£1,819k, which was received in May 2018. 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

Loss per share was 26.8 pence (2017: 18.0 pence).

Cash flow

Net cash used in operating activities was £12.8m (2017: £10.5m), driven by the planned increase in commercial infrastructure, pre-commercialisation activities and development of the late-stage clinical pipeline during the year. Net cash flows from operating activities include an exchange gain of £228k arising from holding a proportion of its cash balances in US dollars in order to provide budgeting certainty for the future costs of its Chronocort® US development activities.

Net cash from investing activities was £11.1m (2017: net cash used in investing activities £3.2m), reflecting the movement of all longer-dated held to maturity financial assets to short-dated cash and cash equivalents. This reflects 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 generated by financing during the prior period of £9.9m reflects the net proceeds of the placing completed in April 2018.

Balance sheet

Total assets decreased to £22.5m (2017: £23.9m), largely reflecting the utilisation of cash in operating activities highlighted above, partly offset by the follow-on financing completed in April 2018.

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, including certain costs which had previously been expensed. Total stock at the year end was £123k (2017: £nil).

Cash and cash equivalents were £17.3m (2017: £8.9m) and held to maturity financial assets were £nil (2017: £11.0m), reflecting the change in treasury arrangements noted above. Total liabilities decreased to £5.7m (2017: £6.9m), reflecting an increase in trade payables and accruals at the year end associated with the increased level of operating activities, offset by the early retirement of the convertible loan noted above. Net assets were £16.9m (2017: £17.1m).

Richard Bungay
Chief Financial Officer
19 September 2018

Consolidated income statement
for the year ended 30 June 2018

		Year ended 30 June 2018 £000	Year ended 30 June 2017 £000
	Note		
Sales		73	-
Cost of sales		(15)	-
Gross profit		<u>58</u>	<u>-</u>
Research and development expenditure		(10,024)	(8,340)
Administrative expenses		(6,813)	(3,734)
Other operating income		-	9
Operating loss		<u>(16,779)</u>	<u>(12,065)</u>
Financial income	5	95	182
Financial expense	6	(221)	(272)
Loss before tax		<u>(16,905)</u>	<u>(12,155)</u>
Taxation	7	2,282	2,730
Loss for the year		<u>(14,623)</u>	<u>(9,425)</u>
Basic and diluted loss per share (pence per share)	8	<u>(26.8)</u>	<u>(18.0)</u>

All activities relate to continuing operations.

Consolidated statement of comprehensive income
for the year ended 30 June 2018

	Year ended 30 June 2018 £000	Year ended 30 June 2017 £000
Loss for the year	<u>(14,623)</u>	<u>(9,425)</u>

Consolidated balance sheet
as at 30 June 2018

	Note	2018 £000	2017 £000
Non-current assets			
Intangible assets		16	4
Property, plant and equipment		26	18
		<u>42</u>	<u>22</u>
Current assets			
Inventories	9	123	-
Trade and other receivables	10	5,093	4,025
Held to maturity financial assets	11	-	11,000
Cash and cash equivalents	12	17,284	8,881
		<u>22,500</u>	<u>23,906</u>
Total assets		<u>22,542</u>	<u>23,928</u>
Current liabilities			
Trade and other payables	13	(5,661)	(3,341)
		<u>(5,661)</u>	<u>(3,341)</u>
Non-current liabilities			
Loans and borrowings	14	-	(3,511)
		<u>-</u>	<u>(3,511)</u>
Total liabilities		<u>(5,661)</u>	<u>(6,852)</u>
Net assets		<u>16,881</u>	<u>17,076</u>
Equity			
Share capital	15	3,067	2,616
Share premium		37,769	23,675
Group reconstruction reserve		(2,943)	(2,943)
Other reserve		-	1,458
Accumulated losses		(21,012)	(7,730)
Total equity		<u>16,881</u>	<u>17,076</u>

Consolidated statement of changes in equity
for the year ended 30 June 2018

	Share capital £000	Share premium £000	Group reconstruction reserve £000	Other reserve £000	Retained earnings / (Accumulated losses) £000	Total £000
Balance at 30 June 2016	2,610	23,632	(2,943)	1,458	1,177	25,934
Loss for the year and total comprehensive loss for the year	-	-	-	-	(9,425)	(9,425)
Equity settled share-based payment transactions	-	-	-	-	518	518
Issue of shares for cash	6	43	-	-	-	49
Total transactions with owners recorded directly in equity	6	43	-	-	518	567
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

Consolidated cash flow statement
for the year ended 30 June 2018

	Note	Year ended 30 June 2018 £000	Year ended 30 June 2017 £000
Cash flows from operating activities			
Loss for the year		(14,623)	(9,425)
<i>Adjustments for:</i>			
Depreciation, amortisation and impairment		14	7
Share-based payment		808	518
Net foreign exchange gain		(203)	(16)
Financial income	5	(95)	(182)
Finance expenses	6	221	272
Taxation	7	(2,282)	(2,730)
Increase in inventories		(123)	-
Increase in trade and other receivables		(1,535)	(771)
Increase in trade and other payables		2,320	1,861
Cash used in operations		<u>(15,498)</u>	<u>(10,466)</u>
Interest paid		(2)	-
Tax received	8	2,737	-
Net cash used in operating activities		<u>(12,763)</u>	<u>(10,466)</u>
Cash flows from investing activities			
Additions of property, plant and equipment		(19)	(20)
Capitalisation of research and development		(15)	-
Purchases of held to maturity financial assets		(5,500)	(11,000)
Disposal of held to maturity financial assets		16,500	14,000
Interest received		107	189
Net cash from investing activities		<u>11,073</u>	<u>3,169</u>
Cash flows from financing activities			
Net proceeds from issue of share capital		9,890	48
Net cash from financing activities		<u>9,890</u>	<u>48</u>
Net increase / (decrease) in cash and cash equivalents		8,200	(7,249)
Cash and cash equivalents at the start of the year		8,881	16,114
Effect of exchange rate changes on cash and cash equivalents		203	16
Cash and cash equivalents at the end of the year		<u>17,284</u>	<u>8,881</u>

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 2018 or 2017 but is derived from those accounts. Statutory accounts for 2017 have been delivered to the registrar of companies, and those for 2018 will be delivered in due course. The auditor has reported on those accounts; their report for 2018 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. Their report for 2017 was (i) unqualified, (ii) did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498 (2) or (3) of the Companies Act 2006.

The consolidated financial information has been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union, IFRIC 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 accounting policies used in the financial information are consistent with those used in the prior year. The following adopted IFRSs have been issued but have not been applied by the Group in these financial statements. Their adoption is not expected to have a material effect on the financial statements unless otherwise indicated:

- IFRS 17 ‘Insurance Contracts’ effective 1 January 2021
- IFRS 9 ‘Financial Instruments’ effective 1 January 2018
- IFRS 15 ‘Revenue from Contracts with Customers’ effective 1 January 2018
- IFRS 16 ‘Leases’ effective 1 January 2019
- IFRIC 22 ‘Foreign Currency Transactions and Advance Consideration’ effective 1 January 2018
- IFRIC 23 ‘Uncertainty over Income Tax Treatments’ effective 1 January 2019
- IAS 19 ‘Employee Benefits’ Amendments regarding plan amendments, curtailments or settlements effective 1 January 2019
- IAS 28 ‘Investments in Associates and Joint Ventures’ Amendments regarding long-term interests in associates and joint ventures effective 1 January 2019
- IAS 40 ‘Investment Property’ Amendments to clarify transfers or property to, or from, investment property effective 1 January 2018
- Amendments resulting from Annual Improvements 2015–2017 Cycle effective 1 January 2019.

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 2018, the Group made an operating loss of £16.8m on revenue of £0.07m, with the gross profit being £0.05m, and used net cash in operating activities of £12.8m. Cash and cash equivalents at 30 June 2018 were £17.3m.

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 2019. Based on this, additional equity funding is expected to be required by the end of Q1 2019. In addition, further funding may be required in the medium term to support the Group in reaching sustainable profitability. The level of additional funds required (if any) will be dependent upon the amount funds raised in Q1 2019, the Group's performance against forecasts, and the level of income generated from licensing activities, which itself is dependent upon the forthcoming result from the Phase III trial of Chronocort® in Europe.

The Group completed a £10.5m fundraising with existing and new investors in April 2018. The Directors have a reasonable expectation that the Group will be able to raise further equity financing to support its ongoing development and commercialisation activities. The funding environment is expected to be more challenging in the event that the result of the Phase III trial of Chronocort® in Europe is not positive. However, 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 Alkindi® in the event that the result of the Phase III trial of Chronocort® in Europe is not positive.

However, there can be no guarantee that the result of the Phase III trial of Chronocort® in Europe will be positive, 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 additional funding required in Q1 2019 is delayed, the Directors consider that the Group would be able to reduce expenditure on its development programmes, and also accelerate licensing arrangements for Alkindi® and, subject to its Phase III results, Chronocort®, in order to continue funding its operations until additional financing is secured.

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

Previously, the Group reported one segment, which is Clinical Development. Reflecting the approval of the Alkindi® paediatric use marketing authorisation (PUMA) during the year, 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.

	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)

	Alkindi®	Chronocort®	Central and early-stage	Total
	2017	2017	2017	2017
	£000	£000	£000	£000
Revenue	-	-	-	-
Operating loss	(2,188)	(4,896)	(4,981)	(12,065)
Financial income	-	-	182	182
Financial expense	-	-	(272)	(272)
Taxation	-	-	2,730	2,730
Loss for the year	(2,188)	(4,896)	(2,341)	(9,425)

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

	Year ended 30 June 2018	Year ended 30 June 2017
	£000	£000
Europe	73	-

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

	Year ended 30 June 2018	Year ended 30 June 2017
	£000	£000
Customer A	55	-
Customer B	17	-
Other customers	1	-
	<u>73</u>	<u>-</u>

5. Finance income

	Year ended 30 June 2018	Year ended 30 June 2017
	£000	£000
Interest receivable on cash and cash equivalents and term deposits	<u>95</u>	<u>182</u>
Total finance income	<u>95</u>	<u>182</u>

6. Finance expenses

	Year ended 30 June 2018	Year ended 30 June 2017
	£000	£000
Total interest payable on loans	<u>221</u>	<u>272</u>
Total finance expense	<u>221</u>	<u>272</u>

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 (see Note 14).

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). The tax credit included in the income statement for the year ended 30 June 2016 reflected the approval by HMRC of the R&D tax credit claim in respect of the 13 month period ended 30 June 2015. 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. Consequently, the income statement for the year ended 30 June 2017 reflects the R&D tax credit claim for the year ended 30 June 2016, which was approved by HMRC in July 2017, along with the estimated claim for the year ended 30 June 2017, which was received in May 2018. The amount in respect of the year ended 30 June 2018 has not yet been agreed with HMRC, although there is no reason to believe that this claim will be rejected.

	Year ended 30 June 2018 £000	Year ended 30 June 2017 £000
Current tax:		
- UK corporation tax on losses of year	-	-
- Research and development tax credit receivable for the current year	(2,275)	(1,819)
- Prior year adjustment in respect of research and development tax credit	(7)	(911)
Deferred tax:		
- Origination and reversal of temporary differences	-	-
Tax on loss on ordinary activities	<u>(2,282)</u>	<u>(2,730)</u>

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 2018 £000	Year ended 30 June 2017 £000
Loss on ordinary activities before tax	<u>(16,905)</u>	<u>(12,155)</u>
Tax at the standard rate of UK corporation tax rate of 19% (2016/17: 19.75%)	(3,212)	(2,401)
Effects of:		
Expenses not deductible for tax purposes	154	1
Depreciation in excess of capital allowances	(2)	(3)
Enhanced research and development relief	(978)	(741)
Share-based payments	(62)	102
Prior year adjustments	(7)	(911)
Tax losses carried forward	1,825	1,223
Current tax credits for the year	<u>(2,282)</u>	<u>(2,730)</u>

The standard rate of UK corporation tax was reduced from 20% to 19% with effect from 1 April 2017, giving rise to an effective rate of tax for the year ended 30 June 2018 of 19% (year ended 30 June 2017: 19.75%).

8. Loss per share

	Year ended 30 June 2018	Year ended 30 June 2017
Loss for the year (£000)	(14,623)	(9,425)
Weighted average number of shares (000)	54,596	52,235
Basic and diluted loss per share (pence per share)	<u>(26.8)</u>	<u>(18.0)</u>

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

	2018	2017
	£000	£000
Work in progress	14	-
Finished goods	109	-
	<u>123</u>	<u>-</u>

10. Trade and other receivables

	2018	2017
	£000	£000
Trade receivables	77	-
VAT recoverable	732	300
Prepayments	1,904	705
Other debtors	105	290
R&D tax credit claims receivable	2,275	2,730
	<u>5,093</u>	<u>4,025</u>

11. Held to maturity financial assets

	2018	2017
	£000	£000
Bank term deposits	<u>-</u>	<u>11,000</u>

During the year, the Group changed its treasury arrangements to a segregated cash facility with instant access to deposits; consequently, there were no held to maturity financial assets as at 30 June 2018.

12. Cash and cash equivalents

	2018	2017
	£000	£000
Cash at bank and on hand	<u>17,284</u>	<u>8,881</u>

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.

13. Trade and other payables

	2018	2017
	£000	£000
Trade payables	3,159	1,724
Other payables	9	-
Other tax and social security	72	65
Accrued expenses	2,421	1,552
	<u>5,661</u>	<u>3,341</u>

14. Loans and borrowings

	2018	2017
	£000	£000
Non-current loans and borrowings		
Convertible Loans	<u>-</u>	<u>3,511</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 with a maturity date of 24 December 2020 (or such other date as the parties may agree) at which point the Company may either repay the principal amount outstanding in full or convert such amount into non-voting shares at a lower nominal value to that of the ordinary shares to ensure that IP2IPO Limited did not have control of the Company. 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 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 (see Note 6). 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.

15. Share capital

	2018	2018	2017	2017
	Number	£000	Number	£000
Ordinary shares of £0.05 each	<u>61,336,523</u>	<u>3,067</u>	<u>52,320,759</u>	<u>2,616</u>