23 February 2021

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

Interim Results for the Six Months Ended 31 December 2020

Alkindi® sales grow while new deals enable further geographic expansion; EMA approval of second drug, Chronocort®, expected in Q1 2021

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces its results for the six months ended 31 December 2020 (the "Period") and follows publication of a trading update on 14 January 2021.

Operational highlights

- **Alkindi®** (hydrocortisone granules in capsules for opening)
  - Alkindi® Sprinkle approved in the US with subsequent launch by partner Eton Pharmaceuticals ("Eton") in late 2020
  - Further Alkindi® approvals in Australia and Israel

- **Chronocort®** (modified-release hydrocortisone)
  - Chronocort® Day 120 responses submitted on time to the European Medicines Agency (EMA); remains on track for anticipated Committee for Medicinal Products for Human Use (CHMP) recommendation in Q1 2021
  - Continued progress in both Europe and US post-period end:
    - Received and replied to Chronocort® Day 180 questions from EMA
    - Chronocort® marketing authorisation application (MAA) submitted to the UK Medicines and Healthcare products Regulatory Agency (MHRA) in parallel with EMA review
    - Commencement of market access activities for Chronocort® in its target European markets, with the first commercial launch scheduled for Q3 2021
    - Positive Type A meeting with US Food and Drug Administration (FDA) to agree Chronocort® US development programme

- **DITEST™** (native oral testosterone formulation)
  - Positive meeting with the US FDA confirming abbreviated 505(b)(2) development pathway, with potential to be the first effective oral native testosterone treatment in an estimated $4.8bn global market

- **Continued expansion of global footprint post-period end:**
  - Extension of Eton US licensing arrangement for Alkindi® Sprinkle to add Canada
  - Distribution agreement with Er-Kim for Alkindi® and Chronocort® in Turkey
  - Licensing agreement with Citrine Medicine for Alkindi® in China; $0.5m non-refundable cash payment received and up to $12.75m additional cash payments upon achieving certain regulatory and sales milestones
  - Distribution agreement with Consilient Health in the Nordics for Chronocort®

Financial highlights

- As previously announced, Alkindi® product sales for the six months ended 31 December 2020 increased to £1,191k, representing year-on-year growth of 4% (six months ended 31 December 2019: £1,147k; year ended 30 June 2020: £2,390k) and total revenue for the six months ended 31 December 2020, including licensing income, was £1,214k, representing year-on-year growth of 6% (six months ended 31 December 2019: £1,147k; year ended 30 June 2020: £6,313k)

- The roll-out of Alkindi® in all markets was significantly impacted by Covid-19 restrictions and patients' ability to visit hospitals and, consequently, physicians' ability to switch these patients to Alkindi®. Despite these restrictions, Alkindi® revenues grew by over 20% in the UK and Germany

- Operating loss for the six months ended 31 December 2020 of £5,262k, increased 15% year-on-year (six months ended 31 December 2019: £4,575k), reflecting increased investment in the product pipeline and preparations for anticipated Chronocort® European launch

- Cash and cash equivalents at 31 December 2020: £20,344k (year ended 30 June 2020: £15,434k)
  - Placing and Open Offer completed in October 2020 raising £9.8m before expenses, primarily to fund development of DITEST™ and other pipeline opportunities

Martin Whitaker, PhD, Chief Executive Officer of Diurnal, commented:
"Diurnal has continued to make excellent progress during the Period in making Alkindi® available to patients around the world. Notably, Alkindi® Sprinkle received regulatory approval in the US and was subsequently launched there by our partner, Eton. We are pleased with the growth in Alkindi® revenues, despite previously highlighted pandemic-related restrictions in Europe, and look forward to this growth accelerating, especially when pandemic restrictions begin to lift."

"Looking forward, our commercial focus is now on preparation for the anticipated approval and initial launches of Chronocort® in congenital adrenal hyperplasia during 2021, to significantly expand our European cortisol deficiency franchise, towards profitability. Separately, we continue to make good progress in development activities with Chronocort® in the US and Japan, as well as potential indication expansion into adrenal insufficiency. In addition, we are preparing for the next phase of development of DITEST™ in the US as an innovative, testosterone-based, potential treatment for hypogonadism and this is a major commercial opportunity within our pipeline of products."

In the Interim Results:

- "bn", "m" and "k" represent billion, million and thousand, respectively
- "Group" is the Company and its subsidiary undertakings, Diurnal Limited and Diurnal Europe B.V.

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

For further information, please visit www.diurnal.co.uk or contact:

Diurnal Group plc	**+44 (0)20 3727 1000**
Martin Whitaker, Chief Executive Officer Richard Bungay, Chief Financial Officer	
Panmure Gordon (UK) Limited (Nominated Adviser and Sole Broker)	**+44 (0)20 7886 2500**
Corporate Finance: Freddy Crossley, Emma Earl Corporate Broking: Rupert Dearden	
FTI Consulting (Media and Investor Relations)	**+44 (0)20 3727 1000**
Simon Conway Victoria Foster Mitchell	

Notes to Editors

About Diurnal Group plc

Founded in 2004, Diurnal is a UK-headquartered, European specialty pharma company developing hormone therapeutics for the global market for the life-long treatment of chronic endocrine conditions, including congenital adrenal hyperplasia, adrenal insufficiency and hypogonadism. Its expertise and innovative research

activities focus on circadian-based endocrinology to yield novel product candidates in the rare and chronic endocrine disease arena.

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

Forward looking statements

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

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

Chief Executive Review

During the Period, Diurnal has continued to make strong progress towards its vision of becoming a world-leading endocrinology specialty pharma company, despite the challenging backdrop posed by Covid-19 restrictions.

Underpinning this vision is the development of a strong commercial business in Europe, initially focused on delivery of the Group's two lead products, Alkindi® and Chronocort®, for patients suffering from the orphan diseases adrenal insufficiency (AI) and congenital adrenal hyperplasia (CAH), a combined potential market of $2.1bn. The Group is also seeking to maximise the value of its products in the rest of the world, with particular reference to the large opportunities for CAH and AI in the US (c. $1.1bn) and Japan (c. $0.4bn).

The Group is also building a pipeline of valuable opportunities, with the successful completion of a £9.8m fundraising during the Period enabling it to progress clinical development of DITEST™, its native oral testosterone replacement product for the treatment of hypogonadism, a potential global market of approximately $4.8bn.

Alkindi®: establishing a global product presence

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 in a formulation specifically designed for children. Diurnal's commercialisation efforts for Alkindi® are focused on the larger European markets, and initially on patients aged 0-6 years where the unmet need is highest. Diurnal's long-term strategy is underpinned by its commercialisation infrastructure in key European markets. Diurnal has built one of the few dedicated endocrinology-focused commercial teams in Europe, focused on building awareness of its products within the concentrated prescribing community of endocrinologists, initially with Alkindi® following its regulatory approval in 2018. Outside of these core markets, Diurnal is pursuing distribution or licensing deals to make its products, once approved, available to as broad a range of patients as possible.

In Europe, Alkindi® has now been launched by Diurnal in the UK, Germany, Italy and Austria, and by its partner FrostPharma in Sweden, Denmark, Norway and Iceland. During the Period, the Group saw continued growth of Alkindi® sales in the UK and Germany, despite the impact of the Covid-19 pandemic on patients' ability to visit hospitals and, consequently, physicians' ability to switch these patients to Alkindi®. Growth from new territories where Alkindi® was launched during the Period was modest, reflecting the limitation of impactful in-country launches due to the Covid-19 pandemic. The Financial Review provides further detail on the development of Alkindi® revenues.

During the Period, Diurnal further extended the reach of Alkindi® through execution of distribution deals with Consilient Health, covering the Benelux countries, and with EffRx in Switzerland. Pricing for Alkindi® has been approved in the Netherlands and the launch planning is underway by Consilient Health whilst EffRx submitted a marketing authorisation application (MAA) to SwissMedic during the Period, with approval anticipated during 2021.

Diurnal, and its distribution and licensing partners, achieved three regulatory approvals during the Period for Alkindi®. In the US, where the product is called Alkindi® Sprinkle, approval from the US Food and Drug Administration (FDA) was received at the end of September 2020 for children aged under 17 years of age. In November, less than two months after approval, Diurnal's partner, Eton Pharmaceuticals ("Eton"), announced the launch of the product. Diurnal and Eton are awaiting confirmation of Orphan Drug Status from the FDA, which will trigger a $2.5m milestone payment to Diurnal. During the Period, Diurnal also announced that its Australian partner, Emerge Health, had received approval for Alkindi®, with no age restriction, and its partner in Israel, Medison Pharma, had received approval for Alkindi® in children under 18 years of age. Launches in these territories are expected following completion of pricing and reimbursement activities.

The Company further expanded the global reach for Alkindi® after the end of the Period, with an extension of its licensing deal with Eton to cover Canada, a licensing deal with Er-Kim in Turkey to supply Alkindi® on a named patient basis, and a licensing deal with Citrine Medicine in China for Alkindi®.

Diurnal continues to assess the opportunity for Alkindi® in Japan and, during the Period, the Company formulated a development and regulatory strategy for this market. Consistent with this strategy, a submission for regulatory protection was submitted to the Japanese Ministry of Health, Labour and Welfare (MHLW) shortly after the end of the Period.

Chronocort®: expanding the cortisol deficiency franchise

Diurnal's second product candidate, Chronocort®, provides a drug release profile that is designed to improve disease treatment for adults with CAH, as measured by androgen (male sex hormone) control.

Diurnal submitted an MAA to the EMA for Chronocort® as a treatment for adult and adolescent patients with CAH in December 2019. This followed completion of a Phase 3 study conducted in a total of 122 patients enrolled across 11 clinical sites, the largest ever interventional clinical trial completed in CAH, and a subsequent positive meeting with the EMA providing written formal Scientific Advice confirming the clinical and regulatory pathway for Chronocort®. The Phase 3 data was supported by detailed analysis of data from an open-label safety extension study for patients completing treatment in the Phase 3 study, which is 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 rates in this study have been high, with a number of patients on this trial having been treated for over 54 months. Patients on this trial have, to date, shown sustained benefit from extended Chronocort® treatment.

Shortly after the end of the Period, Diurnal received the second formal set of questions from the EMA ("Day 180 questions") and has responded to these in line with the EMA's timetable. Assuming responses to these (and any subsequent) questions are acceptable to the EMA, Diurnal anticipates receiving recommendation for approval of Chronocort® in Europe in March 2021, with formal approval from the European Commission to follow in Q2 2021. In parallel with the MAA submission, Diurnal will apply for confirmation of Orphan Drug Status for Chronocort® in CAH.

Reflecting the UK Medicines and Healthcare products Regulatory Agency's (MHRA) guidance following the end of the Brexit Transition Period, an 'in flight' MAA has been submitted to the MHRA seeking approval for Chronocort® in Great Britain based on the same application submitted to the EMA. Approval from the MHRA is also expected during Q1 2021. In parallel with the MHRA submission, Diurnal will seek confirmation of British Orphan Drug Status for Chronocort® in CAH, which requires the Company to demonstrate significant clinical benefit for the product compared to existing therapies.

Following the end of the Period, Diurnal announced the publication of the peer-reviewed results of the Phase 3 clinical trial and extension study for Chronocort® in the *Journal of Clinical Endocrinology and Metabolism (*"JCEM"). The Phase 3 study results published by the JCEM found that although the standard-deviation-score-focused primary endpoint of the study was missed, Chronocort® improved morning and early afternoon biochemical control for adults with CAH over standard glucocorticoid therapy. In the safety extension study, biochemical control was sustained for 18 months on median hydrocortisone doses in the range recommended for cortisol replacement therapy and lower than glucocorticoid doses normally used in the treatment of CAH.

To facilitate a timely commercial launch assuming approval by the EMA and MHRA, Diurnal has commenced market access activities for Chronocort® in its target European markets, with the first commercial launch scheduled for Q3 2021. Assuming approval of Chronocort® in Europe as expected, the Company intends to mirror its strategy for Alkindi® by commercialising the product itself in core European markets. The Company is manufacturing launch stocks for Chronocort® during the first half of 2021, utilising many aspects of the supply chain that has already been established for Alkindi®. In addition, the Company is undertaking several initiatives to enhance capacity and reduce cost of goods of Chronocort® in the mid-term.

Outside of its core European markets, Diurnal intends to make Chronocort® available commercially through distribution or licensing deals with local partners who can quickly gain market access. Diurnal expanded its global reach during the Period through entering into distribution deals with Consilient Health for the Benelux countries and with Er-Kim to supply Alkindi® on a named patient basis in Turkey, adding to the Group's existing Chronocort® distribution agreements with Emerge Health in Australia and Medison Pharma in Israel. Following the end of the Period, Diurnal extended its partnership with Consilient Health to include commercialisation of Chronocort® in the Nordic region.

Outside Europe, Diurnal continues to progress plans for development of Chronocort® in major markets. In the US, the FDA has previously indicated that the registration package for CAH requires an additional study to the European Phase 3 CAH study. Diurnal is seeking formal agreement of the US Phase 3 protocol with the FDA through a Special Protocol Assessment (SPA). Following a positive Type A meeting with the FDA, as part of the SPA process, after the end of the Period, the US Phase 3 protocol has now been finalised and Diurnal will seek confirmation of the SPA from the FDA during H1 2021. In parallel with the regulatory discussions, the Company is assessing the opportunity to fund the US Phase 3 development itself in order to increase the future value of the programme, as well as significantly broadening the pool of potential commercialisation partners.

Diurnal has also been working with a global Clinical Research Organisation (CRO) to determine the optimum registration route for Chronocort® in Japan, including the potential to include a cohort of Japanese patients in a US Phase 3 clinical study. Diurnal intends to seek Orphan Drug Designation for Chronocort® in Japan once the development path has been determined.

In addition to expanding the global availability of Chronocort® to CAH patients, Diurnal is also seeking to expand its utility into the related condition, AI, a market opportunity of approximately $2.8bn across Europe and the US. Part of the fundraising completed in October 2020 will enable Diurnal to commence a study of Chronocort® compared to the approved product Plenadren® in Europe, which Diurnal believes, along with the Phase 3 CAH study, will facilitate submission of a line extension to AI in Europe, and will also provide valuable insights into potential future development of Chronocort® in AI in the US.

DITEST™: expanding the innovative product pipeline

Diurnal's third novel product, DITEST™, is a native oral testosterone therapy for the treatment of male hypogonadism. The estimated $4.8bn market in US and Europe for testosterone-based products for the treatment of hypogonadism is dominated by topically-available products, which have compliance and safety issues, while key issues with the use of alternative, oral modified testosterone products (testosterone undecanoate) have been the variability in absorption and the requirement for a high-fat meal to achieve therapeutic testosterone levels.

A Phase 1 study evaluating the pharmacokinetics, safety and tolerability of DITEST™ in adult men with primary or secondary hypogonadism demonstrated the achievement of testosterone levels within the healthy young male adult normal range after oral administration, with levels that were less variable than the comparator, testosterone undecanoate. Secondary endpoints demonstrated that there was no impact on the rate and extent of absorption of testosterone from DITEST™ whether taken with either food or in the fasted state, representing a major difference with testosterone undecanoate. The study also demonstrated that there were no serious adverse events in the DITEST™ arm of the study, and levels of the potent testosterone derived androgen, dihydrotestosterone (DHT), were lower than with testosterone undecanoate.

Following these positive results, the Group met with the FDA during the Period, who confirmed that DITEST™ can progress to a New Drug Application (NDA) via the abbreviated 505(b)(2) route, which relies, in part, on published literature and other non-Company studies to support a marketing application and can significantly accelerate the time to approval, compared to FDA-designated New Chemical Entities. Diurnal is currently completing non-clinical activities requested by the FDA in order to submit an Investigational New Drug (IND) submission around the middle of 2021, with a view to commencing a multiple ascending dose study in male patients with low testosterone shortly thereafter. Assuming this study is successful, the FDA indicated that a single Phase 3 study should be sufficient to obtain approval for DITEST™ in the US.

Outlook

If approved by the EMA, Chronocort® will provide the Company's commercial cortisol replacement therapy franchise with critical mass, enabling Diurnal to build a strong and profitable European business through penetration of the combined addressable market for the treatment of CAH and paediatric AI, which is estimated by the Company to be worth c.$300 million in Europe alone. In addition, the Group expects an increased contribution from its licensing and distribution partners outside of Europe once regulatory and/or pricing and reimbursement activities for Alkindi® are completed in these territories.

In the US, Diurnal continues to assess the optimal timing for seeking a partner for the commercialisation of Chronocort, which may be following the completion of Phase 3 development itself: if successful, this would be expected to markedly increase the value of the asset.

DITEST™ represents a further valuable addition to Diurnal's growing pipeline of novel endocrinology treatments and, following the fundraising in October 2020, the Company will move forward with the next stage of development in order to maximise the value of this product in the $4.8bn potential market in the US and Europe.

Financial Review

Revenues and gross margin

Alkindi® product sales for the Period were £1,191k, representing year-on-year growth of 4% (six months ended 31 December 2019: £1,147k). Total revenue for the six months ended 31 December 2020, including licensing income, was £1,214k, representing year-on-year growth of 6% (six months ended 31 December 2019: £1,147k).

The roll-out of Alkindi® during the Period was significantly impacted by Covid-19 restrictions, with sales in all markets below the Company's expectations. The UK and Germany demonstrated continued growth, with sales increasing by over 20% despite the impact of the Covid-19 pandemic on patients' ability to visit hospitals and, consequently, physicians' ability to switch these patients to Alkindi®. The revenue contribution from Italy was modest, reflecting the curtailment of an impactful launch due to the pandemic. Overall sales growth in Diurnal's core commercial markets was offset by timing of bulk sales to Nordic partner, Frost Pharma, with sales into the Nordic region for the Period £207k lower than the prior period. Growth of Alkindi® product revenues is expected to accelerate once Covid-19 pandemic restrictions begin to lift.

Cost of goods relates entirely to product sales of Alkindi®. Gross margin for Alkindi® product sales during the Period was 71% (six months ended 31 December 2019: 74%). Cost of goods and revenues includes sale of initial Alkindi® Sprinkle launch stocks to Eton, which are supplied at cost under the terms of the exclusive licensing agreement announced in March 2020. Excluding these sales to Eton from revenues and cost of goods, gross margin for the Period was 76%. The overall gross margin is determined by the mix of sales by country, particularly in regions where Diurnal divides revenue with its distribution partners, and by dose strength. Underlying gross margins are beginning to benefit from margin improvements through growth in production volumes and other manufacturing efficiencies: Diurnal has implemented several initiatives with its manufacturing partners to further reduce cost of goods in the medium-term.

Operating expenses

Research and development (R&D) expenditure for the Period was £2,633k (six months ended 31 December 2019: £2,388k). During the Period, R&D activities increased as a result of several new activities, including initial manufacturing scale-up activities for Chronocort®, which are expensed to the consolidated income statement, DITEST™ non-clinical activities in support of the planned Investigational New Drug (IND) submission to the US Food and Drug Administration (FDA) during 2021, and activities in support of planning the development and regulatory pathway for Alkindi® and Chronocort® in Japan. As highlighted during the fundraising completed in October 2020, R&D expenditure is expected to further increase in the second half of the financial year as preparations commence in support of the planned DITEST™ multiple ascending dose study, the proposed study with Chronocort® versus Plenadren® in adrenal insufficiency, and acceleration of Alkindi® development activities in Japan.

Selling and distribution expenses for the Period increased to £2,457k (six months ended 31 December 2019: £1,977k) as the Company prepares for the anticipated first commercial launches of Chronocort® during 2021. In particular, the Company has initiated health economic modelling and pricing work to support pricing and reimbursement applications across Europe which are expected to be submitted following the anticipated approval of Chronocort® in the European Economic Area (EEA) by the EMA and in Great Britain by the MHRA during the current financial year.

Administrative expenses for the Period were £1,629k (six months ended 31 December 2019: £1,054k). The expenses for the prior period were reported net of a foreign exchange gain of £362k arising from the settlement of US dollar commitments relating to the closedown of the Chronocort® US clinical studies; excluding this gain, the underlying administrative expenses would have been £1,416k. Costs for the current Period include an increase in the provision for National Insurance payments on unexercised share options of £105k, arising from the increase in share price during the Period, compared to a decrease in this provision in the prior period of £73k. In addition, in line with many other companies Diurnal has experienced increased costs for audit fees and corporate insurances during the Period, reflecting a broader economic backdrop of increased risk arising from recent corporate failures and also Covid-19 impacts.

Operating loss

Operating loss for the Period increased to £5,262k (six months ended 31 December 2019: £4,575k), reflecting the impact of increased operating expenses outlined above. Operating loss for the Period includes an unrealised gain for the Period of £590k relating to the shares held in Eton that were received as part of the

upfront consideration for the exclusive licence agreement of Alkindi® Sprinkle in the US, which is shown under 'Other gains – net' in the consolidated income statement.

Financial income and expense

Financial income in the Period was £56k (six months ended 31 December 2019: £34k), reflecting the higher average cash balances held by the Group during the Period.

Loss on ordinary activities before tax

Loss before tax for the Period was £5,206k (six months ended 31 December 2019: £4,544k).

Tax

During the Period the Company finalised and submitted its R&D tax credit claim in respect of the year ended 30 June 2020; this final amount of £1,199k was received before the end of the Period.

The current year includes an estimate of the R&D tax credit attributable to the Period, shown as an amount receivable in the consolidated balance sheet of £542k as at 31 December 2020.

The Group has not recognised any deferred tax assets in respect of trading losses arising in the Period.

Earnings per share

Loss per share decreased to 3.7 pence (six months ended 31 December 2019: 4.7 pence), with the increase in loss for the Period more than offset by the increase in weighted average number of shares outstanding in the Period following the fundraisings in March 2020 and October 2020.

Cash flow

Net cash used in operating activities during the Period was £4,169k (six months ended 31 December 2019: £4,957k), with the increased operating loss during the Period and increase in Alkindi® inventory at the end of the Period being more than offset by an increase in accrued expenses and earlier receipt of the R&D tax credit repayment compared to the prior period.

Net cash from financing activities during the Period of £9,136k represents the net proceeds of the placing completed in October 2020 of £9,116k along with proceeds of exercise of share options of £20k.

Balance sheet

Total assets increased to £26,364k (30 June 2020: £18,385k), primarily reflecting the fundraising in October 2020, offset by operating outflows.

Inventories at 31 December 2020 increased to £1,666k (30 June 2020: £1,241k), reflecting an increase in Alkindi® stocks both as a result of planned stockpiling to support recent market launches as well as a temporary increase in finished goods arising from lower than anticipated Alkindi® product sales. Inventories also reflect increased holdings of bulk hydrocortisone, following a strategic decision to increase raw material holdings. Levels of Alkindi® stocks are expected to reduce over the next 12 months as market requirements become more predictable; however, in advance of the anticipated launch of Chronocort® the Company expects to begin building launch stocks during the remainder of the financial year which is likely to lead to a further increase in inventories at the financial year end.

Investments held at fair value through profit and loss of £2,258k (30 June 2020: £1,668k) solely relate to the shares held in Eton noted above. The value of the Eton shareholding had increased by £1,217k from receipt of the shares to 31 December 2020.

Cash and cash equivalents at 31 December 2020 were £20,344k (30 June 2020: £15,434k).

Total liabilities increased to £3,225k (30 June 2020: £2,591k), reflecting an increased level of trade payables compared to the prior period.

Net assets were £23,139k (30 June 2020: £18,385k).

Financial outlook

Following the fundraising in March 2020 and October 2020, Diurnal expects its cash resources to take its core commercial European cortisol deficiency franchise through to profitability based upon current plans and assumptions, including expectations regarding the timing of product approvals and sales projections. The Company intends to 'ringfence' this franchise and to seek incremental funding and/or partnering arrangements for discrete, future development opportunities. To this end, the fundraising that was completed in October 2020 will finance the next stage of development of DITEST™ in the US, the expansion of Chronocort® into adrenal insufficiency in Europe, and the development of Alkindi® in Japan. Pursuit of additional opportunities, including the potential for investment in DITEST™ Phase 3 clinical development and/or Chronocort® US registration studies, will be subject to additional financing being available to the Company, though additional equity investment, non-dilutive financing and/or partnering arrangements.

Principal risks and uncertainties

Diurnal considers strategic, operational and financial risks and identifies actions to mitigate these risks. The principal risks and uncertainties are set out in the Group's Annual Report and Accounts for the year ended 30 June 2020, available on the website www.diurnal.co.uk. There are no changes to these principal risks since the issue of the Annual Report and Accounts.

Consolidated income statement
for the six months ended 31 December 2020

	Note	Unaudited 6 months ended 31 Dec 2020 £000	Unaudited 6 months ended 31 Dec 2019 £000	Audited 12 months ended 30 Jun 2020 £000
Revenue	5	1,214	1,147	6,313
Cost of sales		(347)	(303)	(668)
Gross profit		867	844	5,645
Research and development expenditure		(2,633)	(2,388)	(4,625)
Selling and distribution expenses		(2,457)	(1,977)	(4,135)
Administrative expenses		(1,629)	(1,054)	(2,904)
Other gains - net		590	-	627
Operating loss		(5,262)	(4,575)	(5,392)
Net financial income		56	31	114
Loss before tax		(5,206)	(4,544)	(5,278)
Taxation	7	545	509	1,206
Loss for the period		(4,661)	(4,035)	(4,072)
Basic and diluted loss per share (pence per share)	6	(3.7)	(4.7)	(4.3)

All activities relate to continuing operations.

The Notes form part of this condensed financial information.

Consolidated statement of comprehensive income
for the six months ended 31 December 2020

	Unaudited 6 months ended 31 Dec 2020 £000	Unaudited 6 months ended 31 Dec 2019 £000	Audited 12 months ended 30 Jun 2020 £000
Loss for the period and total comprehensive loss for the period	(4,661)	(4,035)	(4,072)

The Notes form part of this condensed financial information.

Consolidated balance sheet
as at 31 December 2020

	Note	Unaudited As at 31 Dec 2020 £000	Audited As at 30 Jun 2020 £000	Unaudited As at 31 Dec 2019 £000
Non-current assets				
Intangible assets		79	79	61
Property, plant and equipment	8	97	23	83
Investments held at fair value through profit and loss	9	2,258	1,668	-
		2,434	1,770	144
Current assets				
Inventories	10	1,666	1,241	764
Research and development tax credit claims receivable		542	1,194	2,614
Trade and other receivables	11	1,378	1,337	1,410
Cash and cash equivalents		20,344	15,434	4,625
		23,930	19,206	9,413
Total assets		26,364	20,976	9,557
Current liabilities				
Trade and other payables	12	(3,210)	(2,555)	(2,109)
		(3,210)	(2,555)	(2,109)
Non-current liabilities				
Trade and other payables	12	(15)	(36)	(15)
		(15)	(36)	(15)
Total liabilities		(3,225)	(2,591)	(2,124)
Net assets		23,139	18,385	7,433
Equity				
Share capital		6,917	6,082	4,327
Share premium		59,268	50,967	42,149
Group reconstruction reserve		(2,943)	(2,943)	(2,943)
Accumulated losses		(40,103)	(35,721)	(36,100)
Total equity		23,139	18,385	7,433

The Notes form part of this condensed financial information.

Consolidated statement of changes in equity
for the six months ended 31 December 2020

	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited
	Share capital	Share premium	Group reconstruction reserve	Accumulated losses	Total
	£000	£000	£000	£000	£000
Balance at 30 June 2019	**4,226**	**42,153**	**(2,943)**	**(32,492)**	**10,944**
Loss for the period and total comprehensive loss for the period	-	-	-	(4,035)	(4,035)
Equity settled share-based payment transactions	-	-	-	427	427
Issue of shares for cash	101	3	-	-	104
Costs charged against share premium	-	(7)	-	-	(7)
Total transactions with owners recorded directly in equity	101	(4)	-	427	524
Balance at 31 December 2019	**4,327**	**42,149**	**(2,943)**	**(36,100)**	**7,433**
Loss for the period and total comprehensive loss for the period	-	-	-	(37)	(37)
Equity settled share-based payment transactions	-	-	-	416	416
Issue of shares for cash	1,755	9,421	-	-	11,176
Costs charged against share premium	-	(603)	-	-	(603)
Total transactions with owners recorded directly in equity	1,755	8,818	-	416	10,989
Balance at 30 June 2020	**6,082**	**50,967**	**(2,943)**	**(35,721)**	**18,385**
Loss for the period and total comprehensive loss for the period	-	-	-	(4,661)	(4,661)
Equity settled share-based payment transactions	-	-	-	279	279
Issue of shares for cash	835	8,970	-	-	9,805
Costs charged against share premium	-	(669)	-	-	(669)
Total transactions with owners recorded directly in equity	835	8,301	-	279	9,415
Balance at 31 December 2020	**6,917**	**59,268**	**(2,943)**	**(40,103)**	**23,139**

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

Consolidated statement of cash flows
for the six months ended 31 December 2020

	Unaudited 6 months ended 31 Dec 2020 £000	Unaudited 6 months ended 31 Dec 2019 £000	Audited 12 months ended 30 Jun 2020 £000
Cash flows from operating activities			
Loss for the period	(4,661)	(4,035)	(4,072)
Adjustments for:			
Licensing income received as non-cash consideration	-	-	(1,041)
Fair value adjustment to investments	(590)	-	(627)
Depreciation, amortisation and impairment	12	39	25
Share-based payment	279	427	843
Net foreign exchange loss/(gain)	26	(352)	(357)
Finance income	(56)	(34)	(114)
Finance expenses	-	3	-
Taxation	(545)	(509)	(1,206)
(Increase) in inventories	(425)	(92)	(569)
(Increase)/decrease in trade and other receivables	(41)	47	119
Increase/(decrease) in trade and other payables	634	(451)	70
Cash used in operations	(5,367)	(4,957)	(6,929)
Net tax received	1,198	-	2,120
Net cash used in operating activities	(4,169)	(4,957)	(4,809)
Cash flows from investing activities			
Additions of property, plant and equipment	(81)	(3)	(7)
Capitalisation of research and development expenditure	(6)	(16)	(38)
Interest received	56	34	114
Net cash from investing activities	(31)	15	69
Cash flows from financing activities			
Net proceeds from issue of share capital	9,136	97	10,670
Repayment of lease liabilities	-	(29)	-
Net cash from financing activities	9,136	68	10,670
Net (decrease)/increase in cash and cash equivalents	4,936	(4,874)	5,930
Cash and cash equivalents at the start of the period	15,434	9,147	9,147
Effects of exchange rate changes on cash and cash equivalents	(26)	352	357
Cash and cash equivalents at the end of the period	20,344	4,625	15,434

Notes to the consolidated financial statements

1 General information

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

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

2 Basis of preparation

As permitted these unaudited consolidated interim financial statements have been prepared and approved by the Directors in accordance with UK AIM rules and the IAS 34 'Interim financial reporting' as adopted by the European Union. They should be read in conjunction with audited consolidated financial statements for the year ended 30 June 2020, which were prepared in accordance with IFRS as adopted by the European Union.

The financial information contained in these interim financial statements has been prepared under the historical cost convention, and on a going concern basis. The interim financial information for the six months ended 31 December 2020 and for the six months ended 31 December 2019 contained within this interim report do not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006. The figures for the year ended 30 June 2020 have been extracted from the audited statutory accounts which were approved by the Board of Directors on 14 September 2020 and delivered to the Registrar of Companies. The report of the auditors on those accounts was unqualified and did not contain statements under 498 (2) or (3) of the Companies Act 2006.

3 Going concern

For the Period ended 31 December 2020, the Group made an operating loss of £5,262k on revenue of £1,214k and used net cash in operating activities of £4,169k. Cash and cash equivalents at 31 December 2020 were £20,344k.

The Board has considered the applicability of the going concern basis in the preparation of the financial statements. Based on the Directors' current forecasts and plans (including modelling of a number of scenarios reflecting potential outcomes of the ongoing impact of Covid-19 on product sales and the Group's ongoing regulatory review for Chronocort®), and considering the cash and cash equivalents at 31 December 2020 of £20,344k (which reflects the £9.1m net fundraising completed in October 2020), the Group has sufficient funding for the foreseeable future and at least 12 months from the date of approval of this report. For this reason, the Directors continue to adopt the going concern basis in preparing the financial statements. The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate.

4 Accounting policies

These consolidated interim financial statements for the six months ended 31 December 2020 include the results of Diurnal Group plc and its wholly-owned subsidiaries, Diurnal Limited and Diurnal Europe B.V. The unaudited results for the period have been prepared on the basis of accounting policies adopted in the audited accounts for the year ended 30 June 2020 and expected to be adopted in the financial year ending 30 June 2021. Where new IFRS standards amendments or interpretations became effective in the six months to the 31 December 2020, there has been no material impact on the net assets or results of the Group.

5 Segmental information

The Board regularly reviews the Group's performance and balance sheet position for its operations and receives financial information for the Group in order to assess performance and make strategic decisions about the allocation of resources. The Group considers its business to operate in a single segment, namely the development and supply of novel therapeutic agents for the treatment of chronic endocrine disorders.

Disaggregation of revenue

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

	Unaudited 6 months ended 31 Dec 2020 £000	Unaudited 6 months ended 31 Dec 2019 £000	Audited 12 months ended 30 Jun 2020 £000
Sales of goods	1,191	1,147	2,390
Licence fees	23	-	3,923
	1,214	1,147	6,313

An analysis of revenue by the country of destination is set out below:

	Unaudited 6 months ended 31 Dec 2020 £000	Unaudited 6 months ended 31 Dec 2019 £000	Audited 12 months ended 30 Jun 2020 £000
Europe	1,132	1,147	2,390
USA	82	-	3,923
	1,214	1,147	6,313

The Group's customers are wholesalers, distributors and licensing partners in the markets in which it has launched Alkindi®. An analysis of revenue from the sale of goods by customer is set out in the table below:

	Unaudited 6 months ended 31 Dec 2020 £000	Unaudited 6 months ended 31 Dec 2019 £000	Audited 12 months ended 30 Jun 2020 £000
Customer A	570	457	900
Customer B	188	395	725
Customer C	82	-	-
Customer D	81	55	194
Customer E	76	-	32
Other customers	194	240	539
	1,191	1,147	2,390

6 Loss per share

	Unaudited 6 months ended 31 Dec 2020	Unaudited 6 months ended 31 Dec 2019	Audited 12 months ended 30 Jun 2020
Loss for the period (£000)	(4,661)	(4,035)	(4,072)
Weighted average number of shares (000)	127,644	86,366	95,228
Basic and diluted loss per share (pence per share)	(3.7)	(4.7)	(4.3)

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

7 Taxation

	Unaudited 6 months ended 31 Dec 2020 £000	Unaudited 6 months ended 31 Dec 2019 £000	Audited 12 months ended 30 Jun 2020 £000
Current tax:			
- UK corporation tax on losses of period	-	-	-
- Dutch corporation tax on subsidiary profits for the period	2	-	2
- Research and development tax credit receivable for the current period	(542)	(495)	(1,194)
- Prior period adjustment in respect of research and development tax credit	(5)	(14)	(14)
Deferred tax:			
- Origination and reversal of temporary differences	-	-	-
Tax on loss on ordinary activities	(545)	(509)	(1,206)

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 Group's claim for R&D tax credits for the year ended 30 June 2020 was finalised at £1,199k, which was received from HMRC during the Period.

8 Property, plant and equipment

	Unaudited 31 Dec 2020 £000	Audited 30 Jun 2020 £000	Unaudited 31 Dec 2019 £000
Cost			
Opening balance	84	77	77
Recognition of right of use assets	-	-	83
Additions	81	7	3
Disposals	(1)	-	-
Closing balance	164	84	163
Depreciation			
Opening balance	61	44	44
Charge for the period	7	17	36
Disposals	(1)	-	-
Closing balance	67	61	80
Net book value			
At start of period	23	33	33
At end of period	97	23	83

The prior period included recognition of right of use assets reflecting the adoption by the Group of IFRS 16, which requires the capitalisation of future operating lease payments. Upon a detailed review of the requirements of IFRS 16 as at 30 June 2020, the Group determined that all of its leasing arrangements were outside of the capitalisation requirements of IFRS 16; consequently, all associated entries (including the recognition of right of use assets and associated depreciation) were reversed in the audited results for the year ended 30 June 2020

9 Investments held at fair value through profit and loss

	Unaudited As at 31 Dec 2020 £000	Audited As at 30 Jun 2020 £000	Unaudited As at 31 Dec 2019 £000
Balance at the start of period	1,668	-	-
Additions	-	1,041	-
Fair value adjustment to investments	590	627	-
	2,258	1,668	-

Additions to investments in the year ended 30 June 2020 solely relate to the 379,474 shares held in Eton Pharmaceuticals that were received as part of the upfront consideration for the exclusive licence agreement of Alkindi® Sprinkle in the US. The shares in Eton are treated as a level 1 financial investment in the IFRS 13 fair value hierarchy as the shares are traded in an active market and therefore the value is based on quoted market prices. The fair value adjustment of these shares represents the entire amount charged to the income statement as 'other gains – net'.

10 Inventories

	Unaudited As at 31 Dec 2020 £000	Audited As at 30 Jun 2020 £000	Unaudited As at 31 Dec 2019 £000
Raw materials	126	192	-
Work in progress	872	733	524
Finished goods	668	316	240
	1,666	1,241	764

11 Trade and other receivables

	Unaudited As at 31 Dec 2020 £000	Audited As at 30 Jun 2020 £000	Unaudited As at 31 Dec 2019 £000
Trade receivables	353	393	525
VAT receivable	375	188	241
Prepayments	460	576	644
Other receivables	190	180	-
	1,378	1,337	1,410

12 Trade and other payables

	Unaudited As at 31 Dec 2020 £000	Audited As at 30 Jun 2020 £000	Unaudited As at 31 Dec 2019 £000
Current liabilities			
Trade payables	1,450	807	1,096
Tax and social security	102	91	93
Accrued expenses	1,623	1,598	825
Lease liabilities	-	-	56
Other payables	35	59	39
	3,210	2,555	2,109
Non-current liabilities			
Lease liabilities	-	-	1
Accrued expenses	15	36	14
	15	36	15

The prior period included recognition of right of use assets and the corresponding lease liabilities reflecting the adoption by the Group of IFRS 16. Upon a detailed review of the requirements of IFRS 16 as at 30 June 2020, the Group determined that all of its leasing arrangements were outside of the capitalisation requirements of IFRS 16; consequently, all associated entries (including the recognition of right of use assets and associated lease liability) were reversed in the audited results for the year ended 30 June 2020

The Group accrues for employer National Insurance contributions that may become due on unexercised share-based payments. In the Period £15k (31 Dec 2019: £14k) of the accrual has been classified as a non-current liability.

13 Related party transactions

Transactions between the Company and its subsidiaries Diurnal Limited and Diurnal Europe B.V., which are related parties, have been eliminated on consolidation. The Company holds the Group's treasury balances and provides funds to Diurnal Limited in order to fund its operating activities. Such movements are recorded through an intercompany loan account. The Company makes a management charge to Diurnal Limited each year, which is disclosed in the table below. Diurnal Europe B.V. recharges its operating expenses along with a management charge to Diurnal Limited, which is disclosed in the table below.

The following transactions with shareholders (subsidiaries of IP Group plc) were recorded, excluding VAT, during the period:

	Unaudited 6 months ended 31 Dec 2020 £000	Unaudited 6 months ended 31 Dec 2019 £000	Audited 12 months ended 30 Jun 2020 £000
Purchase of goods and services			
IP Group plc and subsidiaries	36	14	29
Recharges between group companies			
Sales of goods from Diurnal Limited to Diurnal Europe B.V.	2,203	-	1,159
Charges from Diurnal Group plc to Diurnal Limited	336	347	659
Charges from Diurnal Europe B.V. plc to Diurnal Limited	74	87	205

Purchase of goods and services from related parties comprise management and consulting services, corporate finance, recruitment, provision of Non-Executive Director, monitoring fees together with expenses. These were made at arm's length and on normal commercial trading terms.

Recharges between group companies are eliminated in the consolidated financial statements.