22 March 2022

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

Interim Results for the Six Months Ended 31 December 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 2021 (the "Period") and follows the publication of a trading update on 26 January 2022.

Operational highlights

- **Commercial products**
    - **Alkindi®** (hydrocortisone granules in capsules for opening)
        - Alkindi® approved in Switzerland by SwissMedic
        - US partner Eton Pharmaceuticals announced co-promotion for Alkindi Sprinkle® in US with Tolmar Pharmaceuticals
    - **Efmody®** (modified-release hydrocortisone)
        - Initial commercial launches in Germany, UK and Austria
        - Post-Period end, following an announcement by the Scottish Medicines Consortium (SMC) that Efmody® was not recommended for automatic reimbursement within NHS Scotland, Diurnal will generate further clinical and health-economic data to support a re-submission to the SMC at the earliest possible opportunity
        - Post-Period end, reimbursement approved in Norway
    - Continued expansion of the Company's global footprint through distribution agreement with ExCEEd Orphan for Alkindi® and Efmody® in Central and Eastern Europe (CEE) countries
- **Development products**
    - **DNL-0200** (modified-release hydrocortisone – previously referred to as Chronocort®)
        - Agreement of Special Protocol Assessment (SPA) for DNL-0200 US Phase 3 study (CONnECT) in congenital adrenal hyperplasia (CAH) with the US Food and Drug Administration (FDA)
        - Agreement with Japanese Pharmaceuticals and Medical Devices Agency (PMDA) that CONnECT study can act as the registration study for DNL-0200 in Japan
        - First sites opened for recruitment in the US for the CONnECT study
        - First sites opened for recruitment for CHAMPAIN study (European Phase 2 trial of DNL-0200 in adrenal insufficiency (AI)), with first patient dosed post-Period end, and headline data expected around the end of 2022
    - **DNL-0300** (native oral testosterone formulation)
        - Post-Period end, submission of Investigational New Drug (IND) application for next stage of clinical development; feedback received from FDA expected to facilitate study commencement following requested protocol amendments

Financial highlights

- Total revenue for the Period increased to £2.13m, representing year-on-year growth of 75% (six months ended 31 December 2020: £1.21m)
- Alkindi® product sales (including royalties) for the Period increased to £1.74m, representing year-on-year growth of 46% (six months ended 31 December 2020: £1.19m)
    - Continued growth achieved in core markets (UK, Germany, Italy and Austria) with sales of £1.28m for the Period (six months ended 31 December 2020: £0.92m), an increase of 39% year-on-year

despite the continued impact of the Covid-19 pandemic on patients' ability to visit hospitals and consequently physicians' ability to switch these patients to Alkindi®

- Efmody® initial product sales for the Period of £0.39m (six months ended 31 December 2020: £nil) were in line with the Company's expectations, reflecting sales in the initial launch markets of Germany, UK and Austria since the first pricing approvals in September 2021

- Operating loss for the Period of £9.20m (six months ended 31 December 2020: £5.26m), reflecting increased investment in the product pipeline and preparations for the anticipated Efmody® launches across Europe

- Cash and cash equivalents as at 31 December 2021: £24.36m (as at 30 June 2021: £34.04m), including R&D tax credit of £1.51m received in December 2021.

- The Company's initial assessment of the impact of the recent SMC decision is that, despite continued strong growth (expected to be in excess of 100% for the 12-month period ended 30 June 2022), near-term sales expectations for Efmody® are unlikely to be met and that further funding will be required to reach profitability. The Board remains confident that Efmody® can become a profitable franchise but, based on current resource allocation, this will depend on approval of the drug in the treatment of adrenal insufficiency (AI) in 2024. To accelerate near-term Efmody® uptake and sales growth, the Company will be reallocating resources towards key territories with immediate effect. The impact of this on Efmody® sales and the extent of further financing for the Company to reach profitability will be assessed over the coming months. In parallel, the Company is exploring financing options, including non-dilutive funding.

Corporate highlights

- Appointment of Anders Härfstrand as Chairman and Jean-Michel Cosséry and Deborah Jorn as Non-Executive Directors, each bringing significant commercial experience to the Board

Martin Whitaker, PhD, Chief Executive Officer of Diurnal, commented:
"Diurnal has continued to make incremental progress during the Period in making Alkindi® available to patients around the world. We are pleased with Alkindi®'s growth in revenues, despite the continued impact of pandemic-related restrictions in Europe and look forward to this growth accelerating as hospitals begin to return to normal. Further growth is expected from launches of Alkindi® by our partners in new markets over the coming period and we look forward to continuing to expand our commercial footprint through further distribution agreements."

"In early March 2022, we were disappointed to receive the SMC decision not to recommend Efmody® for automatic reimbursement in Scotland, which will impact near-term revenues in the UK. Looking forward, our near-term focus is on the continued commercial roll-out of Efmody® for CAH in other major European territories and ensuring the Company has adequate resources to maximise the commercial opportunity. In the longer-term, we are focused on the generation of new clinical data from the CHAMPAIN and CONnECT studies, which we believe will highlight the value and benefits of physiological cortisol replacement with Efmody® in both CAH and AI globally and provide additional data for continued reimbursement discussions in Europe"

Diurnal plans to hold its R&D Day for analysts and institutional investors on 7 September 2022, having re-scheduled the event from February 2022. The R&D Day will be held in-person at FTI Consulting, 200 Aldersgate, Aldersgate Street, London, EC1A 4HD, with the option to attend virtually. To register to attend in person, or to receive a link to the webcast, please contact diurnal@fticonsulting.com.

As reported at the Company's results for the year ended 30 June 2021 on 14 September 2021, Diurnal's financial year end has been changed to 31 December, with the next statutory reporting due for the 18-month period to 31 December 2022.

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 is a business press release containing financial information and/or data for the benefit of shareholders and potential investors. Data are included to allow informed investment decisions.

This announcement contains inside information for the purposes of the UK Market Abuse Regulation (UK MAR).

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

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Notes to Editors

About Diurnal Group plc

Diurnal Group plc is a European, UK-headquartered, specialty pharmaceutical company dedicated to developing hormone therapeutics to aid lifelong treatment for rare and chronic endocrine conditions, including congenital adrenal hyperplasia, adrenal insufficiency, hypogonadism and hypothyroidism. 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 incremental progress towards its vision of becoming a world-leading endocrinology specialty pharma company. Diurnal strengthened its leadership with the addition of a new Chairman and two Non-Executive Directors, each with substantial commercial experience, which the Company believes will support further progression towards this vision.

Underpinning this objective is the development of a strong commercial business, initially focused on delivery of the Group's two lead products, Alkindi® and Efmody®, for patients suffering from the rare diseases adrenal insufficiency (AI) and congenital adrenal hyperplasia (CAH), a combined potential market of $2.3bn. 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 most advanced being DNL-0300, its native oral testosterone replacement product for the treatment of hypogonadism, a potential global market of approximately $5bn.

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 (as Alkindi Sprinkle®) in the US and has been proven to be effective in a formulation specifically designed for children. Alkindi® has granted patents covering the product until 2034, as well as regulatory protection in Europe until 2028 through the paediatric use marketing authorisation (PUMA) that was granted in 2018.

Diurnal's go-to-market strategy for Alkindi® is to focus its own commercialisation activities on the larger European markets (currently with a presence in the UK, Germany and Italy) and to pursue distribution or licensing deals outside of these key territories, to make its products, once approved, available to as broad a range of patients as possible. The Company's long-term strategy is underpinned by this commercialisation infrastructure as 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.

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 its core markets (UK, Germany, Italy and Austria) despite the continued impact of the Covid-19 pandemic on patients' ability to visit hospitals and consequently physicians' ability to switch these patients to Alkindi®. The Financial Review provides further detail on Alkindi® revenues for the Period.

During the Period, Diurnal further extended the reach of Alkindi® through execution of a distribution deal with ExCEEd Orphan, covering the remaining unpartnered Central Eastern European countries (excluding Russia) Diurnal's partners continued to make good progress during the Period, notably with the approval of EffRx's Alkindi® marketing authorisation application (MAA) by SwissMedic during the Period. The Company expects Alkindi® launches by its distribution partners in the Netherlands, Switzerland and Bulgaria during the second quarter of calendar year 2022, which are expected to further underpin the growth of Alkindi®.

In the US, Diurnal's partner Eton Pharmaceuticals entered into a co-promotion agreement with Tolmar Pharmaceuticals, which has significantly expanded the commercial effort behind Alkindi Sprinkle®. By the end of January 2022, Tolmar Pharmaceutical's 62-person commercial sales force was fully trained and promoting Alkindi Sprinkle® across the US. In tandem with the co-promotion launch, Eton also announced plans to introduce an expanded digital marketing campaign targeted at raising awareness among patients and caregivers. Eton expects these initiatives to substantially accelerate the modest initial Alkindi Sprinkle® sales.

Diurnal continues to assess the opportunity for Alkindi® in other global markets and expects to announce further distribution deals during the remainder of 2022.

Efmody®: expanding the European cortisol deficiency commercial franchise

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

granted patents covering the product until 2034, as well as the potential to obtain Orphan Drug Status in the US and other territories.

Efmody® was approved in the European Economic Area (EEA) by the European Medicines Agency (EMA) and in Great Britain (GB) by the UK Medicines and Healthcare products Regulatory Agency during 2021. The Company intends to use the same go-to-market strategy as Alkindi® for Efmody® in Europe, using the same commercial infrastructure and supply chain that is already in place. The first launch market for Efmody® was in Germany, where pricing and reimbursement are already agreed. During the Period, the product was subsequently made commercially available in the UK and Austria. Initial product sales for the Period, as outlined in the Financial Review, reflected primarily sales in Germany.

Following the end of the Period, the Company was disappointed to receive notification from the Scottish Medicines Consortium (SMC) that Efmody® had not been recommended for automatic reimbursement within Scotland. As a result of the SMC decision, the Company's Efmody® sales forecasts for the UK will be significantly impacted, reflecting the reliance of a number of healthcare clinical commissioning groups on the SMC assessment. The Company intends to generate further clinical and health-economic data to support a re-submission to the SMC at the earliest possible opportunity. In the meantime, Diurnal will continue to make Efmody® available to patients in Scotland and is committed to patient access through a number of means including support for clinicians wishing to utilise Efmody® in their clinics.

Encouragingly, Efmody® was approved for reimbursement in Norway post-Period end. Pricing and reimbursement activities remain ongoing in other key markets, most notably in Italy and Spain, with these reviews expected to conclude during 2022. Diurnal's partner, Consilient Health, expects to launch Efmody® alongside Alkindi® in the Netherlands in Q2 2022.

Outside of its core European markets, Diurnal intends to make Efmody® available commercially through distribution or licensing deals with local partners who can quickly gain market access. Diurnal expanded its reach during the Period through entering into a distribution deal with ExCEEd Orphan for the remaining unpartnered Central Eastern European countries (excluding Russia). Diurnal continues to assess the opportunity for Efmody® in other global markets and expects to announce further distribution deals during 2022.

DNL-0200: expanding to global markets

Outside Europe, Diurnal continues to progress plans for development of DNL-0200 (commercialised as Efmody® in Europe) in major markets. Following agreement of a Special Protocol Assessment (SPA) with the FDA during the Period, Diurnal has now commenced the CONnECT Phase 3 study, which will act as the registration study for CAH in the US. Following a positive dialogue with the Japanese Pharmaceutical and Medical Devices Agency (PMDA), CONnECT will also act as the registration study for Japan, through inclusion of a cohort of Japanese patients in the study. The study will also include sites in France and Turkey, in order to maximise patient accrual rates. CONnECT is expected to take 12 months to recruit, and patients will remain on study for 52 weeks. Headline data from CONnECT is expected in the first half of 2024.

In addition to expanding the global availability of DNL-0200 to CAH patients, Diurnal is seeking to expand its utility into the related condition, AI, a market opportunity of approximately $2.8bn across Europe and the US. The Company has commenced a Phase 2 study of DNL-0200 compared to the approved product Plenadren® in Europe (CHAMPAIN), 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 DNL-0200 in AI in the US. Headline data from the CHAMPAIN study is expected around the end of 2022.

DNL-0300: expanding the innovative product pipeline

Diurnal's third novel product, DNL-0300 (formerly DITEST™), is a native oral testosterone therapy for the treatment of male hypogonadism. The estimated $5bn market in the 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.

Following the successful completion of a Phase 1 study evaluating the pharmacokinetics, safety and tolerability of a single dose of DNL-0300 in adult men with primary or secondary hypogonadism the Group received

confirmation from the FDA that DNL-0300 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.

Having completed during the Period non-clinical activities requested by the FDA in order to submit an Investigational New Drug (IND) for a Phase 1 study exploring extended dosing of DNL-0300, the Company submitted its IND in January 2022 and, in March 2022, received feedback from FDA enabling it to finalise the clinical trial design and resubmit a revised protocol to the IND for commencement of the Phase 1 clinical study.

Outlook

The Company continues to believe that its cortisol replacement therapy franchise will enable it to build a strong and profitable European business, despite our recent reimbursement challenges, 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.$300m in Europe alone. Diurnal expects an increased contribution from its licensing and distribution partners once regulatory and/or pricing and reimbursement activities for Alkindi® and Efmody® are completed in these territories. There are a series of Alkindi® launches planned by Diurnal's global distribution partners in the first half of calendar year 2022, which are expected to further underpin the growth of Alkindi®. In addition, the Board continues to assess external opportunities that will enable it to further leverage its commercial infrastructure in key European markets.

The Company continues to believe that there is a significant opportunity in adult AI, a market estimated to be worth $2.9bn in the US and Europe, and awaits data from the CHAMPAIN study which is due to provide headline data around the end of 2022. The Company continues to assess the optimal route to commercialisation of Efmody® in the US, assuming successful completion of the ongoing CONnECT study which is expected to provide headline data in 2024. In the Company's earlier stage pipeline, DNL-0300 represents a further valuable addition to Diurnal's growing pipeline of novel endocrinology treatments, with the Company well positioned to move ahead with the next stage of development in H2 2022.

Martin Whitaker
Chief Executive Officer

21 March 2022

Financial Review

During the Period the Group changed its financial year end from 30 June to 31 December. Accordingly, the Group's next statutory reporting period will be the 18 months ended 31 December 2022. This first interim report covers the six months ended 31 December 2021; a further interim report will be issued for the 12 months ended 30 June 2022. Note 15 to this report contains proforma financial information for the 12 month periods ended 31 December 2020 and 31 December 2021. The statutory accounts for the 18 month period ended 31 December 2022 will include proforma financial information for the 12 month period ended 31 December 2022.

Revenues and gross margin

Alkindi® product sales for the Period were £1.74m, representing year-on-year growth of 46% (six months ended 31 December 2020: £1.19m). Additionally, the Company recorded initial Efmody sales for the Period of £0.39m, primarily from Germany, the first launch market. Total revenue for the six months ended 31 December 2021, was £2.13m, representing year-on-year growth of 75% (six months ended 31 December 2020: £1.21m).

The progression of Alkindi® during the Period continued to be significantly impacted by Covid-19 restrictions, with sales in all markets below the Company's expectations. The Company's key markets (UK, Germany, Italy and Austria) demonstrated continued growth, with sales increasing by 39% 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 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® and Efmody®. Gross margin for the Period was 78% (six months ended 31 December 2020: 71%), with the improvement in margin primarily arising from the initial contribution of Efmody®, which has a higher margin than Alkindi®. Underlying gross margins are also beginning to benefit from margin improvements through growth in production volumes and other manufacturing efficiencies, and 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 £5.89m (six months ended 31 December 2020: £2.63m). The significant planned increase in R&D costs during the Period primarily reflected the start-up of the CONnECT US Phase 3 study with Efmody® in CAH and the CHAMPAIN European Phase 2 study with Efmody® in AI, following successful fundraisings of £9.8m in 2020 and £20.7m in 2021 to support the further clinical development of the Group's products. Other significant activities included ongoing activities relating to the manufacturing scale-up for Efmody®, which is expensed to the consolidated income statement, and DNL-0300 non-clinical activities in support of the IND submission to the FDA in January 2022. R&D expenditure is expected to remain at the current level during 2022, reflecting the expected recruitment and treatment timelines for CONnECT along with the planned initiation of a long-term follow-on study (DIUR-015) for patients completing treatment in CONnECT.

Selling and distribution expenses for the Period increased to £3.07m (six months ended 31 December 2020: £2.46m) reflecting the ongoing preparation for further commercial launches of Efmody® in Europe during 2022. In particular, the Company initiated health economic modelling and pricing work to support pricing and reimbursement applications across Europe which were submitted following the regulatory approval of Efmody® in the EEA and in Great Britain during 2021. Selling and distribution expenses are expected to remain at the current level during 2022, with a planned investment in digital channels to add to the current commercialisation efforts being offset by the tail-off in health economic and pricing work as countries complete their health economic assessments. Selling and distribution expenses for the Period also contain a provision for obsolete inventories amounting to £0.38m (six months ended 31 December 2020: £nil) and an impairment expense of £0.13m relating to tooling that has become idle (six months ended 31 December 2021: £nil).

Administrative expenses for the Period were £1.79m (six months ended 31 December 2020: £1.63m). Costs for the Period included recruitment fees relating to the Board changes and increased audit fees relating to the year end change. Both of these costs are not expected to be recurring. In addition, in line with many other companies Diurnal has experienced continued increases in the cost of 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 £9.20m (six months ended 31 December 2020: £5.26m), reflecting the impact of increased operating expenses outlined above. Operating loss for the Period includes a loss of £0.11m (six months ended 31 December 2020: gain of £0.59m) 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 (losses)/gains – net' in the consolidated income statement. The Eton shares were fully disposed of during the Period, with the overall gain from acquisition of the shares amounting to £0.53m.

Financial income and expense

Financial income in the Period was £0.03m (six months ended 31 December 2019: £0.06m).

Loss on ordinary activities before tax

Loss before tax for the Period was £9.16m (six months ended 31 December 2020: £5.21m).

Tax

During the Period the Company finalised and submitted its R&D tax credit claim in respect of the year ended 30 June 2021; this final amount of £1.51m 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 £1.19m as at 31 December 2021.

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

Earnings per share

Loss per share increased to 4.7 pence (six months ended 31 December 2020: 3.7 pence), with the increase in loss for the Period partly mitigated by the increase in weighted average number of shares outstanding in the Period following the fundraising in May 2021.

Cash flow

Net cash used in operating activities during the Period was £10.61m (six months ended 31 December 2020: £4.17m), with the increase primarily arising from the increase in R&D expenditure relating to the CONnECT, CHAMPAIN and DIUR-015 clinical studies, including prepayments at the period end of £4.00m made to the contract research organisations (CROs) who are running these studies.

Net cash from financing activities during the Period of £0.11m represents the proceeds of exercise of share options.

Balance sheet

Total assets decreased to £34.57m (30 June 2021: £41.79m), primarily reflecting an increase in operating outflows.

Inventories at 31 December 2021 increased to £1.76m (30 June 2021: £1.63m), reflecting a temporary increase in Alkindi® stocks arising from lower than anticipated Alkindi® product sales along with accumulation of launch stocks for Efmody®. Inventories also reflect increased holdings of bulk hydrocortisone, following a strategic decision to increase raw material holdings. Levels of Alkindi® and Efmody® stocks are expected to reduce in the future as market requirements become more predictable.

Cash and cash equivalents at 31 December 2021 were £24.36m (30 June 2021: £34.04m).

Total liabilities increased to £4.65m (30 June 2021: £4.23m), reflecting an increased level of trade payables and accrued expenses compared to the prior period as a result of the increase in clinical trial activity in the Period.

Net assets were £29.92 (30 June 2021: £37.56m).

Financial outlook

The Company expects total product revenues for the twelve months to 30 June 2022 of at least £4.6m, on the assumption that the impacts of Covid-19 in Europe and the US continue to lessen.

The Company's initial assessment of the impact of the recent SMC decision is that, despite continued strong growth, near-term sales expectations for Efmody® are unlikely to be met and that further funding will be required to reach profitability. The Board remains confident that Efmody® can become a profitable franchise but, based on current resource allocation, this will depend on approval of the drug in the treatment of adrenal insufficiency (AI) in 2024. To accelerate near-term Efmody® uptake and sales growth, the Company will be reallocating resources towards key territories with immediate effect. The impact of this on Efmody® sales and the extent of further financing for the Company to reach profitability will be assessed over the coming months. In parallel, the Company is exploring financing options, including non-dilutive funding.

Principal risks and uncertainties

Diurnal considers strategic, operational and financial risks and identifies actions to mitigate these risks. The principal risks and uncertainties are set out in the Group's Annual Report and Accounts for the year ended 30 June 2021, 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.

Richard Bungay
Chief Financial Officer

21 March 2022

Consolidated income statement
for the six months ended 31 December 2021

	Note	Unaudited 6 months ended 31 Dec 2021 £000	Unaudited 6 months ended 31 Dec 2020 £000
Revenue	5	2,125	1,214
Cost of sales		(459)	(347)
Gross profit		1,666	867
Research and development expenditure		(5,889)	(2,633)
Selling and distribution expenses		(3,069)	(2,457)
Administrative expenses		(1,794)	(1,629)
Other (losses)/gains - net		(109)	590
Operating loss		(9,195)	(5,262)
Net financial income		32	56
Loss before tax		(9,163)	(5,206)
Taxation	7	1,212	545
Loss for the period		(7,951)	(4,661)
Basic and diluted loss per share (pence per share)	6	(4.7)	(3.7)

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 2021

	Unaudited 6 months ended 31 Dec 2021 £000	Unaudited 6 months ended 31 Dec 2020 £000
Loss for the period and total comprehensive loss for the period	(7,951)	(4,661)

The Notes form part of this condensed financial information.

Consolidated balance sheet
as at 31 December 2021

	Note	Unaudited As at 31 Dec 2021 £000	Audited As at 30 Jun 2021 £000
Non-current assets			
Intangible assets	9	130	92
Property, plant and equipment	8	18	148
		148	240
Current assets			
Inventories	11	1,762	1,625
Research and development tax credit claims receivable		1,194	1,485
Trade and other receivables	12	7,104	3,433
Investments held at fair value through profit and loss	10	-	970
Cash and cash equivalents		24,357	34,037
		34,417	41,550
Total assets		34,565	41,790
Current liabilities			
Trade and other payables	13	(4,577)	(4,163)
		(4,577)	(4,163)
Non-current liabilities			
Trade and other payables	13	(72)	(63)
		(72)	(63)
Total liabilities		(4,649)	(4,226)
Net assets		29,916	37,564
Equity			
Share capital		8,457	8,397
Share premium		77,461	77,414
Group reconstruction reserve		(2,943)	(2,943)
Accumulated losses		(53,059)	(45,304)
Total equity		29,916	37,564

The Notes form part of this condensed financial information.

Consolidated statement of changes in equity
for the six months ended 31 December 2021

	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited
	Share capital	Share premium	Group reconstruction reserve	Accumulated losses	Total
	£000	£000	£000	£000	£000
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 and total comprehensive loss for the period	-	-	-	(5,388)	(5,388)
Equity settled share-based payment transactions	-	-	-	187	187
Issue of shares for cash	1,480	19,235	-	-	20,715
Costs charged against share premium	-	(1,089)	-	-	(1,089)
Total transactions with owners recorded directly in equity	1,480	18,146	-	187	19,813
Balance at 30 June 2021	**8,397**	**77,414**	**(2,943)**	**(45,304)**	**37,564**
Loss for the period and total comprehensive loss for the period	-	-	-	(7,951)	(7,951)
Equity settled share-based payment transactions	-	-	-	196	196
Issue of shares for cash	60	47	-	-	107
Costs charged against share premium	-	-	-	-	-
Total transactions with owners recorded directly in equity	60	47	-	196	303
Balance at 31 December 2021	**8,457**	**77,461**	**(2,943)**	**(53,059)**	**29,916**

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 2021

	Unaudited 6 months ended 31 Dec 2021 £000	Unaudited 6 months ended 31 Dec 2020 £000
Cash flows from operating activities		
Loss for the period	(7,951)	(4,661)
Adjustments for:		
Fair value adjustment to investments	109	(590)
Depreciation, amortisation and impairment	140	12
Share-based payment	196	279
Net foreign exchange loss/(gain)	26	26
Finance income	(32)	(56)
Taxation	(1,212)	(545)
(Increase) in inventories	(137)	(425)
(Increase) in trade and other receivables	(3,671)	(41)
Increase in trade and other payables	423	634
Cash used in operations	(12,109)	(5,367)
Net tax received	1,504	1,198
Net cash used in operating activities	(10,605)	(4,169)
Cash flows from investing activities		
Additions of property, plant and equipment	(4)	(81)
Capitalisation of research and development expenditure	(45)	(6)
Proceeds from sale of investment	861	-
Interest received	32	56
Net cash from investing activities	844	(31)
Cash flows from financing activities		
Net proceeds from issue of share capital	107	9,136
Net cash from financing activities	107	9,136
Net (decrease)/increase in cash and cash equivalents	(9,654)	4,936
Cash and cash equivalents at the start of the period	34,037	15,434
Effects of exchange rate changes on cash and cash equivalents	(26)	(26)
Cash and cash equivalents at the end of the period	24,357	20,344

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 2021, 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 2021 and for the six months ended 31 December 2020 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 2021 have been extracted from the audited statutory accounts which were approved by the Board of Directors on 13 September 2021 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

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

The Group has historically experienced net losses and significant cash outflows from cash used in operating activities, which reflect the development and early commercialisation stage of the portfolio. For the Period ended 31 December 2021, the Group made an operating loss of £9,195k on revenue of £2,125k and used net cash in operating activities of £10,605k. Cash and cash equivalents at 31 December 2021 were £24,357k.

The Directors have prepared cash flow forecasts and considered the cash flow requirement for the Group. These forecasts show that to continue funding development and commercialisation, further financing will be required prior to the Group reaching sustainable profitability. This requirement for additional financing represents a material uncertainty that may cast significant doubt upon the Group's and parent company's ability to continue as a going concern.

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

Based on the above, the Directors believe it remains appropriate to prepare the financial statements for the six months ended 31 December 2021 on a going concern basis. However, these circumstances represent a material uncertainty that may cast significant doubt upon the Group's ability to continue as a going concern and, therefore to continue realising its assets and discharging its liabilities in the normal course of business.

The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate.

4 Accounting policies

These consolidated interim financial statements for the six months ended 31 December 2021 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 2021 and expected to be adopted in the financial period ending 31 December 2022. Where new IFRS standards amendments or interpretations became effective in the six months to the 31 December 2021, 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 2021 £000	**Unaudited 6 months ended 31 Dec 2020 £000**
Sales of goods		
- Alkindi®	1,735	1,191
- Efmody®	390	-
Total sales of goods	2,125	1,191
Licence fees	-	23
	2,125	1,214

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

	Unaudited 6 months ended 31 Dec 2021 £000	**Unaudited 6 months ended 31 Dec 2020 £000**
UK	744	570
Europe	1,243	562
USA	138	82
	2,125	1,214

6 Loss per share

	Unaudited 6 months ended 31 Dec 2021	Unaudited 6 months ended 31 Dec 2020
Loss for the period (£000)	(7,951)	(4,661)
Weighted average number of shares (000)	168,922	127,644
Basic and diluted loss per share (pence per share)	(4.7)	(3.7)

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 2021 £000	Unaudited 6 months ended 31 Dec 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	(1,194)	(542)
- Prior period adjustment in respect of research and development tax credit	(20)	(5)
Deferred tax:		
- Origination and reversal of temporary differences	-	-
Tax on loss on ordinary activities	(1,212)	(545)

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 made in respect of the year ended 30 June 2021 was finalised at £1,505k, and was received from HMRC during the Period.

8 Property, plant and equipment

	Equipment £000
Cost	
Balance at 1 January 2021	163
Additions	57
Disposals	(7)
Balance at 30 June 2021	213
Additions	4
Disposals	(4)
Balance at 31 December 2021	213
Accumulated Depreciation	
Balance at 1 January 2021	66
Charge for the period	6
Disposals	(7)
Balance at 30 June 2021	65
Charge for the period	5
Impairment	128
Disposals	(3)
Balance at 31 December 2021	195
Net book values	
30 June 2021 (audited)	148
31 December 2021 (unaudited)	18

The current period impairment relates to tooling that has become idle and therefore has been fully impaired in the Period.

9 Intangible assets

	Acquired patents and licences £000	Internally generated development costs £000	Total £000
Cost			
Balance at 1 January 2021	39	95	134
Additions	-	20	20
Balance at 30 June 2021	39	115	154
Additions	-	45	45
Balance at 31 December 2021	39	160	199
Accumulated Amortisation			
Balance at 1 January 2021	39	16	55
Charge for the period	-	7	7
Balance at 30 June 2021	39	23	62
Charge for the period	-	7	7
Balance at 31 December 2021	39	30	69
Net book values			
30 June 2021 (audited)	-	92	92
31 December 2021 (unaudited)	-	130	130

Capitalisation of development costs
Capitalisation of development costs requires analysis of the technical feasibility and commercial viability of the project concerned. Capitalisation of the costs will only be made where there is evidence that an economic benefit will flow to the Group. The Group commenced capitalisation of ongoing development costs of its products from the point that the respective market authorisations were received as detailed below:

- European development costs of Alkindi® following approval of the paediatric use marketing authorisation by the European Commission in February 2018
- global development costs of Alkindi® following the grant of US market authorisation by the US Food and Drug Administration in September 2020; and
- European development costs of Efmody® for the treatment of congenital adrenal hyperplasia (CAH) following approval by the European Commission in May 2021

10 Investments held at fair value through profit and loss

	Investments £000
Cost	
Balance at 1 January 2021	2,258
Additions	-
Disposals	(713)
Fair value adjustment to investments	(575)
Balance at 30 June 2021 (audited)	970
Additions	-
Disposals	(861)
Fair value adjustment to investments	(109)
Balance at 31 December 2021	-

Investments held at fair value through the profit and loss solely relate to 379,474 shares of Eton Pharmaceuticals that were received as part of the upfront consideration for the exclusive licence agreement of Alkindi Sprinkle® in the US signed in March 2020. During 2021 the Group sold its entire holding of 379,474 shares realising an overall gain since acquisition of £533k. The fair value adjustment of these shares represents the entire amount charged to the income statement as 'other gains - net'.

11 Inventories

	Unaudited As at 31 Dec 2021 £000	**Unaudited As at 30 Jun 2021 £000**
Raw materials	144	123
Work in progress	1,081	1,046
Finished goods	537	456
	1,762	1,625

Inventories recognised as an expense in cost of sales for the Period to 31 December 2021 amounted to £459k (six months to 31 December 2020: £347k). A provision for obsolete inventories amounting to £378k has been recognised in selling and distribution expenses in the Period (six months to 31 December 2020: £nil).

12 Trade and other receivables

	Unaudited As at 31 Dec 2021 £000	Unaudited As at 30 Jun 2021 £000
Trade receivables	1,002	361
VAT receivable	776	501
Prepayments	4,749	1,460
Other receivables	577	1,111
	7,104	3,433

The increase in prepayments reflects prepaid expenses made to clinical research organisations (CROs) in respect of the CONnECT, CHAMPAIN and DIUR-015 clinical studies totalling £4,001k.

13 Trade and other payables

	Unaudited As at 31 Dec 2021 £000	Unaudited As at 30 Jun 2021 £000
Current liabilities		
Trade payables	2,104	1,728
Tax and social security	130	121
Accrued expenses	2,168	2,195
Other payables	175	119
	4,577	4,163
Non-current liabilities		
Accrued expenses	72	63
	72	63

The Group accrues for employer National Insurance contributions that may become due on unexercised share-based payments. In the Period £72k (30 Jun 2021: £63k) of the accrual has been classified as a non-current liability.

14 Related party transactions

The Group purchases services from related parties in respect of some Non-Executive Director fees and expenses. The following transactions were recorded in respect of such services during the period:

	Unaudited 6 months ended 31 Dec 2021 £000	Unaudited 6 months ended 31 Dec 2020 £000
Purchase of goods and services		
IP Group plc and subsidiaries	26	36

Purchases of the goods and services above were made at arm's length and on normal commercial trading terms. Amounts owing to IP Group plc and subsidiaries as at 31 December 2021 amounted to £nil (30 June 2021: £34k).

15 12 month consolidated income statements

Following the Group's change of year end to 31 December (from 30 June), unaudited proforma information for the 12 month periods ending 31 December 2020 and 31 December 2021 are presented below for purposes of comparison with future accounting periods.

Consolidated income statement
for the twelve months ended 31 December 2021

	Unaudited 12 months ended 31 Dec 2021 £000	Unaudited 12 months ended 31 Dec 2020 £000
Revenue	5,324	6,289
Cost of sales	(792)	(706)
Gross profit	4,532	5,583
Research and development expenditure	(10,264)	(4,870)
Selling and distribution expenses	(5,737)	(4,531)
Administrative expenses	(3,385)	(3,475)
Other (losses)/gains - net	(684)	1,217
Operating loss	(15,538)	(6,076)
Net financial income	37	139
Loss before tax	(15,501)	(5,937)
Taxation	2,155	1,242
Loss for the period	(13,346)	(4,695)
Basic and diluted loss per share (pence per share)	(8.5)	(4.0)

Analysis of revenue
for the twelve months ended 31 December 2021

	Unaudited 12 months ended 31 Dec 2021 £000	Unaudited 12 months ended 31 Dec 2020 £000
Sales of goods		
- Alkindi®	2,853	2,344
- Efmody®	390	-
Total sales of goods	3,243	2,344
Licence fees	2,081	3,945
	5,324	6,289