

14 September 2022

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

**Interim Results for the Twelve Months Ended 30 June 2022**

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces its results for the twelve months ended 30 June 2022 (the "Period") and following the publication of a trading update on 26 July 2022.

**Operational highlights (including post-period):**

- **Proposed acquisition by Neurocrine Biosciences, Inc. ("Neurocrine")**
  - On 30 August 2022, Diurnal announced the terms of a recommended cash acquisition pursuant to which Neurocrine intends to acquire the entire issued and to be issued ordinary share capital of Diurnal
  - The acquisition is currently expected to complete during late October or early November 2022, subject to satisfaction or (where applicable) waiver of the conditions to the acquisition
  
- **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
    - Distribution agreement with Vector Pharma for named patient sales of Alkindi® covering Middle East and North Africa
  - **Efmody®** (hydrocortisone modified-release hard capsules)
    - Initial commercial launches in Germany, UK, Austria and the Netherlands
    - Reimbursement approval in Norway
    - Post-Period end, agreed reimbursement in Italy, with launch planned for September 2022
    - Company to generate further clinical and health-economic data to support a re-submission to the Scottish Medicines Consortium (SMC) at the earliest possible opportunity following announcement that Efmody® was not recommended for automatic reimbursement within NHS Scotland
    - Extension of existing Alkindi® distribution and marketing agreement with EffRx for Alkindi® in Switzerland to cover Efmody®
  - Expansion of global footprint for Alkindi® and Efmody® through a new distribution agreement with ExCEED Orphan for Central Eastern European (CEE) countries and an extension of the existing distribution agreement with Er-Kim covering Greece, Cyprus and Malta

- **Development products**

- **DNL-0200** (hydrocortisone modified-release hard capsules – previously referred to as Chronocort®, commercialised as Efmody® in Europe)
  - 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 patients dosed in the CONnECT study with headline data expected in 2024
  - First patient dosed in the CHAMPAIN study (European Phase 2 trial of DNL-0200 in adrenal insufficiency (AI)), with headline data now expected in Q1 2023
- **DNL-0300** (native oral testosterone formulation – previously referred to as DITEST™)
  - Submission of Investigational New Drug (IND) application and subsequent feedback received from the FDA enabling finalisation of protocol for multiple ascending dose (MAD) Phase I study

### **Financial highlights**

- Product sales (including royalties) for the Period increased to £4.62m, representing year-on-year growth of 104% (twelve months ended 30 June 2021: £2.27m)
  - Alkindi® product sales (including royalties) for the Period increased to £3.65m, representing year-on-year growth of 61% (twelve months ended 30 June 2021: £2.27m)
  - Efmody® initial product sales for the Period of £0.97m (twelve months ended 30 June 2021: £nil)
  - Total revenues for the Period of £4.68m, reflecting licensing income of £0.06m (twelve months ended 30 June 2021: total revenues of £4.37m, reflecting licensing income of £2.10m)
- Operating loss for the Period of £18.96m (twelve months ended 30 June 2021: £11.60m), reflecting increased investment in the product pipeline and the commercial roll-out of Efmody® across Europe
- Cash and cash equivalents at 30 June 2022: £16.49m (30 June 2021: £34.04m)
- As a result of the slower Efmody® sales growth expected following the SMC decision in March 2022, the Company has previously indicated that it will require further financing to reach profitability.

### **Corporate highlights**

- Appointment of Anders Härfstrand as Chairman and Jean-Michel Cosséry and Deborah Jorn as Non-Executive Directors in November 2021, each bringing significant commercial experience to the Board
- Appointment of Richard Bungay as Interim Chief Executive Officer following the departure of Martin Whitaker as Chief Executive Officer

### **Richard Bungay, Interim Chief Executive Officer of Diurnal, commented:**

*“Despite a number of challenges during the Period, we are pleased that Efmody® revenues are currently in line with our expectations in Germany, our first major launch market, and that Alkindi® growth has resumed following a reduction in pandemic-related restrictions.”*

*“Our near-term focus is the commercial roll-out of Efmody® in those European territories where we have been able to secure reimbursement based on our current clinical data. In the longer-term, the Company will continue to drive the momentum of Alkindi®, and focus on the generation of new clinical data from the CHAMPAIN and CONnECT studies, which we believe will provide additional data to support continued Efmody® reimbursement discussions in Europe.”*

As previously reported, 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 is 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](http://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](http://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.

## **Operational Review**

Following the change of leadership in April 2022, the Company refocused resources on key priorities, in particular around the commercial launch of Efmody® in Europe. The near-term focus for Diurnal is the continued growth of its commercial products in key European markets and the delivery of clinical data for Efmody® to support both geographic expansion and use in a broader range of patients with AI. These clinical studies are also expected to provide key data to support future pricing and reimbursement discussions in Europe.

Diurnal has continued to develop its European commercial business, focused initially on the Group's two lead products, Alkindi® and Efmody®, for patients suffering from the rare diseases AI and CAH. The Company's long-term strategy is underpinned by this commercialisation infrastructure and, as a result, 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. The Group has also built a pipeline of opportunities for future development (subject to funding) and, if successful, subsequent commercialisation.

### **Alkindi®: establishing Diurnal's global commercial network**

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 the US (as Alkindi Sprinkle®) 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. The market opportunity for the treatment of paediatric AI in Europe and the US is estimated at \$0.3bn.

Diurnal's commercialisation efforts for Alkindi® and Efmody® are focused on the larger European markets (currently with a presence in the UK, Germany, Austria and Italy). Outside of these territories, Diurnal's strategy is to pursue distribution or licensing deals, to make its products, once approved, available to as broad a range of patients as possible. During the six months ended 30 June 2022, the environment for Alkindi® sales in Diurnal's core markets (UK, Germany, Italy and Austria) improved somewhat, as healthcare systems gradually recover from the impact of the Covid-19 pandemic which has impacted patients' ability to visit hospitals and, consequently, physicians' ability to switch these patients to Alkindi®.

During the first six months of 2022, Diurnal recorded its first revenues from its partnerships in the Netherlands (with Consilient), Switzerland (with EffRx) and several CEE countries (with Er-Kim and ExCEE'd Orphan). This adds to existing European revenues generated by its partnership with FrostPharma in Sweden, Denmark, Norway and Iceland. The Company further extended the reach of Alkindi® through execution of a distribution deal with Vector Pharma for named patient supply in 14 countries across the Middle East and North Africa and an extension of the existing distribution agreement with Er-Kim to cover Greece, Cyprus and Malta.

In the US, Diurnal's partner Eton Pharmaceuticals continues to commercialise Alkindi Sprinkle® in a co-promotion deal with Tolmar Pharmaceuticals, which has significantly expanded the commercial efforts. Diurnal receives a royalty on net sales of Alkindi Sprinkle® in the US, as well as sales-based milestones which are triggered when annual revenues meet pre-determined thresholds.

The Financial Review provides further detail on Alkindi® revenues for the Period.

### **Efmody®: growing the European cortisol deficiency franchise**

Diurnal's second product, 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® is licensed in Europe and the UK and has granted patents covering the product until 2034, as well as the potential to obtain Orphan Drug Status in the US and other territories. The market opportunity for the treatment of CAH in Europe is estimated at \$0.2bn.

In Europe, the Company is using the same commercial infrastructure and supply chain for Efmody® that is already in place for Alkindi®. In particular, there is a significant crossover in the target audience, with Efmody® being available for adolescent patients who are typically treated by the same paediatric endocrinologists who are the target audience for Alkindi®.

Efmody® is currently launched in Germany, the UK, the Netherlands and Austria. In March 2022, the Company was disappointed to receive notification from the 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 resubmit to the SMC at the earliest possible opportunity using clinical data it is generating through its CHAMPAIN and CONnECT clinical studies (as outlined below), as well as real-world evidence being generated by key Efmody® prescribers, particularly in Germany, which are designed to elucidate potential benefits of treatment with Efmody® that have been observed in the European Phase 3 study, the associated open label extension study, and subsequently in-market. In particular, prescribers of Efmody® are interested in understanding the potential impact of fertility for patients with CAH.

Following the end of the Period, the Company was pleased to receive confirmation from the Italian health authorities that Efmody® will be reimbursed. The Company plans to formally launch Efmody® in Italy at a major international conference during September 2022. Pricing and reimbursement activities remain ongoing in other key markets, most notably in Spain, with the outcome of these discussions expected during 2022.

Reflecting the key drivers of its Efmody® European business, Diurnal has recently refocused its European resources and, as a result, has strengthened its German and Italian commercial teams, as well as redeploying budget towards digital marketing activities.

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 extension of its existing distribution deal with EffRx in Switzerland to include both Alkindi® and Efmody®, and an expansion of its existing relationship with Er-Kim to add Greece, Cyprus and Malta. Diurnal continues to assess the opportunity for Efmody® in other global markets.

The Financial Review provides further detail on Efmody® revenues for the Period.

### **DNL-0200: expanding the global cortisol deficiency franchise**

Diurnal continues to progress development of DNL-0200 (commercialised as Efmody® in Europe) in major markets outside of Europe, in particular the US. Diurnal estimates the US market opportunity for CAH is \$0.6bn and for AI is \$4.7bn.

During 2021, the Company agreed a SPA for the CONnECT Phase 3 study with the FDA. CONnECT will act as the registration study for Efmody® as a treatment for CAH in the US and 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. Diurnal announced in early 2022 that the first clinical trial sites had been opened, and in May 2022 announced the first patients had been recruited into the study. CONnECT is expected to take 12 months to recruit, and patients will remain on the study for 52 weeks. Headline data from CONnECT is expected in 2024. Patients completing treatment in CONnECT will be offered the opportunity to participate in a long-term follow-on study (DIUR-015).

In addition to expanding the global availability of DNL-0200 to CAH patients, Diurnal is also seeking to expand its utility into the related condition, AI, a market opportunity of approximately \$6.5bn 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 European 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 now expected during Q1 2023: this small delay from the previous estimated timeline has arisen from delays in receiving the required regulatory approvals, which are now all in place.

### **DNL-0300: expanding the innovative product pipeline**

Diurnal's third novel product, DNL-0300 (formerly referred to as DITEST™), is a native oral testosterone therapy for the treatment of male hypogonadism. The estimated \$4.5bn 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. 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 NDA via the abbreviated 505(b)(2) route. In March 2022, Diurnal received feedback from FDA enabling it to finalise the clinical trial design for its next clinical trial, a MAD study in men with low testosterone. The Company is currently finalising a revised protocol ahead of commencement of this Phase 1 clinical study, which remains subject to securing additional funding.

### **Recommended cash offer by Neurocrine**

On 30 August 2022, the boards of Diurnal and Neurocrine announced that they had reached agreement on the terms of a recommended cash acquisition pursuant to which Neurocrine intends to acquire the entire issued and to be issued ordinary share capital of Diurnal. The offer remains subject to satisfaction (or waiver) of the terms and conditions announced on 30 August 2022 and to the full terms and conditions which shall be set out in the Scheme Document to be sent to Shareholders in due course.

Diurnal continues to operate as an independent business until the potential completion of this transaction.

### **Outlook**

As previously announced, sales of Alkindi® and Efmody® are gaining momentum; however, the ability of the Group to reach profitability in the future remains dependent on the outcome of the Company's clinical trials, funding, and the pace of commercial adoption.

### **Richard Bungay**

Interim Chief Executive Officer

14 September 2022

## Financial Review

During 2021, the Group changed its financial year end from 30 June to 31 December, to better line up with its peer companies in the US. Accordingly, the Group's next statutory reporting period will be the 18 months ended 31 December 2022. The first interim report was issued for the six months ended 31 December 2021; this interim report covers the 12 months ended 30 June 2022.

### Revenues and gross margin

Revenues from Alkindi® product sales (including royalties) for the Period were £3.65m, representing year-on-year growth of 61% (twelve months ended 30 June 2021: £2.27m). The Company's key markets (UK, Germany, Italy and Austria) demonstrated continued growth, with sales increasing by 35% reflecting the easing of the impact of Covid-19 in the second half of the Period which had previously restricted patients' ability to visit hospitals and, consequently, physicians' ability to switch these patients to Alkindi®. The Company has also seen significant growth outside of these key markets with revenue increasing by 116% as a result of the Company's partnering strategy broadening its geographical reach, in particular the sales growth of Alkindi Sprinkle® in the US.

The Company recorded initial Efmody® revenue from product sales for the Period of £0.97m (twelve months ended 30 June 2021: £nil), primarily reflecting sales in Germany since pricing approval in September 2021, along with initial revenues in the UK, the Netherlands and Austria.

Total revenue from product sales (including royalties) for the Period was £4.62m (twelve months ended 30 June 2021: £2.27m), representing year-on-year growth of 104%.

Total revenue for the Period was £4.68m, which included licensing income of £0.06m (twelve months ended 30 June 2021: £4.37m, including licensing income of £2.10m).

Gross margin on product sales for the Period was 78% (twelve months ended 30 June 2021: 66%), with the increase over the previous period driven partly by Efmody® product sales (which are at a higher gross margin than Alkindi®) and Alkindi® royalty revenues that carry higher gross margins, and partly by the suppressed gross margin in 2021 as a result of historic price adjustments and stock obsolescence in the Nordic markets.

### Operating expenses

Research and development (R&D) expenditure for the Period was £12.10m (twelve months ended 30 June 2021: £6.92m). 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, the CHAMPAIN European Phase 2 study with Efmody® in AI and the initiation of a long-term follow-on study (DIUR-015) for patients completing treatment in CONnECT. Other significant R&D costs included ongoing activities relating to the manufacturing scale-up and associated validations for Efmody®, and DNL-0300 non-clinical activities in support of the IND application to the FDA.

Selling and distribution expenses for the Period increased to £6.72m (twelve months ended 30 June 2021: £5.24m) reflecting the preparation and ongoing commercial launches of Efmody® in Europe and global territory expansion of Alkindi®. 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 2021. Other notable selling and distribution expenses included the ongoing investment into digital channels and market intelligence to add to the current commercialisation efforts in the key European territories, a detailed commercial analysis of the potential of Efmody® in the US (see operational review) and costs incurred for the transfer to a new pharmacovigilance provider to support the expansion of the Group's commercial footprint. Selling and distribution expenses for the Period also contain a charge for obsolete inventories amounting to £0.50m (twelve months ended 30 June 2021: £0.08m) and an impairment expense of £0.13m relating to tooling that has become idle (twelve months ended 30 June 2021: £nil).

Administrative expenses for the Period were £3.69m (twelve months ended 30 June 2021: £3.06m). Costs for the Period included recruitment charges and fees relating to the Board and management changes and increased professional fees. 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 the impact of Covid-19.

## **Operating loss**

Operating loss for the Period increased to £18.96m (twelve months ended 30 June 2021: £11.60m), reflecting the impact of increased operating expenses outlined above.

## **Financial income and expense**

Net financial expense in the Period was £0.01m (twelve months ended 30 June 2021: £0.06m income).

## **Loss on ordinary activities before tax**

Loss before tax for the Period was £18.97m (twelve months ended 30 June 2021: £11.54m).

## **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 in 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 £2.38m as at 30 June 2022.

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

## **Earnings per share**

Loss per share for the Period increased to 9.8 pence (twelve months ended 30 June 2021: 7.3 pence), with the increase in loss for the Period partly mitigated by the increase in weighted average number of shares outstanding in the Period.

## **Cash flow**

Net cash used in operating activities during the Period was £18.79m (twelve months ended 30 June 2021: £10.66m), with the increase arising from the increase in operating outflows, including prepayments made to the contract research organisations (CROs) who are running the CONnect, CHAMPAIN and DIUR-015 studies at the Period end of £3.36m (30 June 2021: £0.80m).

Net cash from investing activities during the Period of £0.73m, largely representing the proceeds from the disposal of the entire holding of shares held in Eton Pharmaceuticals.

Net cash from financing activities during the Period of £0.14m represents the proceeds from share option exercises during the period.

## **Balance sheet**

Total assets at 30 June 2022 decreased to £26.60m (30 June 2021: £41.79m), primarily driven by the increase in operating outflows.

Inventories at 30 June 2022 decreased to £1.36m (30 June 2021: £1.63m), primarily reflecting an increase in the Groups provision for obsolete stock (see Note 11).

Cash and cash equivalents at 30 June 2022 were £16.49m (30 June 2021: £34.04m).

Total liabilities at 30 June 2022 increased to £5.08m (30 June 2021: £4.23m), reflecting an increased level of trade payables and accrued expenses as a result of the increase in operating expenses.

Net assets at 30 June 2022 were £21.53m (30 June 2021: £37.56m).



## **Financial outlook**

As previously announced, as a result of the slower Efmody® sales growth now expected following the SMC decision in March 2022, the Company has previously indicated that it will require further financing to reach profitability. Taking into account the Company's existing financial commitments, and its inability to secure access to any material non-dilutive funding, the Company will require additional equity funding in 2023.

## **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](http://www.diurnal.co.uk). There are no changes to these principal risks since the issue of the Annual Report and Accounts.

## **Mike Scott**

Interim Chief Financial Officer

14 September 2022

**Consolidated income statement**  
for the twelve months ended 30 June 2022

|   |             | <b>Unaudited<br/>12 months<br/>ended<br/>30 Jun<br/>2022<br/>£000</b> | <b>Audited<br/>12 months<br/>ended<br/>30 Jun<br/>2021<br/>£000</b> |
|---|-------------|---|---|
|   | <b>Note</b> |   |   |
| Revenue   | 5           | 4,684   | 4,371   |
| Cost of sales   |             | (1,023)   | (779)   |
| <b>Gross profit</b>   |             | <b>3,661</b>  | <b>3,592</b>  |
| Research and development expenditure                          |             | (12,100)  | (6,915)   |
| Selling and distribution expenses                             |             | (6,717)   | (5,236)   |
| Administrative expenses                                       |             | (3,690)   | (3,056)   |
| Other (losses)/gains - net                                    |             | (109)   | 15  |
| <b>Operating loss</b>   |             | <b>(18,955)</b>   | <b>(11,600)</b>   |
| Net financial (expense)/income                                |             | (11)  | 62  |
| <b>Loss before tax</b>  |             | <b>(18,966)</b>   | <b>(11,538)</b>   |
| Taxation  | 6           | 2,396   | 1,489   |
| <b>Loss for the period</b>                                    |             | <b>(16,570)</b>   | <b>(10,049)</b>   |
| <b>Basic and diluted loss per share<br/>(pence per share)</b> | 7           | <b>(9.8)</b>  | <b>(7.3)</b>  |

All activities relate to continuing operations.

The Notes form part of this condensed financial information.

**Consolidated statement of comprehensive income**  
for the twelve months ended 30 June 2022

|  | <b>Unaudited<br/>12 months<br/>ended<br/>30 Jun<br/>2022<br/>£000</b> | <b>Audited<br/>12 months<br/>ended<br/>30 Jun<br/>2021<br/>£000</b> |
|--|---|---|
| <b>Loss for the period and total<br/>comprehensive loss for the period</b> | <b>(16,570)</b>   | <b>(10,049)</b>   |

The Notes form part of this condensed financial information.

**Consolidated balance sheet**  
as at 30 June 2022

|  |             | <b>Unaudited</b> | <b>Audited</b> |
|--|-------------|------------------|----------------|
|  |             | <b>As at</b>     | <b>As at</b>   |
|  |             | <b>30 Jun</b>    | <b>30 Jun</b>  |
|  |             | <b>2022</b>      | <b>2021</b>    |
|  | <b>Note</b> | <b>£000</b>      | <b>£000</b>    |
| <b>Non-current assets</b>                              |             |                  |                |
| Intangible assets                                      | 8           | 184              | 92             |
| Property, plant and equipment                          | 9           | 16               | 148            |
|  |             | <u>200</u>       | <u>240</u>     |
| <b>Current assets</b>                                  |             |                  |                |
| Inventories  | 11          | 1,364            | 1,625          |
| Research and development tax credit claims receivable  |             | 2,381            | 1,485          |
| Trade and other receivables                            | 12          | 6,165            | 3,433          |
| Investments held at fair value through profit and loss | 10          | -                | 970            |
| Cash and cash equivalents                              |             | 16,492           | 34,037         |
|  |             | <u>26,402</u>    | <u>41,550</u>  |
| <b>Total assets</b>                                    |             | <u>26,602</u>    | <u>41,790</u>  |
| <b>Current liabilities</b>                             |             |                  |                |
| Trade and other payables                               | 13          | (5,044)          | (4,163)        |
|  |             | <u>(5,044)</u>   | <u>(4,163)</u> |
| <b>Non-current liabilities</b>                         |             |                  |                |
| Trade and other payables                               | 13          | (32)             | (63)           |
|  |             | <u>(32)</u>      | <u>(63)</u>    |
| <b>Total liabilities</b>                               |             | <u>(5,076)</u>   | <u>(4,226)</u> |
| <b>Net assets</b>                                      |             | <u>21,526</u>    | <u>37,564</u>  |
| <b>Equity</b>  |             |                  |                |
| Share capital  |             | 8,486            | 8,397          |
| Share premium  |             | 77,461           | 77,414         |
| Group reconstruction reserve                           |             | (2,943)          | (2,943)        |
| Accumulated losses                                     |             | (61,478)         | (45,304)       |
| <b>Total equity</b>                                    |             | <u>21,526</u>    | <u>37,564</u>  |

The Notes form part of this condensed financial information.

**Consolidated statement of changes in equity**  
for the twelve months ended 30 June 2022

|   | Share<br>capital<br>£000 | Share<br>premium<br>£000 | Group<br>reconstruction<br>reserve<br>£000 | Accumulated<br>losses<br>£000 | Total<br>£000 |
|---|--------------------------|--------------------------|--|-------------------------------|---------------|
| <b>Balance at 30 June 2020<br/>(audited)</b>                          | <b>6,082</b>             | <b>50,967</b>            | <b>(2,943)</b>                             | <b>(35,721)</b>               | <b>18,385</b> |
| Loss for the period and<br>total comprehensive loss<br>for the period | -                        | -                        | -  | (10,049)                      | (10,049)      |
| Equity settled share-based<br>payment transactions                    | -                        | -                        | -  | 466                           | 466           |
| Issue of shares for cash  | 2,315                    | 28,205                   | -  | -                             | 30,520        |
| Costs charged against<br>share premium                                | -                        | (1,758)                  | -  | -                             | (1,758)       |
| Total transactions with<br>owners recorded directly in<br>equity      | 2,315                    | 26,447                   | -  | 466                           | 29,228        |
| <b>Balance at 30 June 2021<br/>(audited)</b>                          | <b>8,397</b>             | <b>77,414</b>            | <b>(2,943)</b>                             | <b>(45,304)</b>               | <b>37,564</b> |
| Loss for the period and total<br>comprehensive loss for the<br>period | -                        | -                        | -  | (16,570)                      | (16,570)      |
| Equity settled share-based<br>payment transactions                    | -                        | -                        | -  | 396                           | 396           |
| Issue of shares for cash  | 89                       | 47                       | -  | -                             | 136           |
| Total transactions with<br>owners recorded directly in<br>equity      | 89                       | 47                       | -  | 396                           | 532           |
| <b>Balance at 30 June 2022<br/>(unaudited)</b>                        | <b>8,486</b>             | <b>77,461</b>            | <b>(2,943)</b>                             | <b>(61,478)</b>               | <b>21,526</b> |

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 twelve months ended 30 June 2022

|   | Unaudited<br>12 months<br>ended<br>30 Jun 2022<br>£000 | Audited<br>12 months<br>ended<br>30 Jun 2021<br>£000 |
|---|--|--|
| <b>Cash flows from operating activities</b>                   |  |  |
| Loss for the period   | (16,570)   | (10,049)   |
| <i>Adjustments for:</i>                                       |  |  |
| Fair value adjustment to investments                          | 109  | (15)   |
| Depreciation, amortisation and impairment                     | 158  | 24   |
| Share-based payment   | 396  | 466  |
| Net foreign exchange (gain)/loss                              | (373)  | 109  |
| Finance costs - net   | 11   | (62)   |
| Taxation  | (2,396)  | (1,489)  |
| Decrease/(Increase) in inventories                            | 261  | (384)  |
| (Increase) in trade and other receivables                     | (2,732)  | (2,096)  |
| Increase in trade and other payables                          | 850  | 1,635  |
| <b>Cash used in operations</b>                                | (20,286)   | (11,861)   |
| Net tax received  | 1,500  | 1,199  |
| <b>Net cash used in operating activities</b>                  | (18,786)   | (10,662)   |
| <b>Cash flows from investing activities</b>                   |  |  |
| Additions of property, plant and equipment                    | (6)  | (138)  |
| Capitalisation of research and development expenditure        | (112)  | (25)   |
| Proceeds from sale of investment                              | 861  | 713  |
| Interest (paid)/received                                      | (11)   | 62   |
| <b>Net cash from investing activities</b>                     | 732  | 612  |
| <b>Cash flows from financing activities</b>                   |  |  |
| Net proceeds from issue of share capital                      | 136  | 28,762   |
| <b>Net cash from financing activities</b>                     | 136  | 28,762   |
| Net (decrease)/increase in cash and cash equivalents          | (17,918)   | 18,712   |
| Cash and cash equivalents at the start of the period          | 34,037   | 15,434   |
| Effects of exchange rate changes on cash and cash equivalents | 373  | (109)  |
| <b>Cash and cash equivalents at the end of the period</b>     | 16,492   | 34,037   |

## **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 UK adopted IAS 34 'Interim Financial Reporting'. They should be read in conjunction with audited consolidated financial statements for the year ended 30 June 2021, which were prepared in accordance with International Accounting Standards in conformity with the requirements of the Companies Act 2006 as applicable to companies using International Financial Reporting Standards (IFRS) and also in accordance with IFRS adopted pursuant Regulation (EC) No 1606/2002 as it applies in 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 twelve months ended 30 June 2022 and for the financial year ended 30 June 2021 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 30 June 2022, the Group made an operating loss of £18,955k on revenue of £4,684k and used net cash in operating activities of £18,786k. Cash and cash equivalents at 30 June 2022 were £16,492k.

The Directors have prepared cash flow forecasts and considered the cash flow requirement for the Group. These forecasts show that to continue funding currently ongoing clinical trials and European commercialisation activities, further equity financing will be required in 2023. Depending on the commercial progress with its approved products, further equity financing beyond this may be required prior to the Group reaching sustainable profitability. Assuming completion of the proposed acquisition of Diurnal by Neurocrine, the Company expects Neurocrine to support future financing requirements. Prior to completion of the proposed acquisition, 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.

Based on the above, the Directors believe it remains appropriate to prepare the financial statements for the twelve months ended 30 June 2022 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 twelve months ended 30 June 2022 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 twelve months to 30 June 2022, 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:

|                                  | <b>Unaudited<br/>12 months<br/>ended<br/>30 Jun 2022<br/>£000</b> | <b>Audited<br/>12 months<br/>ended<br/>30 Jun 2021<br/>£000</b> |
|----------------------------------|---|---|
| Sales of goods                   |   |   |
| - Alkindi® (including royalties) | 3,653   | 2,267   |
| - Efmody®                        | 969   | -   |
| Total sales of goods             | 4,622   | 2,267   |
| Licence fees                     | 62  | 2,104   |
|                                  | 4,684   | 4,371   |

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

|                     | <b>Unaudited<br/>12 months<br/>ended<br/>30 Jun 2022<br/>£000</b> | <b>Audited<br/>12 months<br/>ended<br/>30 Jun 2021<br/>£000</b> |
|---------------------|---|---|
| UK                  | 1,372   | 1,108   |
| Rest of Europe      | 2,828   | 1,094   |
| USA & Rest of World | 484   | 2,169   |
|                     | 4,684   | 4,371   |

## 6 Taxation

|   | Unaudited<br>12 months<br>ended<br>30 Jun 2022<br>£000 | Audited<br>12 months<br>ended<br>30 Jun 2021<br>£000 |
|---|--|--|
| <b>Current tax:</b>   |  |  |
| - UK corporation tax on losses of period                                    | -  | -  |
| - Dutch corporation tax on subsidiary profits for the period                | 5  | 1  |
| - Research and development tax credit receivable for the current period     | (2,381)  | (1,485)  |
| - Prior period adjustment in respect of research and development tax credit | (20)   | (5)  |
| <b>Deferred tax:</b>  |  |  |
| - Origination and reversal of temporary differences                         | -  | -  |
| <b>Tax on loss on ordinary activities</b>                                   | <u>(2,396)</u>   | <u>(1,489)</u>                                       |

The Group is entitled to claim tax credits in the United Kingdom under the UK research and development (R&D) small or medium-sized enterprise (SME) scheme, which provides additional taxation relief for qualifying expenditure on R&D activities and includes an option to surrender a portion of tax losses arising from qualifying activities in return for a cash payment from HM Revenue & Customs (HMRC).

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.

## 7 Loss per share

|  | Unaudited<br>12 months<br>ended<br>30 Jun 2022 | Audited<br>12 months<br>ended<br>30 Jun 2021 |
|--|--|--|
| Loss for the period (£000)                         | (16,570)                                       | (10,049)                                     |
| Weighted average number of shares (000)            | 169,182  | 137,090                                      |
| Basic and diluted loss per share (pence per share) | <u>(9.8)</u>                                   | <u>(7.3)</u>                                 |

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



## 8 Intangible assets

|                                 | Acquired<br>patents and<br>licences<br>£000 | Internally<br>generated<br>development<br>costs<br>£000 | Total<br>£000 |
|---------------------------------|---|---|---------------|
| <b>Cost</b>                     |   |   |               |
| Balance at 1 July 2020          | 39  | 90  | 129           |
| Additions                       | -   | 25  | 25            |
| Balance at 30 June 2021         | 39  | 115   | 154           |
| Additions                       | -   | 112   | 112           |
| <b>Balance at 30 June 2022</b>  | <b>39</b>                                   | <b>227</b>  | <b>266</b>    |
| <b>Accumulated Amortisation</b> |   |   |               |
| Balance at 1 July 2020          | 39  | 11  | 50            |
| Charge for the period           | -   | 12  | 12            |
| Balance at 30 June 2021         | 39  | 23  | 62            |
| Charge for the period           | -   | 20  | 20            |
| <b>Balance at 30 June 2022</b>  | <b>39</b>                                   | <b>43</b>   | <b>82</b>     |
| <b>Net book values</b>          |   |   |               |
| 30 June 2021 (audited)          | -   | 92  | 92            |
| <b>30 June 2022 (unaudited)</b> | <b>-</b>                                    | <b>184</b>  | <b>184</b>    |

### **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 CAH following approval by the European Commission in May 2021

## 9 Property, plant and equipment

|                                 | <b>Equipment<br/>£000</b> |
|---------------------------------|---------------------------|
| <b>Cost</b>                     |                           |
| Balance at 1 July 2020          | 84                        |
| Additions                       | 138                       |
| Disposals                       | (9)                       |
| Balance at 30 June 2021         | 213                       |
| Additions                       | 6                         |
| Disposals                       | (42)                      |
| <b>Balance at 30 June 2022</b>  | <b>177</b>                |
| <b>Accumulated Depreciation</b> |                           |
| Balance at 1 July 2020          | 61                        |
| Charge for the period           | 12                        |
| Impairment                      | -                         |
| Disposals                       | (8)                       |
| Balance at 30 June 2021         | 65                        |
| Charge for the period           | 10                        |
| Impairment                      | 128                       |
| Disposals                       | (42)                      |
| <b>Balance at 30 June 2022</b>  | <b>161</b>                |
| <b>Net book values</b>          |                           |
| 30 June 2021 (audited)          | 148                       |
| <b>30 June 2022 (unaudited)</b> | <b>16</b>                 |

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

## 10 Investments held at fair value through profit and loss

|                                      | <b>Investments<br/>£000</b> |
|--------------------------------------|-----------------------------|
| <b>Cost</b>                          |                             |
| Balance at 1 July 2020               | 1,668                       |
| Disposals                            | (713)                       |
| Fair value adjustment to investments | 15                          |
| Balance at 30 June 2021 (audited)    | 970                         |
| Additions                            | -                           |
| Disposals                            | (861)                       |
| Fair value adjustment to investments | (109)                       |
| <b>Balance at 30 June 2022</b>       | <b>-</b>                    |

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 (losses)/gains - net'.

## 11 Inventories

|                  | Unaudited<br>As at<br>30 Jun 2022<br>£000 | Audited<br>As at<br>30 Jun 2021<br>£000 |
|------------------|---|---|
| Raw materials    | 106                                       | 123                                     |
| Work in progress | 685                                       | 1,046                                   |
| Finished goods   | 573                                       | 456                                     |
|                  | <u>1,364</u>                              | <u>1,625</u>                            |

Inventories recognised as an expense in cost of sales for the twelve months to 30 June 2022 amounted to £1,023k (twelve months to 30 June 2021: £779k). A charge for obsolete inventories amounting to £503k has been recognised in selling and distribution expenses in the Period (twelve months to 30 June 2021: £78k).

## 12 Trade and other receivables

|                   | Unaudited<br>As at<br>30 Jun 2022<br>£000 | Audited<br>As at<br>30 Jun 2021<br>£000 |
|-------------------|---|---|
| Trade receivables | 1,070                                     | 361                                     |
| VAT receivable    | 354                                       | 501                                     |
| Prepayments       | 4,046                                     | 1,460                                   |
| Other receivables | 695                                       | 1,111                                   |
|                   | <u>6,165</u>                              | <u>3,433</u>                            |

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 £3,359k at 30 June 2022 (30 June 2021: £797k).

## 13 Trade and other payables

|                                | Unaudited<br>As at<br>30 Jun 2022<br>£000 | Audited<br>As at<br>30 Jun 2021<br>£000 |
|--------------------------------|---|---|
| <i>Current liabilities</i>     |   |   |
| Trade payables                 | 1,758                                     | 1,728                                   |
| Tax and social security        | 177                                       | 121                                     |
| Accrued expenses               | 2,868                                     | 2,195                                   |
| Deferred Income                | 135                                       | -                                       |
| Other payables                 | 106                                       | 119                                     |
|                                | <u>5,044</u>                              | <u>4,163</u>                            |
| <i>Non-current liabilities</i> |   |   |
| Accrued expenses               | 32  | 63                                      |
|                                | <u>32</u>                                 | <u>63</u>                               |

The Group accrues for employer National Insurance contributions that may become due on unexercised share-based payments. In the Period £32k (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:

|                                       | <b>Unaudited</b>   | <b>Audited</b>     |
|---------------------------------------|--------------------|--------------------|
|                                       | <b>12 months</b>   | <b>12 months</b>   |
|                                       | <b>ended</b>       | <b>ended</b>       |
|                                       | <b>30 Jun 2022</b> | <b>30 Jun 2021</b> |
|                                       | <b>£000</b>        | <b>£000</b>        |
| <b>Purchase of goods and services</b> |                    |                    |
| IP Group plc and subsidiaries         | 50                 | 50                 |

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 30 June 2022 amounted to £11k (30 June 2021: £34k).