



14 September 2021

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

Results for the year ended 30 June 2021

Significant progress made during the year with two major regulatory approvals

Alkindi® growth of 18% in core markets despite continued impact of Covid-19 on hospital visits

Post-period, launch of Efmody® in Europe, Diurnal's second product on the market following Alkindi®

Diurnal Group plc (AIM: DNL), the specialty pharmaceutical company targeting patient needs in chronic endocrine (hormonal) diseases, announces its audited results for the year ended 30 June 2021.

Operational highlights (including post-period):

Approved products:

Alkindi® (hydrocortisone granules in capsules for opening)

- Continued rollout of Alkindi® across Europe with growth in UK, Germany and Italy, despite the impact of Covid-19 on patients' ability to visit hospitals and physicians' ability to switch patients to Alkindi®.
- Alkindi Sprinkle® approved by the US Food and Drug Administration (FDA) and subsequent launch in the US by Eton Pharmaceuticals (Eton) in November 2020.
- Signed distribution agreements to expand the future availability of Alkindi® in Benelux, Switzerland, Turkey and China.
- Further Alkindi® regulatory approvals in Australia and Israel.

Efmody® (modified-release hydrocortisone)

- Approval of Efmody® as treatment of congenital adrenal hyperplasia (CAH) in adults and adolescents aged 12 years and over.
- Efmody® commercial roll-out initiated in September 2021 with launches in Germany, Austria and Great Britain.
- Successful completion of Special Protocol Assessment (SPA) with the FDA for the pivotal Efmody® US Phase 3 study in CAH; study due to commence in Q4 2021.
- Publication of Efmody® European Phase 3 pivotal trial and extension study data in the *Journal of Clinical Endocrinology and Metabolism* (JCEM).
- Signed further distribution agreements for Efmody® in Benelux, Nordic countries, Turkey, Romania, and Bulgaria.

Development products:

DITEST™ (native oral testosterone formulation)

- Positive meeting with the FDA confirming abbreviated 505(b)(2) development pathway, with potential to be the first effective oral native testosterone treatment in an estimated \$5.0bn global market.

Financial overview

- Total revenues for the year were £4,371k (2020: £6,313k), comprising Alkindi® product sales of £2,267k (2020: £2,390k) and licensing income of £2,104k (2020: £3,923k), with lower Alkindi® product sales predominantly due to lower sales to the Company's Nordic distribution partner.

- Continued growth of Alkindi® sales in core commercial markets of the UK, Germany, Italy and Austria, with proforma sales increasing by 18% in these countries despite the impact of the Covid-19 pandemic.
- Operating loss for the year was £11,600k (2020: £5,392k), reflecting pre-launch commercialisation expenditure for Efmody® and the increase in Research and Development (R&D) expenditure for the set-up costs of upcoming key studies for Efmody® and DITEST™.
- Cash and cash equivalents were £34,037k (2020: £15,434k), reflecting the completion of two oversubscribed Placing and Open Offers during the year, raising a total of £28,762k after expenses, to open up new markets and indications for Efmody® and to further develop DITEST™ and other early-stage pipeline opportunities.
- Diurnal expects its cash resources to take its core commercial European cortisol deficiency franchise through to profitability based upon current plans and assumptions, including expectations regarding the timing of product approvals and sales projections.
- Financial year end to be changed to 31 December, with next statutory reporting due for the 18 month period to 31 December 2022.

Martin Whitaker, CEO of Diurnal, commented:

“Over the past year, Diurnal has continued to make significant progress in its ambition towards becoming a world-leading endocrinology company. We continued to roll-out Alkindi® across Europe and secured FDA approval for the product, which was subsequently launched in the US by our partner Eton. Another key milestone was the approval of our second product, Efmody®, in Europe. The launch is progressing well and we expect to realise synergies in the utilisation of our existing European commercial infrastructure and supply chain from Alkindi® which we anticipate to lead to the rapid uptake of Efmody® as a new treatment option available for patients suffering from CAH as the launch gains momentum.

“In our pipeline, we are excited to progress our development strategy for Efmody® in the US, as well as the clinical development of DITEST™, with an IND application expected to be filed later this year. We continue to believe that Diurnal is well positioned with sufficient cash resources to take our core commercial European cortisol deficiency franchise through to profitability and look forward to reporting on further operational and commercial progress in this current financial period.”

Martin Whitaker, Chief Executive Officer, and Richard Bungay, Chief Financial Officer, will provide a live presentation relating to the Company’s financial results today via the Investor Meeting Company platform at 11:00 BST.

The online presentation is open to all existing and potential shareholders. Investors can sign up to Investor Meet Company for free and interested parties can register to attend the presentation via the following link: <https://www.investormeetcompany.com/diurnal-group-plc/register-investor>.

In the audited results for the year ended 30 June 2021:

- "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 Article 7 of Regulation (EU) 596/2014 (MAR).

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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.

Chairman's Statement

Despite the headwinds caused by the Covid-19 pandemic, Diurnal has had a landmark year with two major product approvals, an exceptional achievement for a rapidly growing company. During the year, Diurnal has expanded its global reach through the execution of new licensing and distribution arrangements and has also successfully completed fundraisings that allow it to expand its pipeline opportunities. In addition, Diurnal has continued to grow product revenues in its core European markets of UK, Germany, Italy and Austria, despite the considerable impacts of the pandemic on its commercial operations. Taken together, these significant advances move Diurnal closer to its vision of becoming a world-leading endocrinology specialty pharma company.

Building a global endocrine leader

Diurnal's core business model is to develop its own products in-house and commercialise these itself in major European markets, where the Group can cost-effectively promote these innovative products to specialist endocrinologists. The launch of Alkindi® has enabled Diurnal to build a fully integrated organisation that has the capabilities to design, develop and market innovative products addressing key unmet patient needs in chronic endocrine diseases. With the recent approval of Efmody® in congenital adrenal hyperplasia (CAH), the Group expects to realise significant synergies in the utilisation of its existing European commercial infrastructure and supply chain. This is also expected to lead to a rapid take up of Efmody®, as the launch gains momentum and the year progresses, and subsequently to create a profitable franchise in diseases of cortisol deficiency.

Outside of its core territories, Diurnal's strategy is to engage licensing or distribution partners who have extensive local knowledge, a strong commitment to our products, and the ability to rapidly gain market access. Diurnal has entered into a number of new partnerships during the last year, validating the Board's belief in the quality of the Group's products.

In the longer term, achieving profitability will enable Diurnal to self-finance its innovative early-stage pipeline, thereby yielding a portfolio of high-quality products to patients, as well as providing major value-accretion for Diurnal's shareholders. Diurnal will also assess external endocrine-focused opportunities that it believes will strengthen its business model.

Investing for the future

During the year, Diurnal successfully completed two oversubscribed fundraisings totalling £30.5m before expenses, designed to support the expansion of its pipeline opportunities in the Group's core cortisol deficiency franchise, as well as bringing forward earlier-stage programmes that sit outside the cortisol deficiency area, such as our native oral testosterone product, DITEST™. I would like to thank Diurnal's shareholders for their continued support of the Company.

It is the Board's expectation that the Group's cash reserves are now sufficient to take it through to profitability based upon current plans and assumptions, including expectations regarding the timing of product approvals and sales projections.

Focus on high-quality science

A key milestone for the Group during the year was the approval of Efmody® for the treatment of CAH in Europe, despite the Phase 3 study having missed its primary endpoint when completed in 2018. As many longer-term shareholders in Diurnal will recall, this was a particularly challenging experience in terms of the stock market reaction and the potentially negative impact it could have had on the morale of the executive team. However, driven by confidence in the benefits of Efmody® for patients and by positive feedback from key opinion leaders, the team stuck to its belief that the data were beneficial enough to warrant regulatory review, and this underlying conviction helped the team guide the programme through the European regulatory submission and review process.

The Board would like to thank the executive team for their persistence in achieving this milestone, as well as those shareholders who supported the Company throughout the period. The team's belief in the benefits of Efmody® were validated through the publication of the European Phase 3 data and follow-on study in the prestigious Journal of Clinical Endocrinology and Metabolism (JCEM), illustrating Diurnal's commitment to

high-quality science through timely and transparent disclosure of data to the medical community via peer-reviewed publications.

Diurnal's scientific credentials were further validated during the year by the Laureate Award for Outstanding Innovation, which was made to Diurnal's founder and Chief Scientific Officer, Professor Richard Ross, by the Endocrine Society.

Strong team with the ability to deliver

Diurnal has had a flexible working ethos since its outset, with most of its staff being home-based. This has enabled it to attract the best people, regardless of location, and has become a significant strength for Diurnal as people across our industry reassess working arrangements as a result of the Covid-19 lockdown. Diurnal has recruited a number of key positions during the year, further strengthening its team to continue to support the growth in the business.

The Covid-19 pandemic has provided unprecedented challenges in many areas of our business, in particular the conduct of clinical trials and commercialisation of our products. Our team has also had to work closely with our suppliers, particularly in manufacturing where staffing levels during the pandemic have created many challenges. I would like to thank all of Diurnal's employees for their resourcefulness and resilience over the last year, which has allowed the Group to meet the significant challenges posed by Covid-19.

There have been significant additional pressures on our administration team this year, with a substantial increase in audit procedures, implementation of new cross-border trading arrangements following the end of the Brexit transition period and increased governance and disclosure requirements. Like many growth companies, Diurnal has a small administration team, and I would like to thank them for their resilience in absorbing this additional workload.

The Covid-19 pandemic has also had an impact on Diurnal's plans to strengthen its Board through the appointment of a permanent Chairman and an additional independent Non-executive Director. With the gradual easing of restrictions on face-to-face meetings, Diurnal anticipates completing these key appointments before the end of 2021.

Well positioned to deliver further growth

Diurnal is heading into an intense period of activity, with a strong focus on the commercial roll-out of Efmody® in Europe together with the commencement of Efmody® development activities in the US, and initiation of new clinical studies to broaden and deepen our product pipeline. In parallel with its own efforts, Diurnal expects its commercial partners to make significant progress in the coming period. Whilst uncertainty remains around the ongoing impact of the Covid-19 pandemic, Diurnal believes that it is well positioned to make significant steps towards becoming a strong, sustainable global endocrinology leader during the forthcoming period.

Sam Williams

Interim Chairman

13 September 2021

Chief Executive Officer's Review

A year of continued progress

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

Underpinning this vision is the development of a strong commercial business in Europe, initially focused on delivery of the Group's two lead products, Alkindi® and Efmody®, for patients suffering from the rare diseases adrenal insufficiency (AI) and congenital adrenal hyperplasia (CAH), a combined potential market of \$2.3bn. Diurnal has built one of the few dedicated endocrinology-focused commercial teams in Europe, focused on building awareness of its products within a concentrated prescribing community, that will cover our core commercial markets (the UK, Germany, Austria, Italy, France and Spain), along with a European-based supply chain that is able to support global distribution of both Alkindi® and Efmody®.

The Group has entered into further licensing and distribution deals during the year which are expected to expand the availability of Alkindi® and Efmody® to patients outside of our core European markets and to maximise the value of these products globally.

The Group is also building a pipeline of valuable opportunities addressing chronic endocrine disorders. In particular, Diurnal has made significant progress in the development of DITEST™, its native oral testosterone replacement product for the treatment of hypogonadism, a potential global market of greater than \$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 has been proven to be effective as a formulation specifically designed for the paediatric setting. Diurnal's commercialisation efforts for Alkindi® are focused on the larger European markets, and initially on patients aged 0-6 years where the unmet need is highest. In Europe, Alkindi® has been launched by Diurnal in the UK, Germany, Italy and Austria, and by its partner FrostPharma in Sweden, Denmark, Norway and Iceland.

During the year, the Group saw continued growth of Alkindi® sales in the UK and Germany, despite the impact of the Covid-19 pandemic on patients' ability to visit hospitals and, consequently, physicians' ability to switch these patients to Alkindi®. Growth from new territories where Alkindi® was launched during the year, including Italy, was modest, reflecting the limitation of impactful in-country launches due to the Covid-19 pandemic. The Group saw a decline in revenues deriving from the Nordic region, largely reflecting timing of sales to its Nordic distribution partner. The Financial Review provides further detail on the development of Alkindi® revenues during the year.

Diurnal has further expanded the availability of Alkindi® in Europe during the year through execution of distribution deals with Consilient Health, covering the Benelux region (the Netherlands, Belgium and Luxembourg), and with EffRx in Switzerland. Pricing for Alkindi® has been approved in the Netherlands and the launch planning is underway by Consilient Health, whilst EffRx submitted a marketing authorisation application (MAA) to SwissMedic during the year, with approval anticipated during H2 2021. Pricing has not yet been agreed for Alkindi® in France or Spain; but for both territories Diurnal intends to resume the opportunity once Efmody® has been launched.

In the US, where the product is called Alkindi Sprinkle®, the US Food and Drug Administration (FDA) approved the product at the end of September 2020 for children aged under 17 years of age. In November 2020, less than two months after approval, Diurnal's partner, Eton Pharmaceuticals (Eton), announced the market launch of the product. Diurnal and Eton are awaiting confirmation of Orphan Drug Status from the FDA, which will trigger a \$2.5m milestone payment to Diurnal. Following the approval of Alkindi Sprinkle® in US, Eton received interest from physicians in Canada and Diurnal subsequently extended its licensing deal with Eton to cover Canada in January 2021.

Diurnal's Australian partner, Chiesi (previously Emerge Health), received approval for Alkindi®, with no age restriction, and the Group's partner in Israel, Medison Pharma, received approval for Alkindi® in children under

18 years of age. Launches in these territories are expected following completion of pricing and reimbursement activities.

Elsewhere in the world, Diurnal entered into a licensing deal with Er-Kim in Turkey to supply Alkindi® on a named patient basis and a licensing deal with Citrine Medicine in China for Alkindi® during the year, both of which represent substantial market opportunities. Er-Kim is currently undertaking pricing and reimbursement activities ahead of the planned launch of Alkindi® and Citrine is preparing a regulatory dossier ahead of submitting Alkindi® for approval in China.

Diurnal continues to assess the opportunity for Alkindi® in Japan and, during the year, the Group formulated a development and regulatory strategy for this market. Consistent with this strategy, a submission for regulatory protection was submitted to the Japanese Ministry of Health, Labour and Welfare (MHLW) by the Japanese Paediatric Endocrine Society on behalf of Diurnal, ahead of commencing any local development activities.

To ensure the Group is able to meet anticipated future demand for Alkindi®, including supplying its global partners, several manufacturing improvement initiatives are underway, including the development of a higher throughput encapsulation and scale up of the granule manufacturing process. It is envisaged that these enhancements will be implemented on a timely basis, including relevant regulatory submissions.

Efmody®: expanding the cortisol deficiency franchise

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

A pivotal event for the Group during the year was the approval of the Marketing Authorisation Application (MAA) for Efmody® as a treatment for adults and adolescents with CAH by the European Medicines Agency (EMA) and, subsequently, the UK Medicines and Healthcare Regulatory Agency (MHRA). These approvals were based upon a Phase 3 study conducted in a total of 122 patients enrolled across 11 clinical sites, the largest ever interventional clinical trial completed in CAH. The Phase 3 data was supported by detailed analysis of data from an open-label safety extension study for patients completing treatment in the Phase 3 study, which is assessing the impact of treatment with Efmody® over an extended period, regardless of whether the patients were initially treated with Efmody® or standard-of-care. A significant proportion of patients eligible to enter the follow-on study did so, and patient retention rates in this study have been high, with a number of patients on this trial having been treated for over five years with Efmody®.

Reflecting the data supporting the Efmody® MAA, Diurnal was pleased to announce during the year the publication of the peer-reviewed results of the Phase 3 clinical trial and extension study for Efmody® in the *Journal of Clinical Endocrinology and Metabolism* (JCEM). The Phase 3 study results published by the JCEM found that although the standard-deviation-score-focused primary endpoint of the study was missed, Efmody® significantly improved morning and early afternoon biochemical control for adults with CAH over standard glucocorticoid therapy. In the safety extension study, biochemical control was sustained for 18 months on median hydrocortisone doses in the range recommended for cortisol replacement therapy and lower than glucocorticoid doses normally used in the treatment of CAH. This important publication reflects Diurnal's goal of high-quality development programmes and transparency with the medical community, and will be a valuable resource for Diurnal in its discussions with potential prescribers.

The regulatory approvals in the European Economic Area (EEA) and Great Britain (GB) have enabled Diurnal to progress pricing applications across Europe, to facilitate a timely commercial launch in its target European markets, with the first commercial launches in Germany, Austria and the UK achieved in September 2021. The Group intends to mirror its strategy for Alkindi® by commercialising the product itself in core European markets. In particular, the approval for the use of Efmody® in adolescent patients (i.e., aged 12-18) will enable Diurnal's commercial organisation to focus on both adult and paediatric endocrinologists, providing significant synergies with the continued promotion of Alkindi®.

Launch stocks for Efmody® have been manufactured in advance of the planned launches, utilising many aspects of the supply chain that have already been established for Alkindi®. As with Alkindi®, the Group is undertaking several initiatives to enhance capacity and reduce cost of goods of Efmody® in the mid-term.

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 global reach during the year through entering into distribution deals with Consilient Health for Benelux and Nordic countries, with Er-Kim to supply Efmody® in Turkey (on a named patient basis) and, subsequently, extended to include Romania and Bulgaria. These new collaborations add to the Group's existing Efmody® distribution agreements with Chiesi in Australia and Medison Pharma in Israel.

In the US, the FDA has previously indicated that the registration package for CAH requires an additional study to the European Phase 3 CAH study. During the year, Diurnal successfully completed a Special Protocol Assessment (SPA), formalising agreement of the US Phase 3 protocol with the FDA. In parallel with the regulatory discussions, the Group has engaged a global clinical research organisation (CRO) to conduct the US Phase 3 development and expects to commence recruitment in this study in Q4 2021. This double-blind, double-dummy study comparing Efmody® to standard of care will be run in several countries in addition to the US. Notably, the study will include centres in Japan, where the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) has agreed this study can act as the registration study for Efmody® in Japan. The study is expected to take approximately 12 months to recruit, with patients being on treatment for 12 months. Diurnal completed a fundraising in May 2021 that will fund this development programme, which the Group believes will significantly increase the future value of the programme, as well as broadening the pool of potential commercialisation partners.

Diurnal continues to seek collaboration opportunities in other global markets, which has been exemplified by the extension of its existing Alkindi® licensing deal for China with Citrine Medicine to include Efmody®.

In addition to expanding the global availability of Efmody® to CAH patients, Diurnal is also seeking to expand its utility into the related condition, AI, a market opportunity of approximately \$2.9bn across Europe and the US. Part of the fundraising completed in October 2020 will enable Diurnal to commence a study of Efmody® compared to the approved product Plenadren® in Europe, which Diurnal believes, along with the Phase 3 CAH study, will facilitate submission of a line extension to AI in Europe, and will also provide valuable insights into future development of Efmody® in AI in the US.

DITEST™: expanding the innovative product pipeline

Diurnal's third novel product, DITEST™, is a native oral testosterone therapy for the treatment of male hypogonadism. The estimated \$5.0bn market in US and Europe for testosterone-based products for the treatment of hypogonadism is dominated by topical products, which have compliance and safety issues, while key issues with the use of alternative, oral modified testosterone products (testosterone undecanoate) have been the variability in absorption and the requirement for a high-fat meal to achieve therapeutic testosterone levels.

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

Following these positive results, the Group has completed non-clinical activities requested following a meeting with the FDA during the year, at which it was confirmed that DITEST™ can progress to a New Drug Application (NDA) via the abbreviated 505(b)(2) route, which relies, in part, on published literature and other non-Company studies to support a marketing application. Diurnal is now progressing towards an Investigational New Drug (IND) submission expected in Q4 2021, with a view to commencing a Phase 1 multiple ascending dose study in the US in male patients with low testosterone shortly thereafter. Assuming this study is successful, the FDA indicated that a single Phase 3 study should be sufficient to obtain approval for DITEST™ in the US.

Outlook

Following the approvals in Europe, Efmody® will provide the Group's commercial cortisol replacement therapy franchise with critical mass, enabling Diurnal to build a strong and profitable European business through

penetration of the combined addressable market for the treatment of CAH and paediatric AI, which is estimated by the Group to be worth over \$300m in Europe alone. In addition, the Group expects an increased contribution from its licensing and distribution partners outside of Europe once regulatory and/or pricing and reimbursement activities for Alkindi® are completed in these territories.

The Group has now commenced the development of Efmody® in AI, initially in Europe but with a view to extending development in due course to the US, where Diurnal is not aware of any competition in the AI indication. In the US, Diurnal will continue to assess a range of options for the commercialisation of Efmody® following the completion of Phase 3 development in CAH.

DITEST™ represents a further valuable addition to Diurnal's growing pipeline of novel endocrinology treatments and the Group is moving forward with the next stage of development in order to maximise the value of this product in the \$5.0bn potential market in the US and Europe.

With the operational progress made over the past year, Diurnal believes it can become a profitable European biopharmaceutical company, based upon successfully taking multiple products from concept to commercialisation.

Martin Whitaker
Chief Executive Officer
13 September 2021

Financial review

Revenues and gross margin

Total revenues for the year were £4,371k (2020: £6,313k), comprising Alkindi® product sales of £2,267k (2020: £2,390k) and licensing income of £2,104k (2020: £3,923k).

Product sales of Alkindi® of £2,267k for the year ended 30 June 2021, on a statutory reporting basis, include a retrospective price adjustment of £104k. This relates to sales to Diurnal's Nordic distribution partner which were originally recorded by Diurnal in the year ended 30 June 2020. In addition, levies and rebates previously included within selling and distribution expenditure have been reclassified as a deduction from Alkindi® product sales, following an internal review of Diurnal's revenue accounting policy. The impact of this was to reduce reported Alkindi® product sales by £88k for the year ended 30 June 2021 and to reduce selling and distribution expenditure by the same amount. The equivalent levies and rebates figure for the prior year, which has not been reclassified in the consolidated income statement, is £79k.

Diurnal saw continued growth of Alkindi® sales in its core commercial markets of the UK, Germany, Italy and Austria, with proforma sales increasing by 18% despite the impact of the Covid-19 pandemic on patients' ability to visit hospitals and, consequently, physicians' ability to switch these patients to Alkindi®. Proforma sales in other markets decreased by 21%, primarily due to timing of bulk sales to the Group's Nordic partner, with proforma sales into the Nordic region for the year 56% lower than the comparative period.

Alkindi® sales growth in existing markets is expected to accelerate with the gradual lifting of Covid-19 restrictions. In addition, the Group expects further country launches during the next 12 months that will provide additional revenue growth opportunities for Alkindi®.

Milestone and licensing income for the year of £2,104k includes a total of \$2,750k (£1,952k) in signature fees and milestone payments from Citrine Medicine relating to the licensing deals for Alkindi® and Efmody® in China. Milestone and licensing income of £3,923k for the year ended 30 June 2020 comprised of a \$5m non-refundable upfront payment relating to the US licensing deal with Eton Pharmaceuticals for Alkindi Sprinkle®. These milestone and upfront payments have been recognised in full in the respective financial years, as they are not associated with any future obligations.

Cost of goods relates entirely to product sales of Alkindi®. Gross margin for Alkindi® product sales during the year was 65% (2020: 72%). Gross margin for the year was depressed by the inclusion in cost of sales of a provision for expiring inventories of finished goods totalling £107k (2020: £17k), primarily relating to stock manufactured for the Nordic market. Excluding this provision, gross margin for Alkindi® product sales during the year was 70%. The overall gross margin was impacted by the mix of sales, in particular between core commercial markets, distributor markets (where Diurnal divides revenue with its distribution partner) and for product supplied to licensing partners from Diurnal's European supply chain at cost. Overall, gross margin during the year for Diurnal's core commercial markets (UK, Germany, Italy and Austria) was 78%.

As Alkindi® sales volumes grow, the Group expects to be able to realise margin improvements through manufacturing efficiencies. Additionally, Diurnal has implemented several measures with its manufacturing partners to further reduce the cost of goods, as detailed in the Chief Executive's Review.

Operating expenses

Research and development (R&D) expenditure for the year was £6,915k (2020: £4,625k). The significant increase in R&D expenditure reflects the set-up of key studies designed to increase the value of Diurnal's pipeline, including the Efmody® US Phase 3 trial in CAH, the Efmody® European comparator trial in AI, and the DITEST™ multiple ascending dose study in the US, along with DITEST™ non-clinical activities in support of the planned Investigational New Drug (IND) submission to the FDA. The increased expenditure also includes development and regulatory pathway planning activities for Alkindi® and Efmody® in Japan and initial manufacturing scale-up activities for Efmody®, which are expensed to the consolidated income statement.

Reflecting this increase in clinical trial activity, R&D expenditure is expected to grow substantially in the next financial year as patient recruitment commences in these studies.

R&D costs are net of capitalised development costs for the development of Alkindi® and for the development of Efmody® for CAH in Europe totalling £25k (2020: £38k). The Group continues to expense development costs relating to the separate programmes for Efmody® development in AI in Europe and in CAH in the US.

Selling and distribution expenses, comprising the costs of the Group's sales and marketing, medical liaison and supply chain activities, were £5,236k (2020: £4,135k). This planned increase in expenditure reflects the Group's preparations for the commercial launches of Efmody® beginning in Q3 2021. In particular, the Group has initiated health economic modelling and pricing work to support pricing and reimbursement applications across Europe following the approval of Efmody® in the European Economic Area and in Great Britain.

Administrative expenses for the year were £3,056k (2020: £2,904k). Expenses for the year reflect substantially increased costs for audit fees and corporate insurances, 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 year increased to £11,600k (2020: £5,392k), reflecting the impact of lower revenues and increased operating expenses outlined above. Operating loss for the year includes a gain of £15k (2020: gain of £627k) relating to the shares held in Eton that were received as part of the upfront consideration for the exclusive licence agreement of Alkindi Sprinkle® in the US, which is shown under 'Other gains – net' in the consolidated income statement. Since the issue of the Eton shares to Diurnal in March 2020, their value has increased by £642k, of which £269k has been realised at 30 June 2021 through the sale of 161,692 shares for total cash proceeds of £713k, and of which £373k remains unrealised at 30 June 2021.

Financial income

Financial income in the year was £62k (2020: £114k), reflecting a reduction in interest rates on commercial deposits following the introduction of economic measures resulting from the Covid-19 pandemic.

Loss on ordinary activities before tax

Loss before tax for the period was £11,538k (2020: £5,278k).

Tax

The current year includes the estimated research and development tax credit claim in respect of the year ended 30 June 2021 of £1,485k, which has not yet been submitted to HMRC, along with an additional £5k in respect of the year ended 30 June 2020 following finalisation and agreement of the claim with HMRC. The increase in R&D tax credit receivable at the year-end mirrors the increased R&D expenditure highlighted above.

The Group has not recognised any deferred tax assets in respect of trading losses arising in either the current financial year or accumulated losses in previous financial years. Following the European approval of Efmody® during the year, the Group expects to be able to achieve profitability on the assumption that Efmody® sales are in line with the Group's internal projections. However, since the Group is in the pre-launch phase there remains uncertainty regarding the Efmody® revenue stream and, consequently, the ability to achieve profitability.

Earnings per share

Loss per share was 7.3 pence (2020: 4.3 pence).

Cash flow

Net cash used in operating activities was £10,662k (2020: £4,809k). The operating cash outflow significantly increased during the year, reflecting the lower revenues and increased operating expenditure detailed above, as well as increases in working capital noted below, particularly the increase in inventories and prepayments.

Net cash from financing activities during the year of £28,762k represents the net proceeds of the placings completed in October 2020 and May 2021. Net cash from financing activities in the prior year of £10,670k reflects the net proceeds of the placing and open offer completed in March 2020.

Balance sheet

Total assets increased to £41,790k (2020: £20,976k), largely reflecting the fundraisings completed in October 2020 and May 2021, offset by the utilisation of cash in operating activities highlighted above.

Stock represents raw materials, components, work in progress and finished goods relating to commercial supplies of Alkindi® and Efmody®. Total stock at the year-end increased substantially to £1,625k (2020: £1,241k); this reflects both an unplanned increase in Alkindi® inventory, reflecting lower revenues than expected resulting from Covid-19 restrictions, as detailed above, along with the planned accumulation of launch stocks for Efmody®. As Covid-19 restrictions lift, it is expected that Alkindi® inventories will reduce with the anticipated growth in product sales.

Trade and other receivables increased to £3,433k (2020: £1,337k), largely driven by up-front payments to clinical research organisations relating to the set-up of Efmody® clinical studies totalling £960k and cash proceeds from the sale of Eton shares not yet transferred to Diurnal of £713k.

Investments held at fair value through profit and loss of £970k (2020: £1,668k) solely relate to the shares held in Eton noted above. Reflecting the intention to dispose of the Eton shares, the investment has been reclassified from non-current to current.

Cash and cash equivalents were £34,037k (2020: £15,434k).

Total liabilities increased to £4,226k (2020: £2,591k), primarily due to timing of payments to trade creditors and an increase in accrued expenses, largely arising from an increase in the accrual for employers National Insurance due on the exercise of share options, reflecting the substantial increase in the Company's share price during the year.

Proposed change of accounting year end

In order to better align Diurnal's reporting calendar to its international peer group, the Group intends to change its accounting year end to 31 December. Diurnal intends to operate an 18-month accounting period to 31 December 2022, with interim results to be issued for the six-month period ended 31 December 2021 and 12-month period ended 30 June 2022. Diurnal will provide comparative information for the calendar years ended 31 December 2020 and 31 December 2021 in order to enable investors better track the performance of the Group.

Financial outlook

During the next financial year, the Group will continue to invest in launch activities for Efmody® and in its development pipeline, and will progress activities designed to improve the gross margin of its products whilst minimising its working capital requirements. The Group also remains focused on maintaining a streamlined organisation and a disciplined cost base.

Diurnal expects its cash resources to take its core commercial European cortisol deficiency franchise through to profitability based upon current plans and assumptions, including expectations regarding the timing of product approvals and sales projections. The Group intends to 'ringfence' this franchise and to seek incremental funding and/or partnering arrangements for discrete, future development opportunities. These plans assume that Diurnal enters into a licensing agreement for the commercialisation of Efmody® in the US, and does not include the potential for investment in DITEST™ Phase 3 clinical development and/or Efmody® US studies in adrenal insufficiency, which could require additional financing being available to the Group if the Group was unable to self-finance these activities through its operating cashflows, through additional equity investment, non-dilutive financing and/or partnering arrangements.

Richard Bungay

Chief Financial Officer
13 September 2021

Consolidated income statement
for the year ended 30 June 2021

		Year ended 30 June 2021 £000	Year ended 30 June 2020 £000
	Note		
Revenue	4	4,371	6,313
Cost of sales		(779)	(668)
Gross profit		<u>3,592</u>	<u>5,645</u>
Research and development expenditure		(6,915)	(4,625)
Selling and distribution expenditure		(5,236)	(4,135)
Administrative expenses		(3,056)	(2,904)
Other gains - net	8	15	627
Operating loss		<u>(11,600)</u>	<u>(5,392)</u>
Finance income	5	62	114
Loss before tax		<u>(11,538)</u>	<u>(5,278)</u>
Taxation	6	1,489	1,206
Loss for the year		<u>(10,049)</u>	<u>(4,072)</u>
Basic and diluted loss per share (pence per share)	7	<u>(7.3)</u>	<u>(4.3)</u>

All activities relate to continuing operations.

Consolidated statement of comprehensive income
for the year ended 30 June 2021

	Year ended 30 June 2021 £000	Year ended 30 June 2020 £000
Loss for the year and total comprehensive loss for the year	<u>(10,049)</u>	<u>(4,072)</u>

Consolidated balance sheet
as at 30 June 2021

	Note	2021 £000	2020 £000
Non-current assets			
Intangible assets		92	79
Property, plant and equipment		148	23
Investments held at fair value through profit and loss	8	-	1,668
		<u>240</u>	<u>1,770</u>
Current assets			
Inventories	9	1,625	1,241
Research and development tax credit claims receivable	6	1,485	1,194
Trade and other receivables	10	3,433	1,337
Investments held at fair value through profit and loss	8	970	-
Cash and cash equivalents	11	<u>34,037</u>	<u>15,434</u>
		41,550	19,206
Total assets		<u>41,790</u>	<u>20,976</u>
Current liabilities			
Trade and other payables	12	(4,163)	(2,555)
		<u>(4,163)</u>	<u>(2,555)</u>
Non-current liabilities			
Trade and other payables	12	(63)	(36)
		<u>(63)</u>	<u>(36)</u>
Total liabilities		<u>(4,226)</u>	<u>(2,591)</u>
Net assets		<u>37,564</u>	<u>18,385</u>
Equity			
Share capital	13	8,397	6,082
Share premium		77,414	50,967
Group reconstruction reserve		(2,943)	(2,943)
Accumulated losses		<u>(45,304)</u>	<u>(35,721)</u>
Total equity		<u>37,564</u>	<u>18,385</u>

Consolidated statement of changes in equity

for the year ended 30 June 2021

	Share capital £000	Share premium £000	Group reconstruction reserve £000	Accumulated losses £000	Total £000
Balance at 1 July 2019	4,226	42,153	(2,943)	(32,492)	10,944
Loss for the year and total comprehensive loss for the year	-	-	-	(4,072)	(4,072)
Equity settled share- based payment transactions	-	-	-	843	843
Issue of shares for cash	1,856	9,424	-	-	11,280
Costs charged against share premium	-	(610)	-	-	(610)
Total transactions with owners recorded directly in equity	1,856	8,814	-	843	11,513
Balance at 30 June 2020	6,082	50,967	(2,943)	(35,721)	18,385
Loss for the year and total comprehensive loss for the year	-	-	-	(10,049)	(10,049)
Equity settled share- based payment transactions	-	-	-	466	466
Issue of shares for cash	2,315	28,205	-	-	30,520
Costs charged against share premium	-	(1,758)	-	-	(1,758)
Total transactions with owners recorded directly in equity	2,315	26,447	-	466	29,228
Balance at 30 June 2021	8,397	77,414	(2,943)	(45,304)	37,564

Consolidated cash flow statement
for the year ended 30 June 2021

	Year ended 30 June 2021	Year ended 30 June 2020
Note	£000	£000
Cash flows from operating activities		
(Loss) for the year	(10,049)	(4,072)
<i>Adjustments for:</i>		
Licensing income received as non-cash consideration	-	(1,041)
Fair value adjustment to investments	(15)	(627)
Depreciation and amortisation	24	25
Share-based payment	466	843
Net foreign exchange loss/(gain)	109	(357)
Finance income	5	(114)
Taxation	6	(1,206)
Increase in inventories	(384)	(569)
(Increase)/decrease in trade and other receivables	(2,096)	119
Increase in trade and other payables	1,635	70
Cash used in operations	<u>(11,861)</u>	<u>(6,929)</u>
Tax received	6	2,120
Net cash used in operating activities	<u>(10,662)</u>	<u>(4,809)</u>
Cash flows from investing activities		
Purchase of property, plant and equipment	(138)	(7)
Purchase of intangible assets	(25)	(38)
Proceeds from sale of investment	713	-
Interest received	62	114
Net cash from investing activities	<u>612</u>	<u>69</u>
Cash flows from financing activities		
Net proceeds from issue of share capital	28,762	10,670
Net cash from financing activities	<u>28,762</u>	<u>10,670</u>
Net increase in cash and cash equivalents	18,712	5,930
Cash and cash equivalents at the start of the year	15,434	9,147
Effect of exchange rate changes on cash and cash equivalents	(109)	357
Cash and cash equivalents at the end of the year	<u>34,037</u>	<u>15,434</u>

Notes to the consolidated financial statements

1 Corporate information

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

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

2. Basis of preparation

The financial information set out above does not constitute the Group's statutory accounts for the years ended 30 June 2020 or 2019 but is derived from those accounts. Statutory accounts for 2020 have been delivered to the registrar of companies, and those for 2021 will be delivered in due course. The auditor has reported on those accounts; their reports for 2021 and 2020 were unqualified.

The consolidated financial statements of the Group have been 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 to Regulation (EC) No 1606/2002 as it applies in the European Union. The financial information contained in these financial statements has been prepared under the historical cost convention (as modified to include the revaluation of financial assets held at fair value through profit and loss) and on a going concern basis.

The Group has applied the following standards and amendments for the first time for their annual reporting period commencing 1 July 2020:

- IFRS 3 Business combinations - Amendments to clarify the definition of a business
- IFRS 7 Financial Instruments: Disclosures, IFRS 9 Financial Instruments and IAS 39 Financial Instruments - Amendments regarding pre-replacement issues in the context of the IBOR reform
- IAS 1 Presentation of Financial Statements and IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors - Amendments regarding the definition of material

All amendments listed above did not have any impact on the amounts recognised in prior periods, did not affect the current period and are not expected to significantly affect future periods. All other accounting policies used in the financial information are consistent with those used in the prior year. At the date of these financial statements there were no standards and interpretations in issue but not yet implemented.

Certain new accounting standards and interpretations have been published that are not mandatory for 30 June 2021 reporting periods and have not been early adopted by the Group. There are no standards that are not yet effective and that would be expected to have a material impact on the current or future reporting periods and on foreseeable future transactions.

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

3. Going concern

For the year ended 30 June 2021, the Group made an operating loss of £11.6m on revenue of £4.4m and used net cash in operating activities of £10.7m. Cash and cash equivalents at 30 June 2021 were £34.0m.

The Board has considered the applicability of the going concern basis in the preparation of the financial statements. Based on the Directors' current forecasts and plans (including modelling of a number of scenarios reflecting potential outcomes of the Group's commercialisation efforts for Alkindi® and Efmody®), and considering the cash and cash equivalents at 30 June 2021 of £34.0 million (which reflects the £20.7 million fundraising completed in May 2021 and the £9.8m fundraising completed in October 2020), the Group has sufficient funding for the foreseeable future and at least one year from the date of approval of the financial

statements. For this reason, the Directors continue to adopt the going concern basis in preparing the financial statements. The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate

4. 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. In light of the common supply chain, commercial infrastructure and prescribing audience, 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. This is in line with reporting to senior management and the information used is the same as that disclosed in the financial statements.

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

	Year ended 30 June 2021	Year ended 30 June 2020
	£000	£000
Sale of goods	2,267	2,390
Licence fees	2,104	3,923
	<u>4,371</u>	<u>6,313</u>

License fees for the year ended 30 June 2021 primarily comprises upfront and milestone payments totalling \$2,750k (£1,952k) received from Citrine Medicine ("Citrine") relating to the licensing agreement for Alkindi® signed in January 2021 and for Efmody® signed in May 2021. Of this amount, a total of \$1,500k (£1,071k) relates to upfront payments and \$1,250k (£881k) relates to milestone payments. License fees for the year ended 30 June 2020 comprise the upfront payment received from Eton Pharmaceuticals ("Eton") relating to the licensing agreement signed in March 2020 for Alkindi Sprinkle®, comprising \$3,500k (£2,882k) in cash and 379,474 shares in Eton, recorded at \$1,263k (£1,041k) based on Eton's closing share price at the date of completion of the licensing agreement.

In addition to the payments noted above, the Group is entitled to receive further amounts that become payable on subsequent completion of future milestones as well as royalties based on future sales for both the Citrine and Eton licensing agreements.

The Group has concluded that there are two distinct performance obligations under both licensing agreements: firstly, the license and secondly the manufacture and supply of Alkindi® and Efmody®, since both Citrine and Eton are able to benefit from the license without having Diurnal supply and manufacture the product.

The agreement contains four elements of consideration, namely:

- upfront payment recorded in the financial statements, as noted above;
- milestone payments;
- sales-based royalty payments; and
- recharges of direct costs for the manufacture of Alkindi® or Efmody® stock.

The Group has determined that the licence agreements with Citrine and Eton represent "right-of-use" licences due to the fact that Alkindi® and Efmody® are marketed products in Europe and there are no ongoing activities that significantly affect its intellectual property in China or the US, respectively. The Group has determined that the recharges of direct costs for the manufacture and supply of Alkindi® or Efmody® stock reflect the stand-alone selling price of these products in the agreements such that the remaining consideration is attributable to the license. As such, the upfront payments from Citrine and Eton have been fully recognised as revenue during the year in which they were paid and the milestone payments from Citrine have also been fully recognised as revenue during the year in which they were paid.

Milestone and royalty payments are linked to specific sales-based activities and will be recognised when the underlying sales occur since neither is associated with any future performance obligations. Recharges of direct costs will be recognised on the collection of stock by Citrine or Eton. During the year, £39k of revenue was recognised in respect of royalty payments (2020: £nil).

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

	Year ended 30 June 2021	Year ended 30 June 2020
	£000	£000
UK	1,108	900
Rest of Europe	1,094	1,490
Rest of World	2,169	3,923
	<u>4,371</u>	<u>6,313</u>

5. Finance income

	Year ended 30 June 2021	Year ended 30 June 2020
	£000	£000
Interest receivable on cash and cash equivalents	62	114
Total finance income	<u>62</u>	<u>114</u>

6. Taxation

The Group's main operating subsidiary, Diurnal Limited, is entitled to claim tax credits in the United Kingdom under the UK 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 HMRC.

The Group has reflected R&D tax credits on an accruals basis since establishing a track record of agreeing claims with HMRC. Consequently, the income statement for the year ended 30 June 2020 reflects the R&D tax credit claim for the year ended 30 June 2020, which was received from HMRC in November 2020. The amount in respect of the year ended 30 June 2021 has not yet been agreed with HMRC, although there is no reason to believe that this claim will be rejected.

	Year ended 30 June 2021	Year ended 30 June 2020
	£000	£000
Current tax:		
- UK corporation tax on losses for the year	-	-
- Dutch corporation tax on subsidiary profits for the year	1	2
- Research and development tax credit receivable for the current year	(1,485)	(1,194)
- Prior year adjustment in respect of research and development tax credit	(5)	(14)
Deferred tax:		
- Origination and reversal of temporary differences	-	-
Tax on loss on ordinary activities	<u>(1,489)</u>	<u>(1,206)</u>

Reconciliation of total tax expense

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

	Year ended 30 June 2021 £000	Year ended 30 June 2020 £000
Loss on ordinary activities before tax	(11,538)	(5,278)
Tax at the standard rate of UK corporation tax rate of 19% (2020: 19%)	(2,192)	(1,003)
Effects of:		
Expenses not deductible for tax purposes	52	96
Temporary timing differences	121	3
Enhanced research and development relief	(644)	(521)
Share-based payments	65	61
Prior year adjustment in respect of research and development tax credit	(5)	(14)
Tax losses carried forward	1,114	172
Total tax credits for the year	(1,489)	(1,206)

The standard rate of UK corporation tax has been 19% from 1 April 2017, although this is set to increase to 25% with effect from 1 April 2023.

The Group has accumulated losses available to carry forward against future trading profits of £30,505k (2020: £23,952k). Diurnal believes that a successful launch of Efmody® in Europe will enable it to achieve profitability in future accounting periods; however, as at the balance sheet date the success of the commercial launch remains uncertain. Consequently, no deferred tax asset has been recognised in respect of tax losses since it is uncertain at the balance sheet date as to whether future profits will be available against which the unused tax losses can be utilised. The increase to the rate of corporation tax from 19% to 25% was announced in the March 2021 budget and subsequently enacted on 24 May 2021, and therefore 25% was the prevailing rate at the balance sheet date. The estimated value of the deferred tax asset not recognised at 30 June 2021 is £7,849k measured at a standard rate of 25% (2020: £4,532k at 19%).

7. Loss per share

	Year ended 30 June 2021	Year ended 30 June 2020
Loss for the year (£000)	(10,049)	(4,072)
Weighted average number of shares (000)	137,090	95,228
Basic and diluted loss per share (pence per share)	<u>(7.3)</u>	<u>(4.3)</u>

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

8. Investments held at fair value through profit and loss

	2021	2020
	£000	£000
Balance at 1 July 2020	1,668	-
Additions	-	1,041
Disposals	(713)	-
Fair value adjustment to investments	15	627
Balance at 30 June 2021	<u>970</u>	<u>1,668</u>
Of which:		
Current	970	-
Non-current	-	1,668
Balance at 30 June 2021	<u>970</u>	<u>1,668</u>

Investments at fair value through profit and loss solely relate to 217,782 (2020: 379,474) shares held in Eton Pharmaceuticals that were received as part of the upfront consideration for the exclusive licence agreement of Alkindi Sprinkle® in the US signed in March 2020. During the year the Group sold 161,692 (2020: nil) shares and the Group intends to sell the remaining shares within a year of the balance sheet date and as such has classified the investment as a current asset at the reporting date.

The shares in Eton are treated as a level 1 financial investment in the IFRS 13 fair value hierarchy as the shares are traded in an active market and therefore the value is based on quoted market prices.

The fair value adjustment of these shares, together with the realised profit made on disposals during the year, represents the entire amount charged to the income statement as 'other gains - net'.

9. Inventories

	2021	2020
	£000	£000
Raw materials	123	192
Work in progress	1,046	733
Finished goods	456	316
	<u>1,625</u>	<u>1,241</u>

Inventories recognised as an expense in cost of sales during the year amounted to £779k (2020: £668k). This amount includes provision for obsolete stock of £107k (2020: £17k) as outlined in the Financial Review.

A further provision for Italian stock that is expected to expire before it can be sold is included within selling and distribution expenditure totalling £78k (2020: £nil) as a result of lower than expected sales in Italy due to the impact of Covid-19 on launch activities.

10. Trade and other receivables

	2021	2020
	£000	£000
Trade receivables	361	393
VAT receivable	501	188
Prepayments	1,460	576
Other receivables	1,111	180
	<u>3,433</u>	<u>1,337</u>

Included within other receivables is £713k (2020: £nil) due in respect of the proceeds from the sale of shares in Eton Pharmaceuticals that had not been received at the reporting date (see Note 8).

The Directors consider that the carrying amount of trade and other receivables approximate to their recoverable amount. Trade and other current receivables were all payable within 90 days.

No interest is charged on outstanding receivables. All significant amounts outstanding at the reporting date have been received since the year end and therefore the provision for expected credit losses at 30 June 2021 is £nil (30 June 2020: £nil).

11. Cash and cash equivalents

	2021	2020
	£000	£000
Cash at bank and on hand	<u>34,037</u>	<u>15,434</u>

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

12. Trade and other payables

	2021	2020
	£000	£000
Trade payables	1,728	807
Tax and social security	121	91
Accrued expenses	2,258	1,634
Other payables	119	59
	<u>4,226</u>	<u>2,591</u>

The Group accrues for employer National Insurance contributions that may become due on unexercised share-based payments that are not HMRC tax-advantaged. In the current year £63k (2020: £36k) of the accrued expenses has been classified as a non-current liability.

13. Share capital

	2021	2021	2020	2020
	Number	£000	Number	£000
Ordinary shares of £0.05 each	<u>167,930,008</u>	<u>8,397</u>	<u>121,633,387</u>	<u>6,082</u>