

6 September 2017

# Diurnal Group plc

("Diurnal" or the "Company")

## Results for the year ended 30 June 2017

First marketing authorisation expected H2 2017

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 2017.

# Operational highlights

- Primary endpoint successfully met in European Phase III Infacort<sup>®</sup> registration trial in paediatric adrenal insufficiency (AI)
- Infacort<sup>®</sup> paediatric use marketing authorisation (PUMA) submitted to the European Medicines Agency (EMA)
- First patient dosed in food matrix compatibility study intended to form part of US Phase III registration package for Infacort<sup>®</sup>; expanded global patent estate with first US patent granted for Infacort<sup>®</sup>
- Completed first phase of establishing the Company's European commercial infrastructure and implemented the commercial supply chain for Infacort<sup>®</sup>
- Significant progress in the European Phase III trial of Chronocort<sup>®</sup> in congenital adrenal hyperplasia (CAH), with over 75% of patients enrolled

## **Financial overview**

- Operating loss of £12.1m (2016: £7.0m) reflecting increased investment to support the Group's anticipated development
- Cash and cash equivalents and held to maturity financial assets at 30 June 2017 of £19.9m (2016: £30.1m)
- Net cash used in operating activities was £10.5m (2016: £5.1m), in line with the Board's expectations

# Post-period highlights

- In line with regulatory evaluation, submitted responses to "Day 120 questions" received from the EMA following review of the Infacort<sup>®</sup> PUMA package
- Submitted a proposed Phase III pivotal US registration study design and supporting data package for Chronocort<sup>®</sup> to the US Food and Drug Administration (FDA)
- Further expanded global patent estate with first US patent granted for Chronocort®

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

"Diurnal has delivered key milestones this year; notably, we have successfully completed the registration study and subsequent regulatory submission of Infacort<sup>®</sup> in Europe, with market authorisation anticipated towards the end of 2017, and commenced the build out of the Group's commercial capability in Europe, with first revenues expected in 2018. Also due in the first half of 2018 is the result of the Chronocort<sup>®</sup> European Phase III trial, with the potential for marketing authorisation in 2019. With a combined market for Infacort<sup>®</sup> and Chronocort<sup>®</sup> estimated to be in excess of 400,000 patients, we believe that the potential for Diurnal over the next 12 months looks very positive."

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#### **Notes to Editors**

#### About Diurnal

Founded in 2004, Diurnal is a UK-based specialty pharma company developing high quality products for the global market for the life-long treatment of chronic endocrine conditions, including the orphan diseases Congenital Adrenal Hyperplasia and Adrenal Insufficiency. Its expertise and innovative research activities focus on circadian-based endocrinology to yield novel product candidates in the rare and chronic endocrine disease arena.

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

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## 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**

It is with great pleasure that I report on the significant progress Diurnal has made this financial year towards becoming a world-leading, endocrinology-focused specialty pharma company. Most notably is the delivery of key milestones towards first commercial revenues. Through this period of development, Diurnal has maintained its entrepreneurial and patient-centric approach, which has enabled the progression of a valuable portfolio of novel prospects and provides a solid platform for our future development.

#### Strategy for success

Diurnal aims to develop and commercialise products to address unmet patient needs in chronic endocrine (hormonal) diseases, typically where there is either no licensed medicine or where current treatment does not sufficiently improve the patients' health. Diurnal has identified a number of such needs within the field of endocrinology, which the Group believes represents a multi-billion dollar combined market opportunity. Diurnal is able to gain valuable insights into the burden of living with these diseases through our interaction with physicians and patient groups. These discussions have helped, and continue to help, shape the Group's development plans, such that we can deliver products that not only address important unmet needs and improve patients' lives but also have a positive impact on healthcare budgets.

## Investing for development and value creation

During the year, Diurnal continued to make significant clinical development progress with its late-stage pipeline products, as well as establishing commercial operations in anticipation of future product launches. Infacort<sup>®</sup> and Chronocort<sup>®</sup> are in late-stage clinical development targeting indications of cortisol deficiency: Infacort<sup>®</sup> has completed a Phase III clinical trial and has been submitted for marketing authorisation in Europe and Chronocort<sup>®</sup> is currently undergoing a Phase III clinical trial in Europe. The Group has put in place strong commercial infrastructure in Europe to support the planned launch of Infacort<sup>®</sup>, for which the Group anticipates receiving market authorisation in Europe towards the end of 2017, at which stage development costs will begin to be capitalised in accordance with IAS. The Group plans to leverage its investment in the commercial team through the timely introduction of Chronocort<sup>®</sup> following completion of the ongoing European Phase III clinical trial and regulatory review, expected around the end of 2019. The Group also remains mindful of external growth opportunities and continues to assess endocrinology assets that fit within its disease focus. The US remains a key market for Diurnal and the Group intends to progress the Phase III development of both Infacort<sup>®</sup> and Chronocort<sup>®</sup> in this region during the new financial year, whilst assessing the optimal commercialisation strategy, in parallel.

As planned, the funds raised at the IPO have allowed the Group to continue to build its team, and we have been able to attract highly skilled individuals across the organisation. The agreement with Ashfield Healthcare, announced during the year, has facilitated a rapid and efficient build-out of our European commercial organisation without the need to undertake costly up-front investment in infrastructure in each of our key territories. I am pleased to see that the Ashfield team has integrated seamlessly with Diurnal staff and are rapidly implementing our launch plans.

Diurnal also continues to invest in its earlier-stage pipeline, with good progress being made with the Group's oral native testosterone product, which entered human clinical trials during the year, as well as our programmes in Cushing's Disease (cortisol excess) and hypothyroidism.

#### Board changes and governance

Diurnal strengthened its Board during the year with the appointment of Richard Bungay as Chief Financial Officer. Richard's extensive experience in corporate roles within the biotechnology and pharmaceutical sector, with a particular focus on financing, investor relations and business development, will be invaluable as the Group executes its ambitious development plans.

As the Group continues its rapid development, the Board and Senior Management are focused on maintaining a strong system of internal controls and appropriate risk management systems, to ensure that the business is well-controlled. The Group has made significant investments during the year to ensure that it maintains the highest standards of quality in its operations. The Board continues to monitor the potential effects of "Brexit" on the Group's business and, in particular, any impact on the regulatory framework for pharmaceutical product development, approval and commercialisation as well as any trading impact as we prepare to commercialise Infacort<sup>®</sup> across Europe.

#### People and culture

I would like to thank our employees for their continued support and hard work in driving the Group's progress towards commercialising its first products. Few companies in the UK have successfully taken their own product into a regulatory review and on to commercialisation: it is a testament to the Diurnal team that our key

milestones have been met during a period of intense activity and change. I would also like to thank my fellow Board members for the progress made this year in overseeing a strategy that will ensure continued and sustainable growth from our pipeline.

Finally, I would like to thank our shareholders for their continued support as Diurnal aims to make a real difference to patients without effective treatment options for chronic endocrine diseases.

Peter Allen Chairman 5 September 2017

## **Operational Review**

The financial year to 30 June 2017 has seen Diurnal continue to build on the momentum following its Initial Public Offering ("IPO") in December 2015 through the delivery of key milestones, contributing towards its vision of becoming a world-leading specialty pharma company focused on endocrinology. In line with the Group's strategy set out at the time of the IPO, and supported by the financial strength provided by the IPO, Diurnal has successfully completed the registration study and subsequent regulatory submission of Infacort<sup>®</sup> in Europe, with market authorisation anticipated towards the end of 2017, and commenced the build out of the Group's commercial capability in Europe, with first revenues expected in 2018. The progress the Group has made over the last year has set the business up for a commercial step change to drive the next stage of development. Diurnal believes that it has an opportunity to become one of the few UK biotechnology companies to successfully take a product from concept to commercialisation.

Diurnal believes that its strategy of developing novel products using well-characterised active ingredients to meet significant unmet medical needs offers a lower risk approach than the development of new chemical or biological entities whilst enabling significant in-market protection through both patent filings and regulatory protection. For example, the active ingredient of both Infacort<sup>®</sup> and Chronocort<sup>®</sup>, hydrocortisone, is extremely well-tolerated, with an extensive safety database through over 50 years of clinical use. Diurnal's product candidates are protected by a wholly owned patent portfolio, benefitting from granted or pending patents in key jurisdictions, along with strong protection through Orphan Drug designations.

## Significant progress towards commercialisation of Infacort<sup>®</sup> in Europe

Infacort<sup>®</sup> is Diurnal's most clinically advanced product and is the first preparation of hydrocortisone (the synthetic version of cortisol) specifically designed for use in children suffering from adrenal insufficiency (AI), including the related disease, congenital adrenal hyperplasia (CAH). Currently there is no licensed hydrocortisone preparation in Europe or the US specifically designed to treat these young patients. Infacort<sup>®</sup> is expected to be the first pharmaceutically defined dose and consistent formulation of hydrocortisone designed specifically for children. The patented, immediate-release oral product has been designed to meet the dosing needs of children and is manufactured using commercially proven technology in paediatric acceptable doses to give maximum flexibility to clinicians in tailoring treatment to children as they develop and grow. Currently, pharmacists often compound (grind) hydrocortisone tablets to a fine powder and reconstitute it into individual capsules or sachets to achieve the lower doses required for children. Compounding is not a licensed method of producing medicines; it can be highly variable and may result in inaccurate dosing to patients.

At the start of the financial year, Diurnal announced positive headline data from the pivotal Phase III clinical trial for Infacort<sup>®</sup> in Europe for paediatric AI. The study met its primary endpoint, demonstrating a statistically significant (p<0.0001) increase in cortisol values following administration of Infacort<sup>®</sup> compared to the predose values. No serious adverse events were reported. AI (and CAH) are identified as rare diseases in Europe where there are estimated to be around 4,000 sufferers younger than the age of six. Left untreated, the disease is associated with significant morbidity. Many patients from the Phase III clinical trial are continuing treatment in the Group's European open-label safety extension trial of long term safety and biochemical disease control, which will provide further valuable safety data to support the registration and commercialisation of Infacort<sup>®</sup>.

Following the positive Phase III results, Diurnal submitted a paediatric use marketing authorisation (PUMA) application for Infacort<sup>®</sup> to the European Medicines Agency (EMA) in December 2016. Shortly after the end of the financial year, and in line with regulatory evaluation, Diurnal provided responses to the questions ("Day 120 questions") received from the EMA following their review of the PUMA package, and the Group continues to anticipate recommendation for marketing authorisation approval for Infacort<sup>®</sup> in Europe towards the end of 2017.

Reflecting a small, focused prescribing base, Diurnal intends to commercialise Infacort<sup>®</sup> itself in the major European markets, following regulatory approval, in order to retain the full value of the product and has made significant progress during the year in establishing its European commercial operations. Diurnal's small inhouse commercial team has been supplemented through a service agreement with the respected global contract sales organisation Ashfield Healthcare ("Ashfield") to support the Group in building its sales and medical infrastructure in major European territories. Ashfield, under the direction of the Group's commercial leadership, has completed the planned first phase of establishing a Europe-wide team to prepare for the anticipated launch of Infacort<sup>®</sup> in 2018, with nine individuals currently in place in key European territories and fully integrated with the Diurnal in-house team. Outside of its core territories, Diurnal will seek local distribution arrangements where there is a significant market for the Group's products and executed the first such agreement early in 2017. During the year, Diurnal has also put in place the commercial supply chain for the manufacture and packaging of Infacort<sup>®</sup> with leading global expert service providers.

#### Continued progress in late-stage product pipeline

Diurnal's second late-stage product candidate, Chronocort<sup>®</sup>, provides a drug release profile that the Group believes mimics the body's natural cortisol circadian rhythm, which current therapy is unable to replicate. Chronocort<sup>®</sup> is designed to improve disease control for adults with CAH: clinical data has shown that approximately two thirds of CAH patients are estimated to have poor disease control. CAH sufferers, even if treated, remain at risk of death through an adrenal crisis, suffer from high morbidity and a poor quality of life. The condition is estimated to affect approximately 51,000 patients in Europe and 20,000 patients in the US, with approximately 405,000 patients in the rest of the world.

Chronocort<sup>®</sup> is currently being assessed in a Phase III trial in Europe, which is designed to study up to 110 patients in an open-label six-month treatment protocol. Enrolled patients currently treated with a single or combination of generic steroids (standard-of-care) will be randomised to Chronocort<sup>®</sup> on a twice-daily "toothbrush" regimen or will continue on their standard-of-care regimen. The primary endpoint of the trial is the control of androgens (sex hormones) on the same or lower total daily dose of steroid when treated with Chronocort<sup>®</sup> compared to standard-of-care treatment. This primary endpoint is identical to the previous successful Phase II clinical trial for Chronocort<sup>®</sup>. Secondary endpoints will include an assessment of fatigue levels and the relative effect of Chronocort<sup>®</sup> on body mass index and bone turnover, all of which are indicative of clinical benefits. The trial continues to progress well with over 75% of patients recruited at the end of the financial year and is scheduled to complete in the first half of 2018, implying a potential market authorisation in Europe could be forthcoming around the end of 2019.

An open-label safety extension trial of long-term safety, efficacy and tolerability of Chronocort<sup>®</sup> in patients with CAH, previously enrolled in the Phase III registration trial, commenced in August 2016 and is intended to provide further valuable safety data to support the registration and commercialisation of Chronocort<sup>®</sup>.

The Company continues to progress discussions with the US Food and Drug Administration (FDA) regarding the requirements for the registration programme for Infacort<sup>®</sup> and Chronocort<sup>®</sup> in the US. Clinical study design requirements for CAH differs between the US and Europe, meaning that a separate clinical programme will be required for registration of these two products in the US. In June 2017, the Group dosed the first patient in a food matrix compatibility study for Infacort<sup>®</sup> in healthy volunteers, which is intended to support the planned US registration package for Infacort<sup>®</sup> for the treatment of paediatric AI. Diurnal is continuing discussions with the FDA to finalise additional requirements for the planned US registration package for Infacort<sup>®</sup>. After the end of the financial year Diurnal submitted a proposed Phase III pivotal US registration study design and supporting data package for Chronocort<sup>®</sup> to the FDA and, subject to their agreement, expects to commence this study around the end of 2017.

#### Building a novel early-stage endocrinology pipeline

During the year, the Group has continued to build on its strong platform in underserved endocrinology diseases such as those associated with the gonads, pituitary and thyroid.

In late 2016, the Group announced dosing of the first patient with its native oral testosterone product, DITEST, for the treatment of male hypogonadism in a Phase I clinical study designed to evaluate pharmacokinetics, safety and tolerability in male patients with hypogonadism. Following a review of data from the first cohort of this study, in which the pharmacokinetics of DITEST were compared to testosterone undecanoate in patients following a meal, DITEST will progress to the second cohort of the study, which will compare its pharmacokinetics in a fed state and fasted state. The results from this study are expected in the first half of 2018.

During the year, the Group initiated studies to assess the potency of different formulations of its oligonucleotide (siRNA) therapy, targeted to the pituitary gland, for the potential treatment of Cushing's Disease (cortisol excess). If successful, these studies would facilitate preclinical efficacy and safety studies, ahead of potentially entering a product candidate into human clinical development.

Following a review of the current market for treatments for hypothyroidism, the Group has concluded that the needs of patients for replacement of T4 (thyroxine) are being met adequately with recently introduced products to the market. Accordingly, the Group has ceased work on its Tri4Combi<sup>™</sup> formulation and is currently finalising plans for the development of a modified-release T3 (triiodothyronine) product, where there remains a significant unmet medical need.

#### Maximising the commercial value of the product pipeline

As highlighted above, the Group has made excellent progress during the year in assembling a European sales and marketing force that is able to commercialise Infacort<sup>®</sup> and subsequently Chronocort<sup>®</sup> and other pipeline products. The environment for the successful introduction of novel healthcare products in the US remains challenging, in particular with regards to ensuring that market access is optimised for a product launch. Accordingly, Diurnal is likely to capitalise on the strong interest in its programmes and seek a US partner for commercialisation of its late-stage pipeline products at an appropriate time. Diurnal will also seek local distribution arrangements for territories outside the US and Europe where there is a significant market for the Group's products. In March 2017, Diurnal announced a distribution agreement with Medison Pharma Limited ("Medison") for Israel. Medison is a leader in the marketing of specialist-focused products in Israel and will help Diurnal optimise the value of Infacort<sup>®</sup> and Chronocort<sup>®</sup> in this territory, subject to approval in Europe and subsequently in Israel. Diurnal continues to assess opportunities for similar agreements, addressing selected high-value markets.

In March 2017, the Group announced a partnership with Clinigen Group plc's IDIS Managed Access division to launch a Patient Access programme in Europe for Infacort<sup>®</sup> and Chronocort<sup>®</sup> to ensure that patients with cortisol deficiency but no other treatment options can access these medicines as efficiently as possible ahead of anticipated European approval and commercial launch.

## Extensive in-market protection

Diurnal continues to protect its product candidates through an extensive patent portfolio, benefitting from a number of granted or pending patents in key jurisdictions. During the year, the Group received notification of the grant of three US Infacort<sup>®</sup> patents, of which two key patents have been granted: a composition of matter patent for the product formulation and a method of treatment patent for all forms of adrenal insufficiency. These granted patents provide in-market protection for Infacort<sup>®</sup> to 2034. The Group expects to continue to expand patent coverage for its pipeline products in the future.

In addition to the strong and growing patent protection for its pipeline products, the FDA has granted Chronocort<sup>®</sup> Orphan Drug Designation in the treatment of both CAH and AI and has granted Infacort<sup>®</sup> Orphan Drug Designation in the treatment of paediatric AI. Diurnal has applied for a PUMA for Infacort<sup>®</sup> in Europe, whilst Chronocort<sup>®</sup> already benefits from orphan drug designations for CAH and AI in Europe. These orphan drug designations mean Infacort<sup>®</sup> and Chronocort<sup>®</sup> have the potential to be granted market and data exclusivity for 10 years in Europe and seven years in the US post market authorisation.

#### Outlook

The Group is well-positioned for its anticipated transformation into a fully-integrated, world-leading, endocrinology-focused speciality pharma company with the approval of its first product, Infacort<sup>®</sup>, which Diurnal continues to expect in H2 2017. Together with its other late-stage product, Chronocort<sup>®</sup>, Diurnal has the opportunity to build a life-long adrenal franchise, providing critical medicine in underserved diseases of cortisol deficiency. With the European Chronocort<sup>®</sup> pivotal trial on track to read out in the first half of 2018 and with over 75% of patients already recruited by the end of the financial year, the Group believes that a marketing authorisation in Europe could be forthcoming around the end of 2019. Reflecting a combined market size estimated at over 400,000 patients in Europe and the US alone for Infacort<sup>®</sup> and Chronocort<sup>®</sup>, the Board believes that the potential for Diurnal looks very positive.

Martin Whitaker Chief Executive Officer 5 September 2017

## **Financial Review**

# **Operating income and expenses**

Operating expenses are in a growth phase, reflecting the increased clinical and development activities together with investment in headcount and business infrastructure to support the transition of the business to a fully-integrated speciality pharma organisation with product origination, development and commercialisation capabilities. This continued investment in the business will support its anticipated growth and development in the coming years.

Research and development expenditure for the year was £8.3m (2016: £3.9m). Expenditure on product development and clinical costs increased in the period as the Group submitted the Infacort<sup>®</sup> PUMA application to the EMA and continued to progress Chronocort<sup>®</sup> in a Phase III registration trial in Europe. The Group also recruited the first patients from the Chronocort<sup>®</sup> Phase III trial into a long-term follow-on study and commenced a Phase I study with its native oral testosterone product in hypogonadal patients. Staff-related expenditure also increased as a result of the appointment of new staff and the full impact of the implementation of a new remuneration policy, comprising annual bonus and long-term incentive schemes in H2 2015, following the IPO. The Group has not capitalised development costs for Infacort<sup>®</sup> during the new financial year following the successful Phase III trial in Europe since a key element of the in-market protection for Infacort<sup>®</sup> is the exclusively afforded by the PUMA, which only takes effect once the product is approved by the EU. The Group intends capitalising Infacort<sup>®</sup> development costs under IAS38 following the anticipated approval of the PUMA.

Administrative expenses for the year were £3.7m (2016: £3.1m). A substantial increase in precommercialisation expenses, as the Group prepares for the anticipated launch of Infacort<sup>®</sup> in 2018, along with the appointment of new staff and the full impact of the implementation of a new remuneration policy in the prior period was offset by costs of £0.6m in the prior period relating to fees paid in connection with the AIM admission.

## **Operating loss**

Operating loss for the year increased to £12.1m (2016: £7.0m), reflecting the increased operating expenses outlined above.

## Financial income and expense

Financial income in the period was £182k (2016: £63k), due to the higher average cash balances during the year: the funds from the IPO fundraising and the convertible loan were received in late December 2015 and consequently only had an impact for half of the prior year. Financial expense for the period was £272k (2016: £133k), being the financial expense of the convertible loan. No interest is payable in cash on this loan, the financial expense representing the effective interest required under accounting standards to charge the transaction costs and equity element of the loan to the income statement over the term of the loan.

#### Loss on ordinary activities before tax

Loss before tax for the period was £12.2m (2016: £7.1m).

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The current year includes Research & Development tax credits relating to the year ended 30 June 2016 of £911k, received in August 2017, as well as the estimated claim in respect of the year ended 30 June 2017 of £1,819k, which has not yet been submitted to HMRC. The prior year includes a credit in respect of the approval by HMRC of the R&D tax credit claim for the period ended 30 June 2015. The Group has not recognised any deferred tax assets in respect of trading losses arising in either the current financial period or accumulated losses in previous financial years.

#### Earnings per share

Loss per share was 18.0 pence (2016: 15.0 pence). Loss per share has increased due to the higher operating costs explained above.

# Cash flow

Net cash used in operating activities was £10.5m (2016: £5.1m), driven by the planned increase in investment in R&D and business infrastructure during the year. Net cash from investing activities was £3.2m (2016: net cash used in investing activities £14.0m) reflecting a net movement from longer-dated held to maturity financial assets to short-dated cash and cash equivalents. Net cash generated by financing during the prior period of £29.1m reflects the net proceeds of the issue of shares in the IPO and funds received from issue of the convertible loan in December 2015.

#### Balance sheet

Total assets decreased to £23.9m (2016: £30.7m), largely reflecting the utilisation of cash in operating activities highlighted above. Held to maturity financial assets were £11.0m (2016: £14.0m) and cash and cash equivalents were £8.9m (2016: £16.1m). Total liabilities increased to £6.9m (2016: £4.7m), reflecting an increase in trade payables and accruals at the year-end associated with the increased level of operating activities. Net assets were £17.1m (2016: £25.9m).

## **Comparative information**

The Group has applied the principles of reverse acquisition accounting under IFRS 3 'Business Combinations' in the presentation of consolidated shareholders' equity for the prior period. These comparative periods show the results of the accounting acquirer (Diurnal Limited) along with the share capital structure of the parent company (Diurnal Group plc). As a result, the consolidated share capital and share premium presented for comparative periods is that which was in existence immediately following the share for share exchange which occurred on 1 December 2015, and which is explained further in Note 2 to the financial statements.

Richard Bungay Chief Financial Officer 5 September 2017

# Consolidated income statement

for the year ended 30 June 2017

	Note	Year ended 30 Jun 2017 £000	Year ended 30 Jun 2016 £000
Research and development expenditure		(8,340)	(3,886)
Administrative expenses		(3,734)	(3,106)
Other operating income		9	-
Operating loss		(12,065)	(6,992)
Financial income	4	182	63
Financial expense	5	(272)	(133)
Loss before tax		(12,155)	(7,062)
Taxation	6	2,730	491
Loss for the year		(9,425)	(6,571)
Basic and diluted loss per share (pence per share)	7	(18.0)	(15.0)

All activities relate to continuing operations.

# Consolidated statement of comprehensive income

for the year ended 30 June 2017

	Year ended 30 Jun 2017 £000	Year ended 30 Jun 2016 £000
Loss for the year	(9,425)	(6,571)

# **Consolidated balance sheet**

as at 30 June 2017

	Note	2017 £000	2016 £000
Non-current assets			
Intangible assets		4	6
Property, plant and equipment		18	3
		22	9
Current assets			
Trade and other receivables	8	4,025	530
Held to maturity financial assets	9	11,000	14,000
Cash and cash equivalents	10	8,881	16,114
		23,906	30,644
Total assets		23,928	30,653
Current liabilities			
Trade and other payables	11	(3,341)	(1,480)
		(3,341)	(1,480)
Non-current liabilities			
Loans and borrowings	12	(3,511)	(3,239)
		(3,511)	(3,239)
Total liabilities		(6,852)	(4,719)
Net assets		17,076	25,934
Equity			
Share capital	13	2,616	2,610
Share premium		23,675	23,632
Consolidation reserve		(2,943)	(2,943)
Other reserve		1,458	1,458
(Accumulated losses)/Retained earnings		(7,730)	1,177
Total equity		17,076	25,934
-			

# **Consolidated statement of changes in equity** for the year ended 30 June 2017

	Share capital £000	Share premium £000	Consolidation reserve £000	Other reserve £000	(Accumulated losses)/ Retained earnings £000	Total £000
Balance at 30 June 2015	15,351	-	(2,943)		(6,367)	6,041
Loss for the year and total comprehensive loss for the year Equity settled share	-	-	-	-	(6,571)	(6,571)
based payment transactions	-	-	-	-	490	490
Reduction of capital	(12,107)	-	-	-	12,107	-
lssue of shares for cash	884	24,465	-	-	-	25,349
Costs charged against share premium	-	(833)	-	-	-	(833)
Equity component of convertible loan	-	-	-	1,486	-	1,486
lssue expenses of convertible loan	-	-	-	(28)	-	(28)
Repurchase of deferred shares Total transactions with	(1,518)	-	-	-	1,518	-
owners recorded directly in equity	(12,741)	23,632	-	1,458	14,115	26,464
Balance at 30 June 2016	2,610	23,632	(2,943)	1,458	1,177	25,934
Loss for the year and total comprehensive loss for the year	-	-	-	-	(9,425)	(9,425)
Equity settled share based payment transactions	-	-	-	-	518	518
lssue of shares for cash	6	43	-	-	-	49
Total transactions with owners recorded directly in equity	6	43	-	-	(8,907)	(8,858)
Balance at 30 June 2017	2,616	23,675	(2,943)	1,458	(7,730)	17,076

# Consolidated cash flow statement

for the year ended 30 June 2017

	Note	Year ended 30 Jun 2017 £000	Year ended 30 Jun 2016 £000
Cash flows from operating activities			
Loss for the year		(9,425)	(6,571)
Adjustments for:			
Depreciation, amortisation and impairment		7	6
Share-based payment		518	490
Financial income	4	(182)	(63)
Finance expenses	5	272	133
Taxation	6	(2,730)	(491)
Increase in trade and other receivables		(771)	(135)
Increase in trade and other payables	_	1,861	1,081
Cash used in operations		(10,450)	(5,550)
Interest paid	-	-	-
Tax received	7 _	- (40, 450)	491
Net cash used in operating activities	_	(10,450)	(5,059)
Oral flows from investing activities			
Cash flows from investing activities		(20)	
Additions of property, plant and equipment Purchases of held to maturity financial assets		(20) (11,000)	- (14,000)
Disposal of held to maturity financial assets		(11,000) 14,000	(14,000)
Interest received		14,000	- 44
	_	3,169	
Net cash from / (used in) investing activities	_	3,109	(13,956)
Cash flows from financing activities			
Net proceeds from issue of share capital		48	24,516
Repayment of borrowings			(24)
Net proceeds from issue of borrowings		-	4,564
Net cash generated by financing activities	—	48	29,056
Net cash generated by maneing activities	<u> </u>		23,000
Net (decrease) / increase in cash and cash equivalents		(7,233)	10,041
Cash and cash equivalents at the start of the year		16,114	6,073
Cash and cash equivalents at the end of the year	_	8,881	16,114

## Notes to the consolidated financial statements

# 1 Corporate information

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

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

To facilitate its IPO in December 2015, the Company was incorporated as Project Dime Limited on 28 October 2015, acquired the entire issued share capital of Diurnal Limited under a share for share exchange on 1 December 2015 and reregistered as a public company and changed its name to Diurnal Group plc on 4 December 2015. The Company has applied the principles of reverse acquisition accounting in the preparation of the consolidated financial information.

# 2. Basis of preparation

The financial information set out above does not constitute the Group's statutory accounts for the years ended 30 June 2017 or 2016 but is derived from those accounts. Statutory accounts for 2016 have been delivered to the registrar of companies, and those for 2017 will be delivered in due course. The auditor has reported on those accounts; their reports were (i) unqualified, (ii) did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying their report and (iii) did not contain a statement under section 498 (2) or (3) of the Companies Act 2006.

The consolidated financial information has been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union, IFRIC interpretations and the Companies Act 2006. The financial information contained in these financial statements have been prepared under the historical cost convention, and on a going concern basis.

The accounting policies used in the financial information are consistent with those used in the prior year. The following adopted IFRSs have been issued but have not been applied by the Group in these financial statements. Their adoption is not expected to have a material effect on the financial statements unless otherwise indicated:

- IFRS 2 *Share-based Payment* Amendments to clarify the classification and measurement of sharebased payment transactions effective 1 January 2018
- IFRS 9 *Financial Instruments* effective 1 January 2018
- IFRS 15 Revenue from Contracts with Customers effective 1 January 2018
- IFRS 16 Leases effective 1 January 2019
- IFRS 17 Insurance Contracts effective 1 January 2021
- IAS 1 *Presentation of Financial Statements* Amendments as result of the Disclosure initiative effective 1 January 2017
- IAS 7 Statement of Cash Flows Amendments as result of the Disclosure initiative effective 1 January 2017
- IAS 12 *Income Taxes* Amendments regarding the recognition of deferred tax assets for unrealised losses effective 1 January 2017
- IAS 40 *Investment Property* Amendments to clarify transfers or property to, or from, investment property effective 1 January 2018

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. Segmental information

The Board regularly reviews the Group's performance and balance sheet position for its operations and receives financial information for the Group as a whole. As a consequence, the Group has one reportable segment, which is Clinical Development. Segmental profit is measured at operating loss level, as shown on the face of the Consolidated Income Statement. As there is only one reportable segment whose losses, expenses, assets, liabilities and cash flows are measured and reported on a basis consistent with the financial statements, no additional numerical disclosures are necessary.

#### 4. Finance income

	Year ended	Year ended
	30 Jun 2017	30 Jun 2016
	£000	£000
Interest receivable on cash and cash equivalents and term deposits	182	63
Total finance income	182	63

# 5. Finance expenses

	Year ended	Year ended
	30 Jun 2017	30 Jun 2016
	£000	£000
Total interest payable on loans	272	133
Total finance expense	272	133

#### 6. Taxation

The Group is entitled to claim tax credits in the United Kingdom under the UK research and development (R&D) small or medium-sized enterprise (SME) scheme, which provides additional taxation relief for qualifying expenditure on R&D activities, and includes an option to surrender a portion of tax losses arising from qualifying activities in return for a cash payment from HM Revenue & Customs (HMRC). The tax credit included in the Income Statement for the year ended 30 June 2016 reflected the approval by HMRC of the R&D tax credit claim in respect of the 13-month period ended 30 June 2015. With effect from the year ended 30 June 2017, the Group will reflect R&D tax credits on an accruals basis since it has established a track record of agreeing claims with HMRC. Consequently, the Income Statement for the year ended 30 June 2016, which was approved by HMRC in July 2017, along with the estimated claim for the year ended 30 June 2017. The amount in respect of the year ended 30 June 2017. The amount in respect of the year ended 30 June 2017 has not yet been agreed with HMRC, although there is no reason to believe that this claim will be rejected.

	Year ended 30 Jun 2017 £000	Year ended 30 Jun 2016 £000
Current tax:		
- UK corporation tax on losses of year	-	-
<ul> <li>Research and development tax credit receivable for the current year</li> <li>Prior year adjustment in respect of research and development tax</li> </ul>	(1,819)	-
credit	(911)	(491)
Deferred tax:		
- Origination and reversal of temporary differences		-
Tax on loss on ordinary activities	(2,730)	(491)

#### Reconciliation of total tax expense

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

	30 Jun 2017 £000	30 Jun 2016 £000
Loss on ordinary activities before tax	(12,155)	(7,062)
Tax at the standard rate of UK corporation tax rate of 19.75% (2015/16: 20%)	(2,401)	(1,412)
Effects of:		
Expenses not deductible for tax purposes	1	-
Depreciation in excess of capital allowances	(3)	-
Enhanced research and development relief	(741)	-
Share based payments	102	104
Prior year adjustments	(911)	(491)
Tax losses carried forward	1,223	1,308
Current tax credits for the year	(2,730)	(491)

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

## 7. Loss per share

	Year ended 30 Jun 2017	Year ended 30 Jun 2016
Loss for the year (£000) Weighted average number of shares (000)	(9,425) 52,235	(6,571) 43,746
Basic and diluted loss per share (pence per share)	(18.0)	(15.0)

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. Trade and other receivables

	2017	2016
	£000	£000
VAT recoverable	300	37
Prepayments	705	345
Other debtors	290	148
R&D tax credit claims receivable	2,730	-
	4,025	530

# 9. Held to maturity financial assets

	2017 £000	2016 £000
Bank term deposits	11,000	14,000

The effective interest rate on bank deposits was 0.64% and these deposits had a weighted average maturity of 7 months. 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 £8m and that the maximum term is 12 months. The Group's deposits are in line with this policy.

# 10. Cash and cash equivalents

	2017	2016
	£000	£000
Cash at bank and on hand	8,881	16,114

The Group holds its cash and cash equivalents with its clearing bank and in a AAA rated Liquidity fund providing same day access to its cash. Although the Liquidity fund balance exceeds the Group's £8m counterparty limit, the Board is satisfied that the individual counterparty risk within the fund is significantly below this amount.

# 11. Trade and other payables

	2017	2016
	£000	£000
Trade payables	1,724	235
Other tax and social security	65	36
Accrued expenses and deferred income	1,552	1,209
	3,341	1,480
12. Loans and borrowings		

	2017 £000	2016 £000
Non-current loans and borrowings		
Convertible Loans	3,511	3,239

# IP Group convertible loan

On 24 December 2015 the Company received £4.7m from IP2IPO Limited, a wholly owned subsidiary of IP Group plc under a convertible loan agreement. The convertible loan facility is interest-free and unsecured with a maturity date of 24 December 2020 (or such other date as the parties may agree) at which point the Company may either repay the principal amount outstanding in full or convert such amount into non-voting shares at a lower nominal value to that of the Ordinary Shares to ensure that IP2IPO Limited did not have control of the Company. IP2IPO Limited may convert the principal outstanding in whole or in parts exceeding £0.1m into ordinary shares calculated at the IPO share price of £1.44 per share conditional on it not having control of the Company resulting from the conversion.

The convertible loan note is a compound financial instrument containing a host financial liability and an equity component as there is a contractual obligation to deliver a fixed number of shares at the IPO price if the loan note is converted.

At 30 June 2017, the amount outstanding comprised:

	2017	2016
	£000	£000
Loan amount brought forward	3,239	-
Face value of convertible loan issued on 24 December 2015	-	4,651
Equity Component	-	(1,486)
Issue costs relating to the liability element	-	(59)
Accrued interest	272	133
Liability component at year end	3,511	3,239
Less amount included in current liabilities		-
Included in non-current liabilities	3,511	3,239

# 13. Share capital

	2017	2017	2016	2016
	Number	£000	Number	£000
Ordinary shares of £0.05 each	52,320,759	2,616	52,210,759	2,610

The Group has applied the principles of reverse acquisition accounting under IFRS 3 'Business Combinations' in the presentation of consolidated shareholders' equity for comparative periods. These comparative periods show the results of the accounting acquirer (Diurnal Limited) along with the share capital structure of the parent company (Diurnal Group plc). As a result, the consolidated share capital and share premium presented for comparative periods is that which was in existence immediately following the share for share exchange which occurred on 1 December 2015.