



# Determined to deliver

**Circassia Pharmaceuticals plc**

Annual report and accounts 2016

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### **Circassia in brief**

Circassia is a world-class specialty respiratory pharmaceutical business with a strong commercial infrastructure, marketed products and portfolio of treatments targeting major market opportunities. The Company sells its novel, market-leading NIOX<sup>®</sup> asthma management products directly to specialists in the United States, United Kingdom and Germany, and in a wide range of other countries through its network of partners. Circassia recently established a collaboration with AstraZeneca in the United States in which it promotes the chronic obstructive pulmonary disease (COPD) treatment Tudorza<sup>®</sup>, and has the US commercial rights to late-stage COPD product Duaklir<sup>®</sup>.

Circassia's broad-based development pipeline includes a range of respiratory medicines. The Company's lead asthma treatment, Fliveo<sup>®</sup>, targets substitution of GSK's Flixotide<sup>®</sup> pMDI and is approved in the UK. Circassia is also developing a direct substitute for Seretide<sup>®</sup> pMDI, Seriveo<sup>®</sup>. In addition, the Company's pipeline includes a number of inhaled medicines for COPD, including single and combination dose products. For more information on Circassia please visit [www.circassia.com](http://www.circassia.com).

## Contents

### Strategic report

- 02 Investment proposition
- 10 Delivering a broad and balanced portfolio
- 12 Chairman's statement
- 14 Operational and financial highlights
- 16 Chief Executive's review
- 18 Business model
- 20 Strategy and progress against objectives
- 22 Strategic review
- 29 Financial review
- 33 Corporate social responsibility
- 36 Risks and risk management

### Corporate governance

- 42 Board of Directors
- 44 Corporate governance
- 55 Remuneration committee report
- 76 Directors' report
- 78 Statement of Directors' responsibilities
- 79 Independent Auditors' report

### Group financial statements

- 84 Consolidated statement of comprehensive income
- 85 Consolidated statement of financial position
- 86 Parent Company statement of financial position
- 87 Consolidated and parent Company statement of cash flows
- 88 Consolidated statement of changes in equity
- 89 Parent Company statement of changes in equity
- 90 Notes to the financial statements
- 115 Glossary
- 116 Advisors and contact details



## We're building a strong portfolio of marketed products

See page 02



## We're strengthening our development pipeline

See page 04



## We're focusing on our customers

See page 06



## We're expanding our global presence

See page 08

# We're building a strong portfolio of marketed products

Specialty products focused on asthma and chronic obstructive pulmonary disease

# 2

marketed products with more close behind



## NIOX® for FeNO

Clinical evidence shows monitoring FeNO helps improve asthma management

- Improves diagnosis by uncovering airway inflammation
- Improves determination of inhaled steroid responsiveness
- Improves stepwise dosing of inhaled steroids
- Improves monitoring of asthma control and treatment adherence
- With potential to reduce exacerbations

## Tudorza® for chronic obstructive pulmonary disease

In our newly established US collaboration with AstraZeneca we will commercialise Tudorza®

- Improves lung function (FEV<sub>1</sub>) in COPD
- Features novel patient-friendly and easy-to-use inhaler
- Improves night-time lung function on day one vs market leader
- With placebo-like anticholinergic side-effects typically associated with product class





## Over 50%

Our NIOX® revenues are growing strongly. We increased our worldwide sales during 2016, and plan to continue growing our revenues in the coming year. So far we are making good progress. During the first quarter of 2017 our US clinical sales are up over 50%, following the expansion of our sales force in 2016.

## \$80 million

During 2016 our collaboration partner AstraZeneca achieved \$80 million of revenues related to Tudorza® US sales. With a focused commercialisation plan in place, we plan to maintain and potentially enhance this performance as we rapidly expand our commercial presence in this major market.

# We're strengthening our development pipeline

Balanced and broad portfolio with near, medium- and longer-term products

# 6

respiratory medicines in development for asthma and chronic obstructive pulmonary disease



## Duaklir®

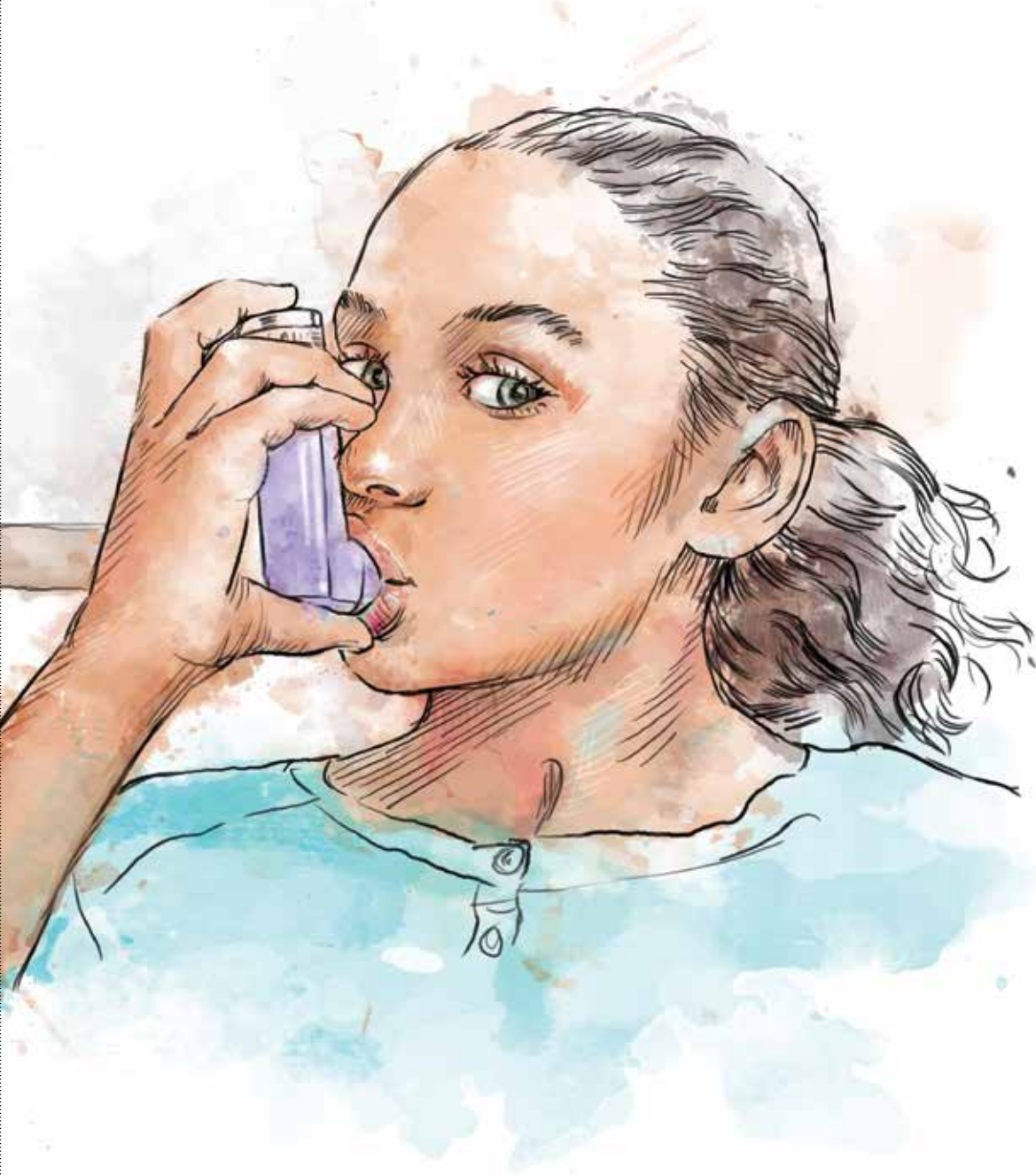
Duaklir® is currently in phase III development for chronic obstructive pulmonary disease (COPD) in the United States. Our partner AstraZeneca plans to submit an NDA to the US regulatory authorities in the first half of 2018 and we hope to launch the product the following year.

## Direct substitutes

Our lead asthma medicine, Fliveo®, is already approved in the UK, and targets direct substitution of GSK's Flixotide® pMDI. We are working with our partner Mylan to develop a similar product for the United States. In parallel, we are working on direct substitutes for GSK's Seretide®/Advair® pMDI and Boehringer Ingelheim's Spiriva Handihaler®.

## Novel formulations

Our novel formulations for COPD are based on approved drugs. These formulations target underserved segments of the specialist moderate-to-severe COPD market, and we have completed initial technical assessments for both.



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## \$24 billion

The respiratory market represents a \$24 billion opportunity. It is predicted to undergo significant change, with current products facing generic competition and new entrants taking an increasing market share, and the overall value growing modestly. We have the opportunity to exploit these dynamics with our direct substitutes in the near-term and novel formulations in the longer-term.

## 3rd

Approximately 15.7 million adults in the United States have been diagnosed with COPD and several million more are estimated to be undiagnosed. The disease is responsible for over 120,000 deaths per year in the US making it the country's third leading cause of mortality.

## GOLD

The 2017 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines now include long-acting muscarinic antagonist containing products (LAMAs), such as our Duaklir® and Tudorza®, as preferred initial treatments for every group of COPD patient. This is a marked move from previous recommendations, supporting a shift to LAMA-based products.



# We're focusing on our customers

Expanding commercial presence targeting key customers in major markets



# 100%

larger commercial team focused on our customers since H1 2016

## NIOX<sup>®</sup> experience

Our teams help customers experience NIOX<sup>®</sup> in their clinical practise through a number of evaluation initiatives. Our US team pioneered a formal experience programme, and our UK and German organisations are maintaining momentum, adopting local versions.

## Tudorza<sup>®</sup> continuity

As we begin the US promotion of Tudorza<sup>®</sup> we are working hard to ensure continuity of the product's brand. As a result we will use existing AstraZeneca marketing materials, training and data to maintain momentum. Our approach is designed to drive promotional efficacy, as well as preserving brand recognition.





## 250,000

Asthma affects over 3% of the world's population. Despite treatment improving considerably since the regular use of anti-inflammatory medicines 20 years ago, approximately 250,000 people die annually as a result of uncontrolled asthma. We are targeting specialists around the world to help improve asthma outcomes.

## 200

In 2016 we doubled the size of our US sales force to approximately 100. Under our commercial collaboration with AstraZeneca we intend to double the team again, and by the end of July will have 200 representatives in the field promoting Tudorza® and NIOX®.

## 80%

Tudorza® prescribers who account for 80% of the product's prescriptions in the US will be the key focus of our sales force. We also plan to target the physicians who account for 40% of non-Tudorza® COPD prescriptions in the US, while also focusing a proportion of our expanded efforts on NIOX® promotion.

# We're expanding our global presence

Specialty commercial presence in the United States, UK, Germany and China

# 40

countries where we sell, or our partners distribute, our NIOX® products

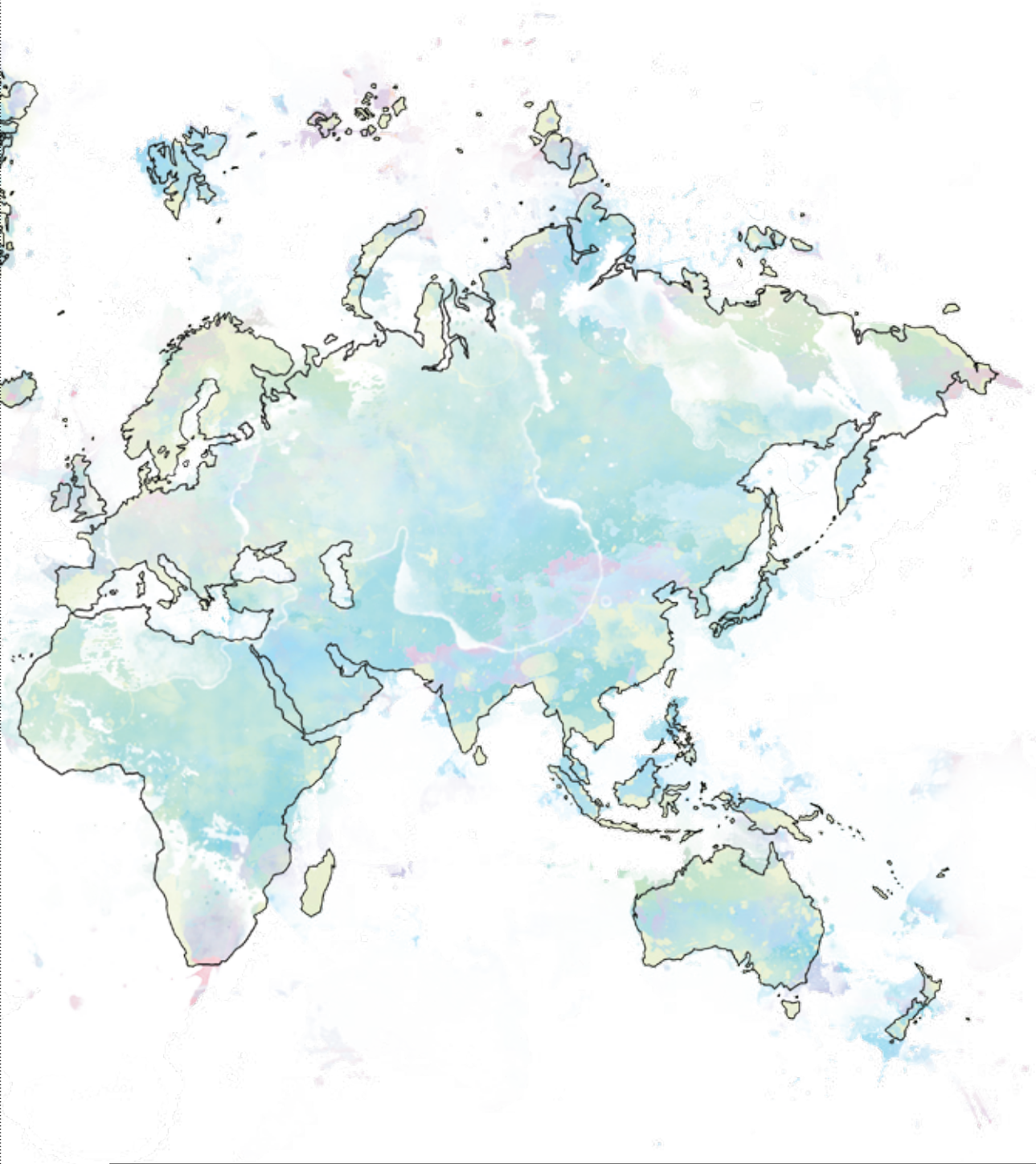
## Speciality sales

Our sales teams target specialist and key primary care physicians in major markets. During 2016, we doubled our US sales force, strengthened our German team and launched our direct presence in the UK. In parallel, we expanded our team in China who support our local distributors.

## Distribution network

We have a broad network of partners to distribute our NIOX® products in countries where we have no direct sales team. These currently total approximately 35, and we are adding new specialist distributors in France and Italy to strengthen our European presence.





## US

The United States is our largest market for NIOX®, and is also the focus of our commercial collaboration with AstraZeneca. From our headquarters in Morrisville, North Carolina, we distribute our NIOX® products nationwide and co-ordinate the activities of our field-based commercial teams.

## Europe

Europe is a key focus, and we promote our NIOX® products direct in the UK and Germany. Our NIOX® distribution hub is located in Uppsala, Sweden from where we ship our products to 40 countries worldwide, while Oxford in the UK is where our corporate and R&D headquarters are located.

## Asia

Asia is an important region for NIOX® with China and Japan both important markets. Our Beijing-based commercial team manages local distributors across China, while in Japan we work with a long-standing partner. Both markets are performing well with 2016 revenues approximately 70% above 2015.

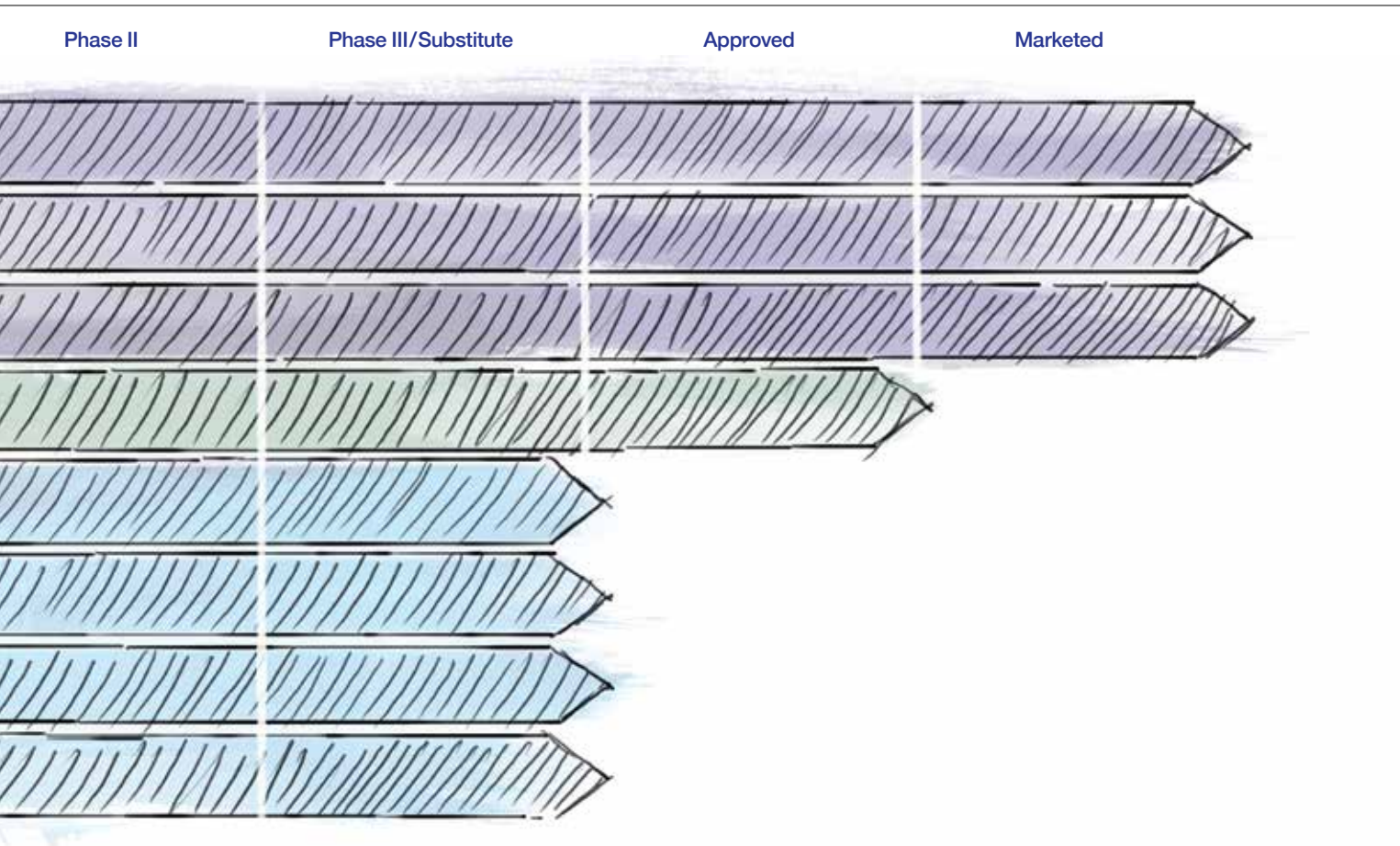
# Delivering a broad and balanced portfolio


 We've a broad portfolio of marketed and development products targeting asthma and chronic obstructive pulmonary disease
 

Product	Research	Preclinical	Phase I	Phase II	Phase III	Marketed
NIOX MINO <sup>®</sup>	██████████	██████████	██████████	██████████	██████████	██████████
NIOX VERO <sup>®</sup>	██████████	██████████	██████████	██████████	██████████	██████████
Tudorza <sup>®***</sup>	██████████	██████████	██████████	██████████	██████████	██████████
Flixotide <sup>®</sup> substitute*	██████████	██████████	██████████	██████████	██████████	██████████
Duaklir <sup>®***</sup>	██████████	██████████	██████████	██████████	██████████	██████████
Seretide <sup>®</sup> substitute	██████████	██████████	██████████	██████████	██████████	██████████
Flovent <sup>®</sup> substitute*	██████████	██████████	██████████	██████████	██████████	██████████
Spiriva <sup>®</sup> substitute	██████████	██████████	██████████	██████████	██████████	██████████
Novel LABA/LAMA formulation	██████████	██████████	██████████	██████████	██████████	██████████
Novel COPD therapy formulation	██████████	██████████	██████████	██████████	██████████	██████████

\* Partnered  
 \*\* US commercial collaboration  
 \*\*\* US commercial rights







Following the setbacks of 2016, Circassia is looking forward with optimism as it builds its revenues and advances its pipeline of promising respiratory treatments 

The past year, and in particular the last ten months, has been a period of great change with Circassia experiencing significant challenges as well as major opportunities. While disappointing phase III allergy results tested the Company's resilience, I am pleased to report that swift action helped conserve shareholders' funds, broaden the development portfolio and establish a transformational commercial collaboration with AstraZeneca. With results from the Company's house dust mite allergy study mirroring the earlier cat allergy phase III data, the Board has taken the difficult decision to cease further investment in the field and to focus Circassia's resources on its respiratory portfolio. With much progress made in a short period of time, the Company is now building positive momentum across its wider business.

#### Robust strategy

Since its establishment, Circassia's strategy has focused on building a world-class specialty pharmaceutical business, directly commercialising its products in key markets and developing a broad and balanced portfolio. During 2015, the Company accelerated this strategy, acquiring a direct specialty sales capability in the US and Germany and broadening its pipeline to include a number of respiratory products. Following the allergy results in 2016, the Board revisited this strategy to ensure the Company continues to focus on building shareholder value.

This strategic review considered multiple approaches, and ultimately concluded that Circassia's strategy continued to offer the best opportunity to exploit the Company's commercial infrastructure and pipeline assets. The Board considered options to accelerate self-sustainability and determined that expansion of the Company's commercial capabilities would offer both revenue growth opportunities and a strategic platform with which to attract third-party products. In parallel, out-licensing out-of-focus pipeline assets, focusing R&D efforts and driving efficiencies would reduce costs and help conserve resources.

#### Rapid action

Following the review, management acted quickly to implement this strategy, expanding the Company's commercial presence, driving efficiencies across the organisation, curtailing allergy investment and halting the development of out-of-focus products. The Company also added three novel formulations to its respiratory pipeline, initiated negotiations for the return of EU rights to its lead asthma treatment and established a transformational commercial collaboration with AstraZeneca.



As a result of this rapid action, Circassia's significantly enhanced commercial capability was an important factor in attracting AstraZeneca as a valued partner. During 2016, the Company doubled its sales force in its largest market, the United States, and as part of its new commercial collaboration will double this team again by the end of July 2017. In 2016, Circassia also launched a direct sales team in the UK and strengthened its commercial teams in Germany and China. In parallel, the Company's market-leading NIOX® asthma management products enjoyed robust sales growth and its pipeline now features additional chronic obstructive pulmonary disease (COPD) treatments. These advances were complemented by significant efficiency savings, with the Company's facilities costs set to decrease by approximately 40% next year and headcount reduced outside the commercial team.

#### **Leveraging infrastructure**

With its commercial infrastructure now firmly established, Circassia is well positioned to commercialise its in-house portfolio as well as third-party specialty products. The Company's respiratory pipeline targets a large and growing market, and is well positioned to leverage Circassia's commercial platform with specialist treatments exploiting its direct sales capabilities and substitute therapies that do not require significant promotion using its distribution, supply chain and market access expertise.

This commercial strategy was recently validated by the Company's collaboration with AstraZeneca, in which Circassia will undertake the US promotion of COPD treatments Tudorza® and Duaklir®, once approved. With this transaction transforming Circassia into a world-class specialty respiratory business, the Company is well positioned to attract further products that can benefit from its highly focused commercial capabilities.

#### **Board changes**

As well as the changes to the Company, Circassia's Board has also evolved. During 2016, Paul Edick and Cathrin Petty retired as Non-Executive Directors, and as announced alongside the preliminary results Tim Corn and Charles Swingland have informed the Company that after serving for over 10 years they will retire at the forthcoming Annual General Meeting. Each of these Directors has provided invaluable counsel and strategic advice based on long-standing industry experience, and we thank them all for their contribution to the progress made by Circassia. Following the addition of two new independent Directors during 2015, the Board remains strong, with five Non-Executive and three Executive members. The Board will continue to review its mix of skills and experience to ensure an optimal composition, both overall and of its Committees.

#### **Positive outlook**

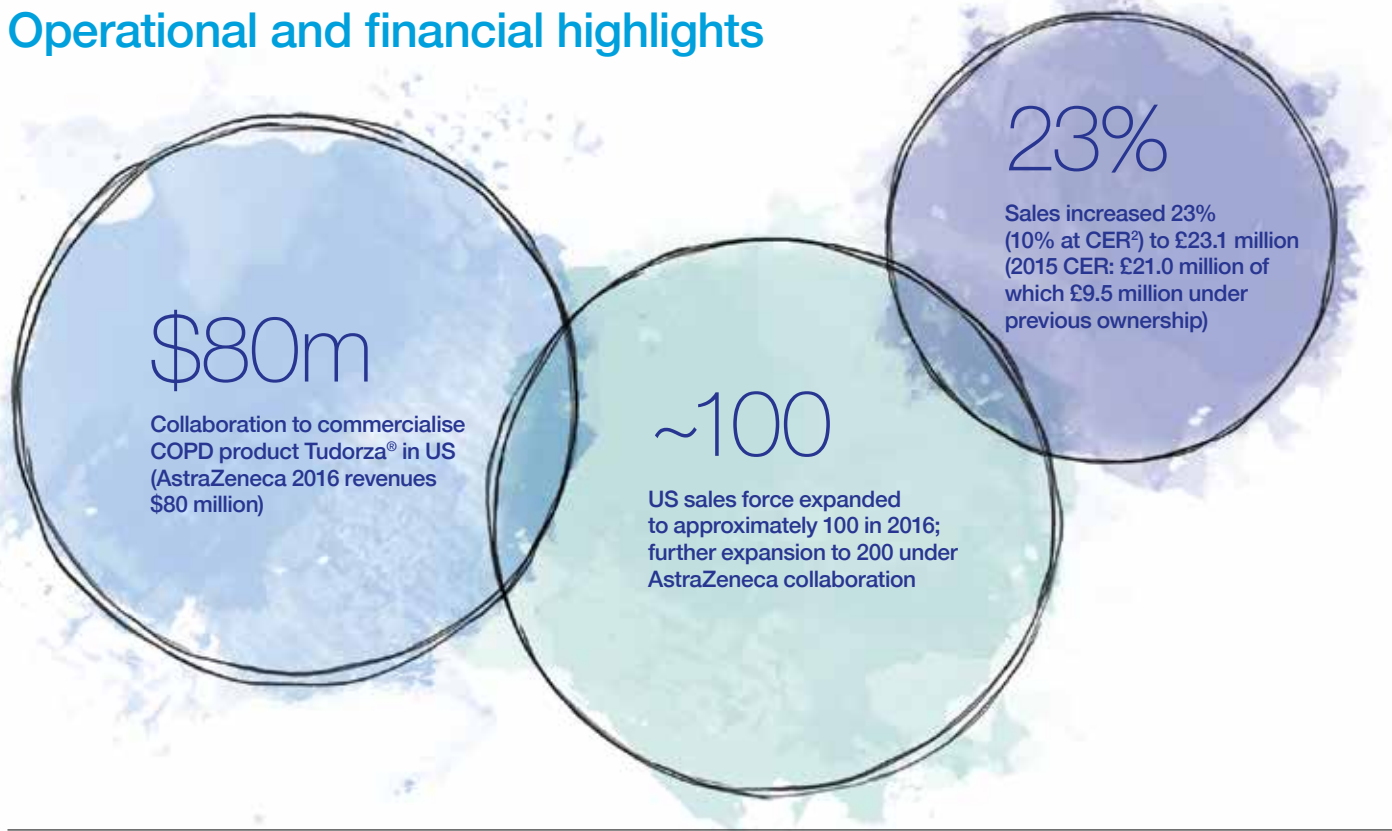
Following the disappointment of the phase III allergy results in June 2016, Circassia has worked to refocus and broaden its business. After a period of consolidation and rebuilding, the Company is positioned for strong growth as it builds momentum in both its commercial and development portfolios. During the coming year, Circassia anticipates further progress with the Company capitalising on its asthma management products' market-leading position, focused promotion of its partnered COPD treatment Tudorza® and pursuit of opportunities to commercialise additional products through its specialty infrastructure. In addition, the Company plans to conclude discussions on the EU rights to its lead asthma treatment, expand its NIOX® registrations in the US and Europe and prepare two new novel COPD formulations to enter the clinic.

Following the setbacks of 2016, Circassia is looking forward with optimism as it builds its revenues and advances its pipeline of promising respiratory treatments. As a result, I believe the Company is increasingly well positioned to achieve its ambition of becoming a world-class, self-sustaining specialty pharmaceutical company.

#### **Dr Francesco Granata**

Chairman

# Operational and financial highlights



## Transformational transaction with AstraZeneca (AZ) announced post-period

- Collaboration to commercialise COPD product Tudorza® in US (AZ 2016 revenues \$80 million)
- Secures US commercial rights to phase III product Duaklir®<sup>1</sup> with filing planned H1 2018
- Collaboration to fund immediate doubling of Circassia's US sales force plus R&D contributions
- \$50 million of shares issued to AZ
- Third-party debt to fund further consideration of up to \$180 million

## Commercial platform expanded as strategic asset

- US sales force expanded to approximately 100 in 2016; further expansion to 200 under AZ collaboration
- US key accounts and managed markets teams established
- UK direct sales force launched
- German and Chinese commercial teams strengthened
- Appointing new specialist distributors in France and Italy

## NIOX® performing strongly

- Sales increased 23% (10% at CER<sup>2</sup>) to £23.1 million (2015 CER<sup>2</sup>: £21.0 million of which £9.5 million under previous ownership)
- Direct clinical sales (i.e. non-research<sup>3</sup>) increased 35% (21% CER<sup>2</sup>) compared with 2015
- Rapid US clinical revenue growth following sales force expansion; 57% increase in Q1 2017 vs Q1 2016
- Reimbursement established with a number of additional health systems in US
- US label extension to include four, five and six year olds filed
- Successful primary ciliary dyskinesia diagnosis study; EU certification update initiated

## Respiratory portfolio progressing

- Fliveo® (Flixotide® pMDI substitute) EU rights discussions initiated H2 2016
- Seriveo® (Seretide® pMDI substitute) filing targeted H1 2019
- Spiriva® DPI substitute pharmacokinetic study planned H1 2018
- Two COPD formulations in development; LABA/LAMA on track to enter clinic 2018



UK

UK direct sales force launched

£23.1m

Revenues increased to  
£23.1 million (2015: £10.8 million)

£117.4m

Strong balance sheet  
with £117.4 million cash<sup>5</sup>  
at 31 December 2016  
(31 December 2015: £203.8 million  
with £33.2 million relating  
to 2015 acquisitions paid  
during 2016)

#### Allergy investment curtailed

- House dust mite allergy phase IIb study did not meet primary endpoint
- Investment in allergy portfolio halted

#### Cost containment ongoing

- Facilities consolidated in US, Sweden and UK; Chicago and Solna closed with Oxford reduced
- Positions reduced in R&D and G&A

#### Financial highlights

- Revenues increased to £23.1 million (2015: £10.8 million)
- R&D investment £46.2 million (2015: £46.8 million) including allergy expenditure of £21.5 million
- Underlying loss for year £57.4 million (2015: £50.0 million); total loss £137.4 million (2015: £50.0 million)
- Allergy portfolio provisions, restructuring costs and impairments £80.0 million<sup>4</sup> (2015: £nil)
- Strong balance sheet with £117.4 million cash<sup>5</sup> at 31 December 2016 (31 December 2015: £203.8 million with £33.2 million relating to 2015 acquisitions paid during 2016)

<sup>1</sup> Duaklir® is a registered trademark in certain European countries; the US trademark is to be confirmed

<sup>2</sup> Constant exchange rates (CER) for 2015 represent reported 2015 numbers re-stated using 2016 average exchange rates; management believes constant currency numbers better represent the underlying performance of the Group due to subsidiary functional currency fluctuations against Sterling

<sup>3</sup> Direct clinical sales to clinicians, hospitals and distributors; research sales to pharmaceutical companies for use in clinical studies

<sup>4</sup> Impairment of goodwill (£74.5 million), intangible assets impairment (£0.3 million), restructuring costs (£2.8 million) and cost for termination of certain contracts (£2.4 million)

<sup>5</sup> Cash, cash equivalents and short-term deposits



With the challenges of 2016 now behind us, we are focused on building a world-leading specialty pharmaceutical business, and are making progress towards this goal 

**Following the receipt of disappointing phase III allergy results in June last year, we worked hard to strengthen our commercial platform and respiratory portfolio. We have substantially increased sales of our market-leading NIOX<sup>®</sup> asthma management products and recently completed a transformational transaction with AstraZeneca to commercialise the COPD (chronic obstructive pulmonary disease) products Tudorza<sup>®</sup> and Duaklir<sup>®</sup> in the United States. We also broadened our respiratory pipeline, adding three earlier-stage COPD products. In addition, we maintained a resolute focus on costs, while continuing to invest in our commercial infrastructure as a strategic growth platform. Following disappointing results from our house dust mite allergy field study, we have taken the difficult decision to curtail investment in our allergy programmes.**

With these significant developments now behind us, we look forward to the coming year with optimism. We have built a strategic asset in our direct specialty sales infrastructure, which we plan to strengthen further as we accelerate our commercial collaboration with AstraZeneca. We also intend to advance our other respiratory products, as well as pursuing additional in-licensing and acquisition opportunities to expand our commercial portfolio. As a result, we are increasingly well positioned to achieve our ambition of becoming a world-class, self-sustaining specialty pharmaceutical business.

#### **Setbacks and opportunities**

The past year has been a period of significant change, with the Company resolutely pursuing opportunities to extend its commercial reach, portfolio of marketed products and development pipeline following the disappointment of our allergy phase III results in the middle of 2016. The whole team responded highly professionally to this setback, cutting costs across the business, refocusing efforts on our respiratory portfolio and recently completing a transformational commercial collaboration with AstraZeneca.

#### **Significant commercial progress**

Since the beginning of 2016 we have made good commercial progress, expanding our presence in key markets and growing sales of our NIOX<sup>®</sup> products. Building a strong platform in the United States was crucial to attracting AstraZeneca as a commercial partner, and with the transaction now complete we are becoming increasingly positioned as a partner-of-choice for products requiring focused specialty commercial expertise. As part of our AstraZeneca collaboration we will further grow our US infrastructure, doubling our existing sale force to 200, supported by a strong team of marketing, operations, key accounts and managed market specialists. This infrastructure is a strategic asset that is rare outside 'big pharma', and provides us with a platform for further growth.



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### **Pipeline development**

Despite the disappointment of our allergy results we have worked hard to build and broaden our pipeline. During the year we added three new COPD products to our portfolio, including a novel tiotropium formulation targeting direct substitution of the market leading long-acting muscarinic antagonist, Spiriva Handihaler®. We recently complemented these products as part of our transaction with AstraZeneca, which brought us the US commercial rights to the phase III COPD treatment Duaklir®.

### **Operational efficiency**

In parallel with our commercial and pipeline expansion, we have taken robust measures to contain costs and conserve our resources. Following the receipt of our allergy phase III results we curtailed major expenditure in the field, immediately halting our grass and ragweed allergy development programmes. We have now gone further, stopping our investment in allergy as we focus on our respiratory portfolio. In parallel, we closed our Solna and Chicago sites as well as one of our Oxford facilities, and rationalised our R&D and back office teams. As a result, we retain a strong balance sheet, with a cash position of £117.4 million, and remain fully funded to deliver on our strategy.

### **Optimistic outlook**

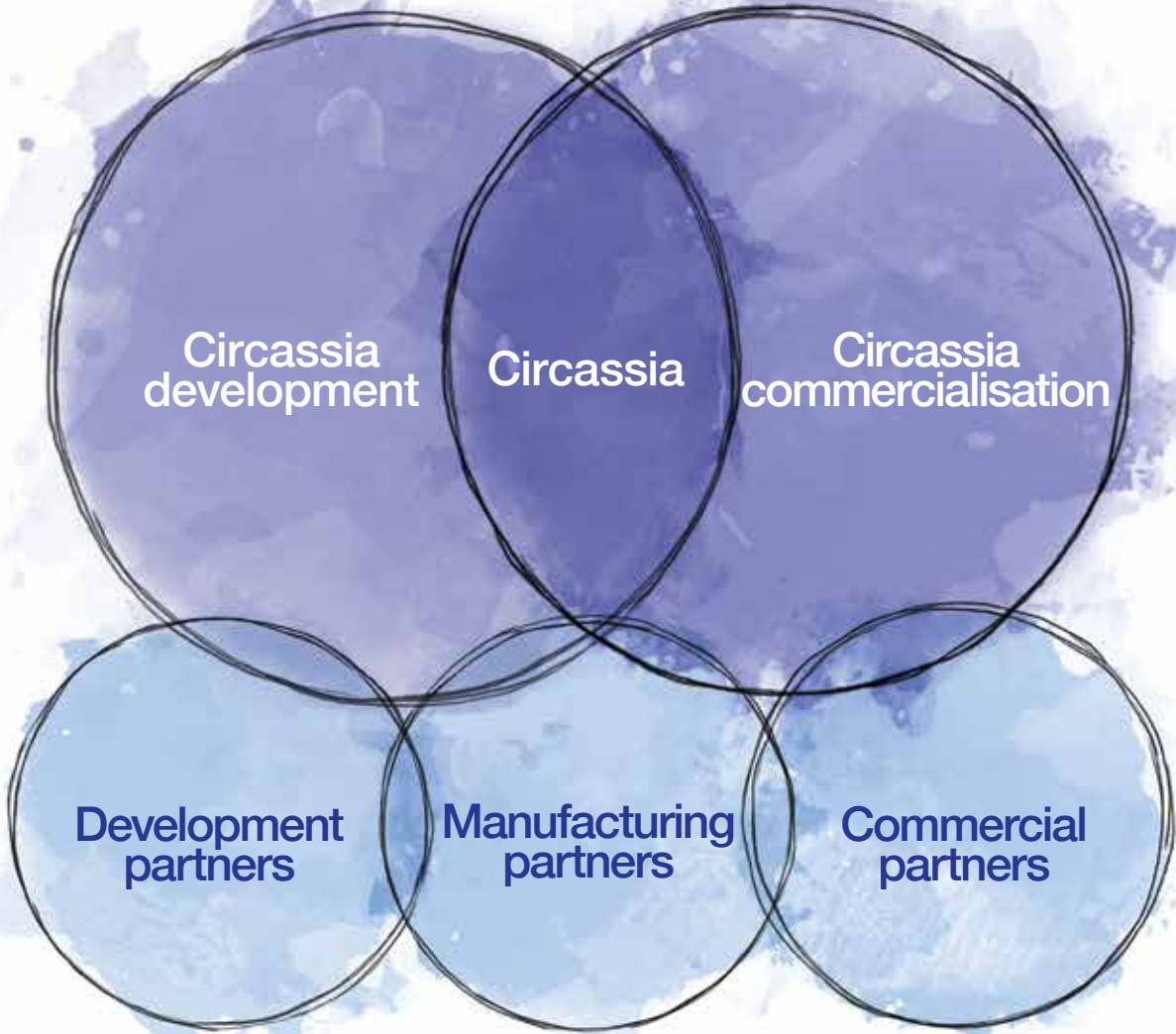
With the challenges of 2016 now behind us, we are focused on building a world-leading specialty pharmaceutical business, and are making progress towards this goal. We are working hard to rapidly expand our US sales force as we take over the promotion of Tudorza® in this major market, and at the same time we look forward to completing preparations to move several of our respiratory products into the clinic. In the coming months, we hope to finalise the commercial approach in Europe for our lead asthma treatment, Fliveo®, which is already approved in the UK, while also pursuing opportunities to out-license non-strategic products as we focus our development resources on our direct substitute and specialty respiratory products. With much progress made in a short period of time we are regaining ground, and consequently we face the future with optimism as we emerge from the challenges of 2016.

### **Steven Harris**

Chief Executive Officer

# Business model

↖↖  
Circassia's business model is designed to ensure efficient operations and includes outsourcing a number of support functions ↘↘





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**Circassia's business model is designed to ensure efficient operations and includes outsourcing a number of support functions. The Company retains critical expertise in-house, including strategic development, intellectual property, clinical study design, regulatory affairs and commercialisation capabilities.**

**To complement these abilities Circassia uses a range of external experts to deliver non-core activities, such as contract research organisations, manufacturers and commercial partners in territories beyond the Company's key markets.**

#### **Our partners**

- Panasonic Healthcare for NIOX<sup>®</sup> supply and ITG for sensor manufacture
- Commercialisation partners for NIOX<sup>®</sup> products outside the United States, United Kingdom and Germany
- AstraZeneca and third-parties for manufacture and supply of Tudorza<sup>®</sup> and Duaklir<sup>®</sup>
- AstraZeneca for distribution, pharmacovigilance and regulatory support for Tudorza<sup>®</sup>
- Contract manufacturing organisations, including Sterling for production of particle-engineered respiratory products and contract manufacturers for fill-finish
- Mylan for commercialisation of lead particle-engineered asthma treatment in specific territories\*
- Parexel for clinical studies
- AstraZeneca for clinical development of Duaklir<sup>®</sup> and Tudorza<sup>®</sup> post approval study

\* US, Canada, Australia, New Zealand, India, the EU, Iceland, Liechtenstein, Norway, Switzerland, Turkey, Russian Federation and the Commonwealth of Independent States

# Strategy and progress against objectives



We are resolutely pursuing our goal of becoming a world-class business in our field 

## Strategic objectives

**Circassia is focused on building a self-sustaining specialty pharmaceutical company with a broad portfolio of innovative therapies commercialised by the Company in key markets and complemented by a strong and balanced development pipeline.**

**During 2016 we reviewed our strategy to ensure we remain focused on building shareholder value. This review reaffirmed the potential of our specialty focus, commercialisation strategy, development approach and outsourced business model, and we are resolutely pursuing our goal of becoming a world-class business in our field.**

### Delivering the pipeline

We are focused on bringing our portfolio of specialty development candidates to market. We have a broad pipeline of respiratory products targeting the treatment of asthma and chronic obstructive pulmonary disease (COPD), comprising direct substitutes for existing therapies and novel formulations designed to provide additional benefits. During 2017 we plan to advance both groups of products as we prepare two new COPD programmes for the clinic and advance the development of Seriveo<sup>®</sup> as a substitute for GSK's Seretide<sup>®</sup> pMDI.

### Marketing specialty products direct in North America and major EU markets and partnering elsewhere

We are making good progress commercialising our NIOX<sup>®</sup> products independently in key marketplaces, with our sales infrastructure now established in the US, UK and Germany. We plan to further bolster this presence in the coming months as we double our US sales force as part of our recent commercial collaboration with AstraZeneca. Under this profit share arrangement we will promote the COPD treatment Tudorza<sup>®</sup> in the United States. This collaboration allows us to dramatically expand our commercial presence without resorting to shareholders for funding while also welcoming AstraZeneca to our share register.

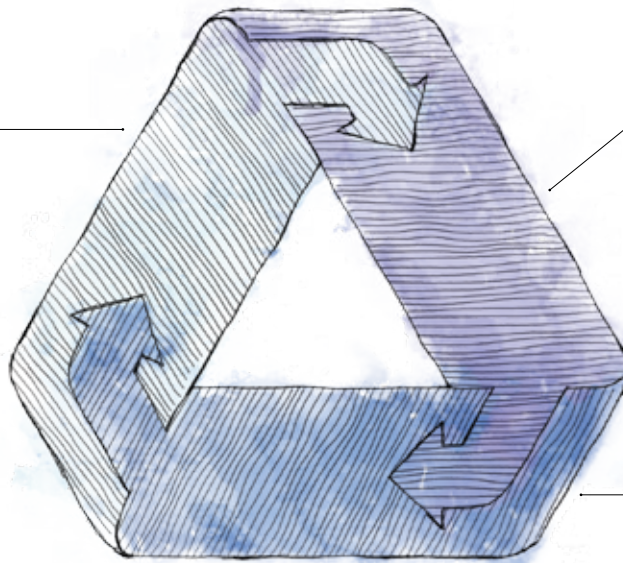
### Building a broad and balanced portfolio

We have a wide range of respiratory treatments in development based on our particle-engineering technology, and we are also working on initial concepts for a next generation NIOX<sup>®</sup> product. Through our recent transaction with AstraZeneca we extended our pipeline with the addition of Duaklir<sup>®</sup>, which is currently in phase III development in the United States for COPD. With the expansion of our commercialisation platform we are increasingly well placed to attract additional specialty products to our portfolio through in-licensing, acquisition and partnership.

**Achieving our strategic objectives involves risks and uncertainties, which are detailed in the 'Risks and risk management' section.**

**Build broad and balanced portfolio**

**Deliver the pipeline**



**Market novel products**

## Progress in 2016

During 2016 we progressed each area of our strategy. We significantly strengthened our commercial presence, added a number of new products to our development portfolio and advanced our pipeline of product candidates. Our development progress was impacted by disappointing results in our allergy franchise, and we took robust, rapid action to curtail expenditure in the field.

### Marketing specialty products

During 2016, we greatly strengthened our commercial presence to increase promotion of our NIOX<sup>®</sup> products and build a strong infrastructure to act as a strategic growth platform. In the second half of the year, we doubled our US sales team, launched our direct sales force in the UK and strengthened our capabilities in Germany and China. This investment is now delivering results, with our NIOX<sup>®</sup> revenues growing 23% during the period and our US team achieving their highest monthly sales at the end of Q1 2017.

### Building a broad and balanced portfolio

Following disappointing phase III allergy results in June 2016 we acted quickly to curtail significant investment in the area and refocus our resources onto our respiratory portfolio. As a result, we added three new products to the pipeline, with a formulation targeting direct substitution of the market leading long-acting muscarinic antagonist, Spiriva Handihaler<sup>®</sup>, and two products targeting an underserved segment of the specialty COPD market.

### Delivering the pipeline

We have continued to progress our non-allergy development programmes during the past year. In addition to moving our new COPD products towards the clinic, we successfully completed two studies designed to extend our NIOX<sup>®</sup> registrations. The first of these demonstrated the utility and reproducibility of the NIOX VERO<sup>®</sup> six- and 10-second test modes in children aged four to six years old, which provides the opportunity to extend our label in the US to match our European certification. We also completed a study that demonstrated the VERO<sup>®</sup>'s ability to diagnose primary ciliary dyskinesia based on the reduced levels of nasal nitric oxide emitted by patients. As a result, we plan to update our product's EU certification in the coming months.



We conducted a formal review of the Company's business. This reconfirmed the significant potential of our specialty business model, the value of a strong direct commercial presence and the importance of using our resources as efficiently as possible

The past year has been a period of significant change and refocusing for Circassia. Our NIOX<sup>®</sup> asthma management products and commercial expansion plans made good progress and we recently established a ground-breaking commercial collaboration with AstraZeneca. However, we also received disappointing clinical data in our allergy portfolio. We acted quickly to curtail allergy-related expenditure, and also broadened our pipeline of respiratory products and realigned our R&D efforts to drive these programmes towards the market as quickly as possible.

In addition, we conducted a formal review of the Company's business. This reconfirmed the significant potential of our specialty business model, the value of a strong direct commercial presence and the importance of using our resources as efficiently as possible. Consequently, we substantially expanded our commercialisation capabilities to act as a strategic growth driver, and identified significant efficiency savings across our global operations.

With this period of consolidation and refocusing complete we have emerged in a strong position. Circassia now features a growing portfolio of marketed products, a broad pipeline of respiratory medicines and a robust balance sheet. With our ambition undimmed, we remain committed to building a world-class company for shareholders, customers and employees alike.

#### NIOX<sup>®</sup> asthma management products

Our NIOX<sup>®</sup> products play an important role helping physicians diagnose and manage asthma by providing an accurate measure of underlying airway inflammation through the monitoring of patients' fractional exhaled nitric oxide (FeNO). NIOX<sup>®</sup> is used both in clinical practise and pharmaceutical companies' studies, and is the market-leading point-of-care FeNO measurement system available across major markets. The current generation VERO<sup>®</sup> device is launched in a wide range of countries, including the US, Europe, Japan and China, and during the first quarter of 2017 was approved in Canada.

#### Strong sales performance

During 2016, NIOX<sup>®</sup> sales increased significantly, growing 23% to £23.1 million (10% CER) versus 2015 (2015: £18.7 million – £10.3 million under Circassia ownership and £8.4 million under previous ownership).

Of these revenues, sales for clinical use increased 35% compared with the year before (21% CER) reflecting significant commercial efforts by Circassia and its partners. NIOX<sup>®</sup> sales to pharmaceutical companies are influenced by the timing of clinical studies and are therefore more unpredictable, and these revenues decreased during the year by 6% (16% CER).

During the first quarter of 2017 this strong sales growth has continued, notably in the key US market following the significant expansion of the sales force in H2 2016. As a result, US clinical sales grew 57% in Q1 2017 versus the same period in 2016.

#### Experience programme performing well

Our NIOX VERO<sup>®</sup> experience programme continues to make good progress. During 2016, our US team continued to roll out the initiative placing approximately 900 devices in specialist clinics, over three times the 2015 level, providing physicians the opportunity to experience NIOX<sup>®</sup> in practise. Of the programme participants, the majority subsequently acquired a new NIOX<sup>®</sup> system, with the period to purchase reducing by approximately 25% compared with 2015. In 2017 we are maintaining momentum, with our teams in Germany and the UK adopting customer evaluation initiatives and our US programme evolving to focus on rapidly converting customers.



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### Reimbursement and key accounts increasing

During the second half of 2016, we also established a team of experienced managed markets professionals to increase the proportion of the US population covered by reimbursement for NIOX<sup>®</sup>. This initiative is now delivering results with a number of important health plans reimbursing NIOX<sup>®</sup> usage, and during the first quarter of 2017 the team made further progress, extending coverage to more than 2.8 million additional Americans through several new plans.

Circassia also established a key accounts team during 2016, which is performing well. By identifying and targeting major health providers in the asthma field, the team has signed 17 significant contracts since the beginning of 2017, with negotiations underway with a similar number of potential customers.

### New US pricing model

Circassia's US commercial team recently completed an economic analysis of potential NIOX<sup>®</sup> pricing models, and in 2017 rolled out a new approach designed to encourage greater use. To measure patients' FeNO, clinicians require both a NIOX<sup>®</sup> device and pre-programmed replaceable test sensor, which are available for a fixed number of tests. The new pricing model aims to increase the number of tests used over the five-year life of the NIOX VERO<sup>®</sup> by separating the cost of the device and the sensors, compared with a bundled price previously. As a result, the new pricing aims to increase the commercial returns for customers while boosting margins for the Company.

### Distributor improvement plan

In addition to our direct sales capabilities, we sell our NIOX<sup>®</sup> products through a network of distributors in approximately 35 further countries around the world. During the second half of 2016, we recruited an experienced Distributor Management Director to manage and improve these partnerships, and conducted a detailed performance review of our distribution network. We are currently further strengthening our distribution management team, and are working with distributors in the EU and other key territories to ensure transparency on local sales and marketing activities and to provide regular performance updates.

During 2016 we terminated our distribution agreements in France and Italy due to poor performance. We have now assessed a range of opportunities to boost our presence in these potentially significant markets, including via direct sales forces. This review concluded that partnering with high performing distributors offers the optimal approach, and we are appointing local specialists in both countries to promote our NIOX<sup>®</sup> products.

### Positive registration extension studies

Recently, we completed two successful clinical studies designed to extend our NIOX VERO<sup>®</sup> usage. The first demonstrated the equivalence and utility of the six- and 10-second test functions in children aged four to six years old. As a result, we have now filed for an extension to the US label to match our European certification, which already includes this age group and both test functions.

Our second study, which included 160 subjects, identified a diagnostic level of FeNO in people with the orphan condition primary ciliary dyskinesia (PCD). PCD affects approximately 50,000 people in the EU and can be complex to diagnose. However, it is known that sufferers have unusually low levels of nasal nitric oxide, and our recently completed study demonstrated that the NIOX VERO<sup>®</sup> system can accurately measure this exhaled gas. As a result, we plan to add PCD diagnosis to our European certification in the coming months.

### NIOX<sup>®</sup> development programme

During the past year, we began initial concept development for a new NIOX<sup>®</sup> generation to ensure we retain our leading position in the FeNO market. With rapid advancements in wireless and web technologies we have the opportunity to build on our ongoing collaboration with Microsoft for cloud-based applications, while also exploring additional functionality to enhance the utility of the NIOX<sup>®</sup> system.

## Commercial collaboration with AstraZeneca

Circassia's recently completed transaction with AstraZeneca is an ideal fit with our strategy and transforms the Company into a world-class respiratory business. It represents a major commercial opportunity, doubling our number of marketed products, with the potential to triple the current number within two years. Under the initial collaboration, we plan to immediately double our US sales team to promote the COPD product Tudorza<sup>®</sup>, as well as our existing NIOX<sup>®</sup> franchise. Additionally, the transaction structure is highly attractive, allowing us to fund the consideration without further investment from shareholders, while at the same time welcoming AstraZeneca as a major shareholder.

## Tudorza<sup>®</sup> collaboration

We have established an initial collaboration and profit share for the commercialisation of Tudorza<sup>®</sup> in the US, and in the next approximately two and half years we will have the option to acquire the full US commercial rights to the product. During the collaboration, Circassia will be responsible for the promotion of Tudorza<sup>®</sup> while AstraZeneca will manufacture and supply the product and provide regulatory and pharmacovigilance support.

Tudorza<sup>®</sup> (aclidinium bromide 400 µg twice daily) is a long-acting muscarinic antagonist (LAMA) indicated for the long-term maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema. It was initially approved in the United States in 2012 and is authorised in approximately 60 countries around the world under a range of brand names. AstraZeneca revenues related to the product's worldwide sales were \$170 million in 2016, of which \$80 million was in the United States.

Tudorza<sup>®</sup> is supported by a broad clinical database, including three pivotal phase III studies and three one-year long-term safety studies. These data demonstrate that Tudorza<sup>®</sup> provides statistically and clinically significant improvements in lung function (FEV<sub>1</sub>, improves symptom severity, and due to its rapid onset of action provides bronchodilation from the first dose, which is sustained over long-term treatment. In a head-to-head comparison with the market-leading LAMA, Spiriva<sup>®</sup> (tiotropium bromide 18 µg once a day), Tudorza<sup>®</sup> demonstrated significantly greater improvements in lung function (FEV<sub>1</sub>) during the night time on day one, which followed the evening dose of aclidinium that provided additional and sustained bronchodilation. Additionally, Tudorza<sup>®</sup> provided improvements in early morning and night-time symptom severity compared with Spiriva<sup>®</sup>. Studies also show that Tudorza<sup>®</sup> is well tolerated, with a low incidence of adverse events that are commonly associated with LAMA-containing products.

## Duaklir<sup>®</sup> follow-on product


As part of the transaction we also secured the US commercial rights to the COPD product Duaklir<sup>®</sup>. The product is an orally inhaled fixed dose long-acting muscarinic antagonist/long-acting beta agonist (LAMA/LABA) combination (400 µg aclidinium bromide/12 µg formoterol fumarate twice daily), which is in late-stage development by AstraZeneca in the United States. The product is currently undergoing a phase III trial, which is anticipated to complete in H2 2017, with a subsequent filing planned for H1 2018. Duaklir<sup>®</sup> was initially approved in the European Union in 2014 and is authorised in approximately 50 countries around the world under a range of brand names. AstraZeneca revenues related to Duaklir<sup>®</sup> sales outside the United States were \$63 million in 2016.

The clinical development programme on which the product was approved in the EU and elsewhere included approximately 4,000 COPD patients, with a number of phase III studies complemented by long-term safety studies. These studies show that Duaklir<sup>®</sup> provided significant and clinically meaningful improvements in lung function (FEV<sub>1</sub>) and symptom reduction compared with placebo and with the product's individual LAMA and LABA components. It also improved daytime, night-time and early morning COPD symptoms and the rate of moderate or severe exacerbations was significantly reduced compared to placebo. In addition, a comparison study versus leading inhaled corticosteroid/long-acting beta agonist (ICS/LABA) combination Seretide<sup>®</sup> showed that Duaklir<sup>®</sup> provided significantly improved FEV<sub>1</sub>, with fewer pneumonia and treatment-related adverse events. Studies also show that Duaklir<sup>®</sup> demonstrated favourable safety and tolerability, which is comparable to its mono-components, with adverse event rates similar to placebo.

## Unique Pressair<sup>®</sup> inhaler

Both Tudorza<sup>®</sup> and Duaklir<sup>®</sup> are delivered by the novel dry powder inhaler Pressair<sup>®</sup>. A number of studies show a clear patient preference for Pressair<sup>®</sup> versus many competing devices, including Handihaler<sup>®</sup> which is used by market leading LAMA Spiriva<sup>®</sup>. Pressair<sup>®</sup> also has fewer steps than many other inhalers, with a simple two-step delivery process. In addition, it prevents the release of a second dose before the first is successfully inhaled to prevent accidental overdosing. It has a unique combination of feedback mechanisms to indicate when the device is ready to use, whether the patient's inhalation is successful and the number of remaining doses. The device also locks after the final dose to prevent further use and it does not require cleaning.



The structure of the transaction is highly attractive. It provides Circassia with the benefits of a broader portfolio and significantly expanded commercial infrastructure without requiring funding from shareholders 

#### Robust commercialisation plan

The US COPD market represents a major opportunity, with 2016 sales estimated at more than \$5 billion. The disease's prevalence is expected to grow, and approximately 15.7 million Americans currently have diagnosed COPD, with several million more undiagnosed. As a result, COPD is responsible for over 120,000 deaths per year, making it the third leading cause of death in the United States.

The Global Initiative for Chronic Obstructive Lung Disease (GOLD), which comprises a number of leading agencies, including the US National Heart, Lung and Blood Institute and National Institutes of Health, has recently released its 2017 treatment guidelines. These support a move away from ICS/LABA products for many COPD patients and LAMA-containing products are now recommended as preferred initial treatments for every patient group. Consequently, these influential guidelines support a market move towards products such as Tudorza® and Duaklir®.

With the transaction with AstraZeneca now complete, Circassia is responsible for Tudorza®'s promotion in the US and we will make the product our lead promotional priority. Through highly focused commercialisation efforts we believe we can maintain the product's recent commercial performance and potentially increase sales in the medium- to longer-term. Third-party estimates suggest the product has peak sales potential of over \$90 million.

As part of our commercial plan, we intend to increase our US field force to approximately 200 by the end of July 2017. We will focus our initial promotional efforts on the highest Tudorza® prescribing physicians, targeting those who account for 80% of its prescriptions. In addition, we will target physicians who account for 40% of non-Tudorza® COPD prescriptions to increase the product's customer base. We believe that by providing highly targeted, focused resources we will significantly increase the level and intensity of one-to-one sales calls where the product benefits can be presented in detail. This will also serve to establish the customer base for future sales of Duaklir® once approved. Additionally, we will use existing AstraZeneca marketing materials, training and data to ensure branding continuity and drive promotional efficiency. As well as having a strong focus on Tudorza® we will continue to advance our NIOX® business. Our expanded sales team will focus 30% of its calls on allergists to promote NIOX®, and will also promote the products to Tudorza® target physicians.

We believe the combination of recent changes to the GOLD guidelines, Tudorza® and Duaklir®'s compelling product benefits and our focused commercialisation plans provide a strong foundation to capture a portion of a large and growing market.


#### Attractive transaction structure

In addition to the commercial opportunity offered by the products, the structure of the transaction is highly attractive. It provides Circassia with the benefits of a broader portfolio and significantly expanded commercial infrastructure without requiring funding from shareholders. It also allows the majority of the consideration to be deferred, with the amount payable dependent on the successful approval of Duaklir® and commercialisation of Tudorza®. As a result, the transaction comprises a number of stages with different amounts payable over a period of approximately two and a half years, up to a maximum of \$230 million plus royalties on future Duaklir® US sales.

With AstraZeneca taking a \$50 million upfront stake in Circassia, we welcome the blue chip pharmaceutical company as a major shareholder. We also anticipate that our commercial collaboration will fund the major expansion of Circassia's US commercial team as well as the Company's R&D contributions to ongoing clinical studies. With third-party funding anticipated to cover the remaining deferred payments, we expect the transaction to be earnings enhancing after one year, broadly cashflow neutral for three years and then cash generative.

## Strategic review continued



This investment is now beginning to deliver, and in Q1 2017 US clinical sales grew over 50% compared with the same period in 2016, with March representing the team's best monthly performance 

### Commercial growth platform

Prior to establishing our AstraZeneca collaboration we greatly strengthened our commercial capabilities to boost NIOX<sup>®</sup> revenues and build an attractive platform for third-party products. In the third quarter of 2016, we doubled the size of our US sales force to approximately 100, targeting over 7,000 key specialist and primary care physicians. We also built a US managed markets team to focus on major healthcare systems and extend NIOX<sup>®</sup> reimbursement coverage. Recent successes have increased coverage to an additional 2.8 million Americans in the first quarter of 2017 and we anticipate further advances in the coming months. Additionally, our US key accounts team is targeting over 160 large customers with a particular focus on healthcare systems, integrated delivery networks, multi-site practises and federal organisations where penetration is currently low. This investment is now beginning to deliver, and in Q1 2017 US clinical sales grew over 50% compared with the same period in 2016, with March representing the team's best monthly performance.

Alongside this growth in the US, we established a direct presence in the UK, launching our new sales force at the end of 2016. The team is actively targeting both healthcare commissioners and specialist physicians, and in the first quarter of 2017 sales increased by approximately 15% compared with our revenues in the same period the prior year. In China, we also strengthened our commercial team during 2016 with the addition of medical and market access expertise to support the promotional activities of our distribution partners, and during the year revenues grew by approximately 70% in this important NIOX<sup>®</sup> market.

In addition to our sales team expansion, we are strengthening our commercial operations to support field-based activities. We have recently recruited an experienced head of global marketing and are expanding our marketing team in the US and adding marketing support in the UK.

As a result of this major commercial expansion, and future sales force growth under our collaboration with AstraZeneca, we are targeting a significantly broader customer base. With an established market-leading position in FeNO measurement, we anticipate continued NIOX<sup>®</sup> revenue growth in the coming year. We are also well positioned to attract additional products to broaden the Company's portfolio through acquisition, in-licensing or partnering, and we intend to pursue further opportunities in the coming year that fit our specialty strategy.

### Respiratory portfolio

#### Fliveo<sup>®</sup> EU rights negotiations

Our lead asthma product, Fliveo<sup>®</sup>, is a particle-engineered fluticasone propionate formulation targeting substitution of GlaxoSmithKline's Flixotide<sup>®</sup> pMDI. Fliveo<sup>®</sup> is currently approved in the UK and the product was out-licensed under previous ownership in a number of major territories, including the EU and US. The United States remains the product's largest potential market, and during the second half of 2016 we initiated discussions with our partner for the potential return of the commercialisation rights in the more modest marketplace in Europe, and we hope to finalise our approach in the coming months.

#### Serveo<sup>®</sup> progressing

Serveo<sup>®</sup>, Circassia's fluticasone/salmeterol asthma therapy, targets direct substitution of GSK's Seretide<sup>®</sup> pMDI. The product has a major market opportunity, with global sales of the GSK originator in pMDI and DPI formats totalling approximately \$4.7 billion last year.

During 2016, we initiated a clinical pharmacokinetic study comparing two Serveo<sup>®</sup> formulations with Seretide<sup>®</sup> to inform further development work. The Company recently received the results, which indicate the fluticasone component of one the formulations matched the originator product. Additionally, the formulation's salmeterol absorbed dose and peak plasma concentration were in the same range as Seretide<sup>®</sup>. However, the salmeterol components differed at the 90% confidence interval required for approval. Based on these results and previous development data Circassia plans to adjust the formulation and delivery device and reiterate the trial before moving to a registration pharmacokinetic study. As a result, the Company anticipates filing a Marketing Authorisation Application in H1 2019.

#### Spiriva<sup>®</sup> DPI substitute advancing

During 2016, we further broadened our respiratory portfolio adding a particle-engineered formulation of tiotropium bromide to the pipeline. The product is designed as a direct substitute for Boehringer Ingelheim's COPD treatment Spiriva Handihaler<sup>®</sup>. Global revenues for Spiriva<sup>®</sup> totalled \$3.3 billion in 2016. The product has made good initial progress and we are initiating formulation scale-up prior to progressing into an exploratory pharmacokinetic clinical study in H1 2018.



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### Novel formulations for COPD

In the second half of 2016, Circassia initiated development of two products targeting an underserved segment of the COPD market, in particular patients with more severe COPD. Circassia has completed initial market research for the products, confirming that both have significant commercial opportunities. Formulation development is progressing well, and the most advanced, a fixed dose LABA/LAMA combination based on existing approved products, is on track to begin an initial clinical study in 2018.

### Non-strategic products

Circassia is focused on building a world-class specialty pharmaceutical company and we intend to divest products that do not fit this strategic focus. Two such out-of-focus COPD products are a 'triple' fixed dose combination and a novel glycopyrronium bromide formulation that is currently partnered in China, Taiwan, Hong Kong and Macau. Both have completed first-in-human clinical studies, which provide a clinical foundation to inform potential partners' development plans. In these studies, the glycopyrronium formulation demonstrated significantly improved lung function versus placebo, while the fixed dose triple combination showed bioavailability for each of the components following inhalation.

### Allergy portfolio

#### Allergy investment curtailed

During 2016, Circassia received unexpected and highly disappointing phase III results from its lead allergy product. Subsequent analysis and expert review concluded that the study's design and conduct were robust and there were no major confounding factors. As a result, the Company minimised expenditure on its broader allergy portfolio, halting development activities for its grass and ragweed allergy products. As ongoing house dust mite and birch allergy studies were well advanced, and required only limited further investment, these continued. During the summer, the Company received results from the birch allergy study, which were encouraging, although this was an early-stage, small-scale (n=64) trial with limited efficacy endpoints.

Subsequently, the Company received disappointing results from its large-scale house dust mite allergy study, which did not meet its primary efficacy endpoint. Following receipt of these data, Circassia has halted investment in its allergy portfolio and will no longer progress its allergy product development programmes.



With a clear strategy, strong commercial products, compelling pipeline and robust balance sheet we have the foundations of a highly successful business



### Focus on costs

During 2016, Circassia took a number of measures to drive efficiencies across its broader business, reduce expenditure in the allergy portfolio and contain costs.

- The Company completed a review of its facilities and consolidated operations onto single sites in the United States and Sweden where previously we operated out of two locations. We have now closed our Chicago and Solna sites and transferred operations to our facilities in Morrisville, North Carolina and Uppsala respectively. In addition, we have downsized our activities in Oxford, vacating one of our previous premises. As a result, we anticipate cutting future facilities costs by approximately 40%.
- As part of this efficiency drive we decreased the size of our back office support functions, and our G&A headcount is now 15% lower than at the end of H1 2016 despite the substantial increase in our commercial presence. We also reduced the size of our R&D organisation and refocused the team on our respiratory programmes. Although we have established a dedicated in-house device team to drive the development of our inhaled products and next generation NIOX<sup>®</sup> device, our R&D headcount remains 20% lower than at the end of H1 2016, and following the decision to halt investment in our allergy portfolio we intend to conduct a further review of future requirements.

### Summary and outlook

The past year has been a period of challenges and major opportunities for Circassia. Our market-leading asthma management products continue to grow strongly and our respiratory portfolio is advancing. We also established a transformational commercial collaboration with AstraZeneca that leverages and expands our US infrastructure and brings new products to the Company. However, this progress was tempered by disappointing allergy data. Following these results we moved quickly to conserve resources, expand our commercial footprint and broaden our respiratory pipeline with the addition of several new products.

During the coming months we intend to build on this progress. We plan to rapidly expand our US sales force to promote Tudorza<sup>®</sup> and increase sales of our NIOX<sup>®</sup> products. With a growing specialty commercial presence in key markets, we are becoming increasingly well placed to attract further products, and we hope to exploit this opportunity in the coming year.

We also anticipate extending our NIOX VERO<sup>®</sup> usage in the US and Europe based on our successful clinical studies and recent filing in the United States. In parallel, we intend to progress our respiratory development programmes with our Spiriva<sup>®</sup> substitute and novel COPD treatment formulations moving towards the clinic and our Seretide<sup>®</sup> pMDI substitute advancing towards the final phase of pharmacokinetic testing.

With a clear strategy, strong commercial products, compelling pipeline and robust balance sheet we have the foundations of a highly successful business. Despite the setbacks of 2016 we remain determined to build a leading specialty pharmaceutical Company and are making good progress towards our goal.



**The financial results for the year reflect two main factors that differentiate this year from 2015. The first is impairment of goodwill that was allocated to the allergy franchise to reflect the future potential benefit of the acquired Aerocrine commercial infrastructure in the commercialisation of the Company's allergy portfolio. Following the disappointing results from the cat allergy phase III study, this goodwill has been fully impaired. The second factor is the full year's contribution from the NIOX® and Prosonix respiratory businesses compared with a little over half a year's contribution in 2015 following their acquisition on 18 June 2015 and 15 June 2015 respectively.**

**The financial results for the year to 31 December 2016 are set out in the table on page 30.**

### Revenue

Revenue of £23.1 million (2015: £10.8 million) reflects the full year contribution from the NIOX® business that accounts for nearly all the Group's turnover for the year. These revenues include sales of NIOX VERO® and NIOX MINO® for clinical use in the US, Europe and rest of world of £18.0 million (2015: £7.3 million), and for research use in pharmaceutical companies' clinical studies of £4.5 million (2015: £2.6 million), as well as other revenues including licence income and freight of £0.6 million (2015: £0.4 million).

In 2015, out of £10.8 million revenue, £10.3 million was NIOX® sales from 19 June to 31 December 2015 and £0.5 million was licence fee and milestone payments related to the respiratory business acquired on 15 June 2015.

### Gross profit

Gross profit on NIOX® sales was £15.1 million (2015: £6.1 million), with a gross margin of 65% (2015: 59%). This increase reflects the continuous growth of NIOX® test sales.

### Sales and marketing

During the year, the underlying sales and marketing expenditure was £28.9 million (2015: £13.5 million). This reflects a significant strengthening of the Group's commercial presence in the US. In particular, the US sales force increased substantially and the teams supporting the commercial infrastructure expanded in support of the Group's sales effort.

Goodwill arising on the acquisition of Aerocrine last year was allocated to reflect the potential benefit provided by the acquired commercial infrastructure in the future commercialisation of the allergy franchise. This goodwill has now been fully impaired following the disappointing outcome of the cat allergy phase III study resulting in a charge of £74.5 million to sales and marketing expenses. Goodwill impairment comprises the majority of the non-underlying items included in sales and marketing costs. For the full breakdown of non-underlying items see note 10 of the consolidated financial statements.

### Research and development

Underlying investment in research and development activities was £42.3 million (2015: £46.8 million). Of this, £19.1 million (2015: £30.5 million) relates to Circassia's portfolio of allergy candidates, £6.9 million (2015: £6.1 million) to the development of the respiratory portfolio and £5.3 million (2015: £2.0 million) to the NIOX® franchise, of which £2.0 million relates to an amortisation charge for acquired R&D technology. Costs not specific to R&D projects, including personnel costs, were £11.0 million (2015: £8.2 million).

Following the results from the cat allergy phase III study in June 2016, expenditure on the allergy portfolio was halted except for the following activities:

- Limited costs that had already been committed
- Completion of the ongoing house dust mite allergy field study (TH005)
- Completion of the two year cat allergy follow up study (CP007A)
- Expenditure required to maintain drug product and drug stability programmes

## Financial review continued

£15.1m

Gross profit of £15.1 million  
(2015: £6.5 million)

£117.4m

Strong balance sheet  
with £117.4 million cash<sup>1</sup>  
as at 31 December 2016  
(2015: 203.8 million)

	Underlying operations £m	Non-underlying items <sup>2</sup> £m	Total Group 2016 £m	Total Group 2015 £m
Revenue	23.1	–	23.1	10.8
Cost of goods sold	(8.0)	–	(8.0)	(4.3)
Gross profit	15.1	–	15.1	6.5
Sales and marketing	(28.9)	(75.8)	(104.7)	(13.5)
Research & development	(42.3)	(3.9)	(46.2)	(46.8)
Administrative expenditure	(15.4)	(0.3)	(15.7)	(13.7)
Other gains	–	–	–	1.1
Operating loss	(71.5)	(80.0)	(151.5)	(66.4)
Finance income net	6.0	–	6.0	3.5
Share of profit of joint venture	0.6	–	0.6	0.1
Loss before tax	(64.9)	(80.0)	(144.9)	(62.8)
Taxation	7.5	–	7.5	12.8
Loss for the financial year	(57.4)	(80.0)	(137.4)	(50.0)
Cash <sup>1</sup>	117.4	–	117.4	203.8

<sup>1</sup> Includes cash and cash equivalents and short-term deposits.

<sup>2</sup> Includes impairment of goodwill (£74.5 million), intangible assets impairment (£0.3 million), restructuring costs (£2.8 million) and cost for termination of certain contracts (£2.4 million)

65%


NIOX<sup>®</sup> gross margin  
increased to 65%  
(2015: 59%)

£6.0m

Net finance income  
increased to £6.0 million  
(2015: £3.5 million)





Following the significant setback of the cat allergy results in June 2016, Circassia reacted swiftly with a significant cost reduction programme to curtail expenditure on the allergy portfolio and consolidate operations 

Of the £19.1 million expenditure on the allergy programme, £13.8 million was incurred in H1 2016 and £5.3 million in H2 2016. Of the total costs of £7.7 million (2015: £14.2 million) in respect of the house dust mite allergy programme, £2.2 million was incurred in H2 2016 on TH005. The total spend on the cat allergy programme was £5.5 million (2015: £9.8 million), of which £2.0 million was incurred in H2 mainly in respect of drug product and stability programmes, committed costs of the cat phase III study (CP007) and the two year follow-up study (CP007A). In H1 2016, the grass allergy programme moved into the final phase of clinical testing with the start of the registration field study (TG005), contributing £4.8 million of expenditure in the year, however the majority of activities were stopped after the cat allergy results.

Investment in the respiratory portfolio mainly relates to the Seretide® / Advair® pMDI substitute development programme and the tiotropium bromide product targeting direct substitution of Spiriva® DPI.

In addition, a charge of £3.9 million has been recorded as non-underlying research and development expenditure. Of this, £2.4 million relates to a contract provision for the manufacture of trial batches for allergy programmes, £1.2 million in redundancy costs and closure of the site in Solna and an impairment of £0.3 million for allergy licences and patents following the cat allergy results.

#### **Administrative expenditure**

Underlying administrative expenses includes overheads specific to corporate functions, centrally managed support functions and corporate costs. These increased to £15.4 million (2015: £13.7 million) reflecting a full year of costs of the two businesses acquired in June 2015.

#### **Financial income**

Net finance income increased to £6.0 million (2015: £3.5 million). Included in this is bank interest income of £0.9 million (2015: £1.7 million) and a net gain on foreign exchange of £5.2 million (2015: £1.8 million). The foreign exchange gain arose as a result of sterling weakening during the year against the US dollar and Swedish krona.

#### **R&D tax credits on qualifying expenditure**

Taxation for the year was £7.5 million credit (2015: £12.8 million credit). Included within this is a tax credit of £8.6 million (2015: 10.3 million) recoverable under current legislation relating to R&D expenditure. The decrease over the previous year reflects the decrease in R&D expenditure qualifying for R&D tax credit, which is due in particular to the decrease in expenditure on the allergy portfolio.

#### **Loss after tax and loss per share**

Total loss for the financial year was £137.4 million (2015: £50.0 million), of which £137.3 million (2015: £49.9 million) was attributable to the owners of Circassia Pharmaceuticals plc. Basic loss per share attributable to the owners of Circassia Pharmaceuticals plc was 48p (2015: 20p). This includes impairment charges and other non-underlying items of £80.0 million. Excluding these costs, the loss per share for the underlying operations was 20p (2015: 20p).

#### **Statement of financial position**


The Group's net assets were £280.7 million at 31 December 2016 (2015: £409.7 million). The decrease includes impairment charges of £74.5 million and £0.3 million to goodwill and intangible assets respectively as well as reduction in cash. Further detail on the impairment charges can be found in notes 14 and 15. Other factors are commented on below.

The weakening of pound sterling against the US dollar and Swedish krona resulted in a credit of £9.8 million to Other Comprehensive Income and Expense due to retranslation of the Group's overseas operations.

Current liabilities were £21.5 million (2015: £48.3 million). The decrease is mainly due to the payment in January 2016 of contingent consideration of £30.0 million for the purchase of Prosonix. This reduction was partly offset by £2.3 million restructuring costs accrued at the year-end (2015: £nil) relating to cost reduction initiatives.

Current tax assets were £8.7 million at 31 December 2016 (2015: £11.8 million), representing the R&D tax credit due from HM Revenue and Customs. A payment of £11.8 million was received in H2 2016 from HMRC.



With a period of challenges now behind the Company, Circassia looks forward to further strengthening its business in 2017 

### Restructuring provisions for Chicago (US) and Solna (Sweden) offices

Following a review of operations to drive efficiencies across the wider business, the Company decided to consolidate its US and Swedish operations and close its Chicago and Solna offices.

As a result, Chicago office closure costs of £1.3 million included in the financial statements relate to severance and compensation for loss of office, and property cost commitments that are deemed non-recoverable. These costs were recorded as non-underlying sales and marketing expenditure. It is expected that the consolidation in the US will ultimately yield annual cost savings of £4.6 million.

Similarly, Solna office closure costs of £1.0 million included in the financial statements relate to severance and compensation for loss of office, and non-recoverable property cost commitments. These costs were recorded as non-underlying expense in sales and marketing (£0.2 million), research and development (£0.5 million), and administrative expenditure (£0.3 million). It is expected that this consolidation will provide annual cost savings of £1.6 million.

### Cash flow

The Group's cash position (including short-term deposits) decreased from £203.8 million at 31 December 2015 to £117.4 million at 31 December 2016. Main cash outflows were:

- £30.0 million deferred consideration paid to the former shareholders of Prosonix in January 2016 following receipt of UK marketing authorisation for its lead product in December 2015
- £56.7 million cash used in operating activities (2015: £55.8 million) reflecting a full year of operations of the two businesses acquired in June 2015 as well as R&D expenditure and the expansion of the US sales and marketing infrastructure
- £3.2 million payment to acquire the remaining 2.1% of issued shares of Aerocrine AB under the Swedish formal 'squeeze out' procedure. Please see note 28 for further details of the transaction

The exchange gain on cash and cash equivalents for the period was £4.1 million (2015: £0.6 million)

### Events occurring after the reporting date

On 17 March, Circassia announced a collaboration and profit share arrangement with AstraZeneca and securing of certain US commercial rights to Tudorza® and Duaklir® for a maximum total consideration of US \$230 million. Circassia will also make R&D contributions of up to US\$62.5 million payable to AstraZeneca as deferred payments and will pay royalties on future sales of Duaklir®. Further details are available in note 34 of the financial statements.

### Summary and outlook

Following the significant setback of the cat allergy results in June 2016, Circassia reacted swiftly with a significant cost reduction programme to curtail expenditure on the allergy portfolio and consolidate operations with the closure of Chicago and Solna together with other redundancies across the Group. In addition, the Company invested significantly in its US commercial operations, increasing field force numbers from 40 to approximately 100 in July and August 2016. This decision was recently validated by the announcement in March 2017 of the collaboration with AstraZeneca to secure US commercial rights to Tudorza® and Duaklir® as well as the continued growth of the Company's NIOX® products.

As a result of these initiatives Circassia continues to have a robust balance sheet, with cash of £117.4 million as at 31 December 2016 and is well funded to deliver on its strategy. With a period of challenges now behind the Company, Circassia looks forward to further strengthening its business in 2017.

**Julien Cotta**  
Chief Financial Officer

# Corporate social responsibility

**The Board has responsibility for all matters relating to corporate social responsibility. The Directors recognise the importance of corporate social responsibility, and seek to take account of the interests of all the Group's stakeholders, including its investors, customers, suppliers, partners, and employees when operating the business. The Board believes that fostering an environment in which employees act in an ethical and socially responsible fashion is critical to its long-term success. The Group strives to be a good corporate citizen and respects the laws of the countries in which it operates.**

## People

Attracting, motivating and retaining a highly skilled workforce is key to the Group's long-term success. The policies put in place by the Group accord with best practice, and stipulate that there should be equal opportunities and an absence of discrimination for all employees.

## Values

Our values, and the behaviours that underpin them, describe the culture of our business.

### Passion

- We are passionate and committed about what we do
- We are excited about our products and technology and the impact they will have on patients' lives
- We take our responsibilities seriously and ensure everything we do is delivered to the appropriate quality
- We thrive on demanding and challenging timelines and seek to exceed expectations and attain our goals
- We are energised to take action, despite obstacles and setbacks

### Recognition

- We identify and acknowledge the contribution that individuals make
- We recognise and reward success internally and with our partners

- We understand mistakes are made; our ability to identify them, correct them, and learn from them makes the difference
- We promote the value of the team above that of the individual to achieve positive outcomes

### Integrity

- We trust, respect and listen to each other
- We act with honesty, integrity and fairness at all times, we always strive to do the right thing
- We believe in constructively challenging each other and expect to be challenged
- We are not afraid to say "I don't know" and go and find out
- We promote open communication and collaboration, encouraging, honest, direct, and respectful feedback
- We take ownership for our actions

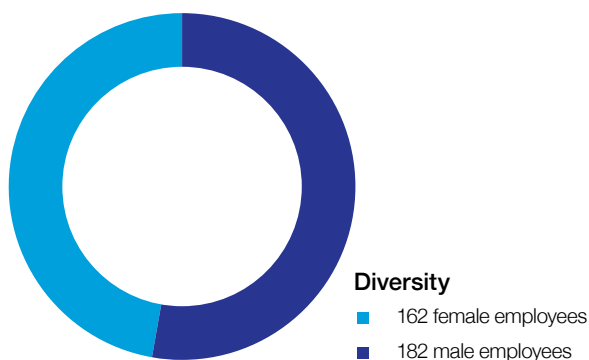
### Drive

- We set ambitious goals and go for them, believing this drives extraordinary behaviour
- We persist, despite setbacks, to achieve goals
- We always convey a strong sense of urgency recognising saving time creates value
- We seek to achieve success even in complex and changing circumstances
- We always aim to meet or exceed our commitments

### Effectiveness

- We understand key business drivers and manage our costs effectively
- We continuously seek to improve our performance and develop more effective ways of working
- We always strive to get the best value for money for our requirements and maximise the return on our investment
- We make informed decisions about the levels of expense needed for the business
- We are clear about roles and responsibilities

# Corporate social responsibility continued



## Diversity

The importance of diversity within the Group is also reflected in its policies and procedures. The Group does not have formal diversity quotas but recognises that a diverse employee profile is of significant benefit. The table below shows the gender profile at different levels of the Group as at 31 December 2016.

Member	Male	Female	Total	%Male	%Female
Plc Board including Non-Executive Directors	9	1	10	90	10
Employees in other senior executive positions	3	1	4	75	25
Directors of subsidiary companies not included in above	0	0			
Total Senior Managers excluding Directors	3	1	4	75	25
All other employees	170	160	330	52	48
<b>Total</b>	<b>182</b>	<b>162</b>	<b>344</b>	<b>53</b>	<b>47</b>

## Employee welfare and involvement

Employees are regularly provided with information about the Group, for example through regular 'open house' sessions at which the Chief Executive Officer and other members of the management team present on various topics such as strategic and operational progress, and employee-related policies. Feedback is frequently sought by line managers and the senior management team through team meetings.

## Employment, training, career development and promotion of disabled persons

The Board recognises the value of diversity at all levels of the Group. The Group has an Equal Treatment, Equal Opportunities and Diversity policy which extends to the Board. This provides that the Group will employ and promote employees on the basis of their abilities and qualifications without regard to age, disability, gender, marriage and civil partnership, pregnancy and maternity, race (including colour, nationality and ethnic or national origins), religion or belief or sexual orientation. The Group appoints, trains, develops and promotes on the basis of merit alone.

## Health and safety

The Group is committed to protecting the health and safety of its employees and endeavours to maintain an effective health and safety culture.

The Group provides ongoing training to individuals who are responsible for health and safety and all staff are notified of health and safety practices. The Group continuously monitors its health and safety policy and practices to ensure they are robust, appropriate, and reflect changes in best practice.

## Ethical and social policies

The Group is a pharmaceutical and medical devices group and accordingly operates in a highly regulated ethical framework. It complies fully with these laws and regulations. The Company has a clear anti-bribery policy which is monitored by the Compliance department.

## Sunshine Act

The Group is committed to promoting transparency of its relationships with healthcare providers. It collects, tracks and reports payments to healthcare professionals and organisations in compliance with the US Physician Payment Sunshine Act.

## Human rights

We support the UN Universal Declaration of Human Rights and recognise the obligation to promote universal respect for and observance of human rights and fundamental freedoms for all, without distinction. We comply with all applicable human rights laws.



### Product development

The Group commissions third-party laboratories to conduct the minimum necessary pre-clinical product safety testing in animal models as required by regulatory authorities before commencing clinical studies. We work according to the 3Rs policy relating to preclinical testing (Refine, Reduce, Replace).

### Environment

The Group is committed to minimising the impact of its activities on the environment. The majority of the Group's employees operate out of modern office suites, although it also occupies laboratory space in Oxford and has warehouses in Uppsala, Sweden and Morrisville, USA. Accordingly, the Group believes that efficient use of energy and materials in those premises, and responsible disposal of hazardous waste, are the most important means of climate protection currently available to it. Office-based initiatives to reduce waste have also been adopted, which include recycling of paper waste, cans, plastics, batteries and printer toners/cartridges. The Group does not possess or make use of corporate jets or private planes.

### Greenhouse gas emission

This section of the Annual report constitutes the Group's disclosure of its greenhouse gas (GHG) emissions in accordance with the Companies Act 2006 (Strategic Report and Directors' Report Regulations 2013).

The Group considers that its current activities have a low environmental impact. Nonetheless, it still actively seeks to make energy savings in a fashion which is environmentally responsible and cost effective.

The increase shown over 2015 in GHG emissions reflects the full year impact of the acquisitions of Aerocrine and Prosonix. These entities were acquired in June 2015 and so the GHG figures for 2015 reflect only six months of activity. The acquisitions added laboratories in Oxford, offices in Solna, Sweden, Bad-Homburg, Germany, and in Morrisville, North Carolina, and warehouse facilities in Uppsala, Sweden and Morrisville.

	2016	2015
CO equivalent emissions – scope 1 (tonnes)	–	–
CO equivalent emissions – scope 2 (tonnes)	218	97
Intensity ratio (kg/m <sup>2</sup> of office space)	40	21

GHG emissions are reported in metric tonnes of carbon dioxide equivalents and calculated using the Defra conversion factors.

Gas and electricity usage information has been obtained from purchase invoices and verified by reference to meter readings.

In order to express annual emissions in relation to a quantifiable factor associated with the Group's business, an intensity ratio has been calculated which shows emissions reported per square metre of the office space occupied by the Group. This is shown in the table above.

### Political and charitable donations

The Group does not make political or charitable donations, although charitable fundraising by employees is encouraged.

### Slavery and human trafficking statement

The Group does not currently meet the turnover threshold which would require it to make a statement pursuant to the Modern Slavery Act 2015. Nonetheless, it is committed to improving its practices to combat slavery and human trafficking. As part of our initiative to identify and mitigate risks we perform due diligence on potential suppliers and distributors and protect whistleblowers, who can raise concerns anonymously through an externally provided reporting service. We are also finalising a Partner Code of Conduct which will be rolled out in 2017.

# Risks and risk management

**The management of risks is a key responsibility of the Board of Directors of the Company. The Board ensures that the risks taken by the Group are understood, and are appropriate in the light of its strategy and objectives, and that internal controls are in place to effectively identify, assess, and manage important risks.**

The risk management strategy adopted by the Company has a number of facets. A risk register has been created and is updated on an annual basis by those individuals in the business who manage risks on a day to day basis. This identifies each risk, assesses the likelihood of its occurrence and the level of impact on the business. This process is coordinated by the Chief Financial Officer. The register is reviewed by the Senior Management Team and subsequently reviewed by the Audit and Risk Committee and reported to the Board. There is a particular emphasis on ensuring that the risk appetite of the Board is fully understood by the Senior Management Team. The register also sets out activities and controls which are designed to mitigate the identified risks, and again the Board and the Senior Management Team analyse these mitigation strategies and ensure that the approach taken is consistent with the nature and degree of risks which are considered acceptable by the Board. Aside from the review, risk owners across the business are responsible for reporting any significant issues on an ongoing basis up to the Senior Management Team and for ensuring that other members of their teams are aware of the risk management process. The Senior Management Team, which meets weekly, receives summary weekly updates and more detailed monthly reports from all areas of the business, and updates the Board on a timely basis where important developments occur. Within the R&D function, project team meetings take place once a month at which the progress and risks of each individual project are discussed and detailed reports are circulated. The Quality Team, Compliance Committee, and Health and Safety Committee also meet regularly. These discussions are documented in reports which are circulated to the Senior Management Team.

The risk management system is designed to manage risks, rather than eliminate them at the expense of achieving corporate objectives. Accordingly, it can only provide a reasonable and not an absolute assurance against material misstatement or loss.

The scope of the Group's commercial risk management activities increased significantly in the second half of 2015 to reflect the fact that, following the acquisition of Aerocrine AB, the Group began selling medical device products in the US, Europe, and Asia. This led to the inclusion of compliance with healthcare regulations as a new category of principal risk in the 2015 Annual report and this focus has continued throughout 2016 and will become even more prominent in 2017 following the commencement of the collaboration with AstraZeneca relating to Tudorza®.

## Principal risks

The main risks relevant to the Group have been identified below, together with an explanation of how they are managed and controlled. Some risks are common across the pharmaceutical industry, while others reflect the Group's specific strategy. The Company considers all of these risks relevant to any decision to invest in it.

## Commercial success

The Group's competitors – many of whom have considerably greater financial and human resources – may develop safer or more effective products or be able to compete more effectively in the markets targeted by the Group. New companies may enter these markets and novel products and technologies may become available which are more commercially successful than those being developed by the Group.

During H1 2017 the Group will commence its collaboration with AstraZeneca to sell the long-acting muscarinic antagonist (LAMA), Tudorza® in the United States and will share in the profits from those sales. There are currently two other LAMA products marketed in the United States, namely Spiriva® (sold by Boehringer Ingelheim) and Incruse® (sold by GSK). A third product Seebri® is expected to be launched in the United States by Sunovion in 2017. Tudorza® will compete directly with all these products.

In addition, the Group may not be able to sell its products profitably if reimbursement from third party payers such as private health insurers and government health authorities is restricted or not available because for example it proves difficult to build a strong enough economic case based on the burden of illness and population impact. Third party payers are increasingly attempting to curtail healthcare costs by challenging the prices that are charged for pharmaceutical products and denying or limiting coverage and the level of reimbursement. Moreover, even if the products can be sold profitably, they may not be accepted by patients and the medical community.

The Group's NIOX MINO® and NIOX VERO® devices compete in Europe with products made by Bedfont Limited and Medisoft. Neither of these competing products are currently available in the US. Two other companies, Bosch Healthcare Solutions GmbH (in Germany) and Spirosure Inc. (in the United States) have also announced they have developed and intend to commercialise devices to measure exhaled nitric oxide although neither of these products has yet been launched. In China, a competing product is supplied to the market by Sunvou Medical.

Outside the US, UK and Germany the Group relies on distributors to sell its NIOX® devices and such relationships must be carefully managed in order to ensure the services provided are of a sufficiently high quality and an appropriate level of resources is applied by the distributor to the marketing of the devices.

The successful commercialisation of the Group's fluticasone propionate product will, when launched, be largely dependent upon its partner Mylan which has the exclusive rights to sell the product in most major markets. Moreover, this product and certain other drug products being developed by the Group for treatment of asthma, such as its fluticasone/salmeterol combination product Seriveo®, are generic products and so will compete with the innovator products as well as potentially generics from other third parties.

Factors that may undermine the Group's efforts to commercialise its products include: the inability to train and retain effective sales and marketing personnel; a failure to persuade prescribers to prescribe products; and higher costs of marketing and promotion than are anticipated by the Group.

### **Mitigating activities**

The Group has developed an initial Promotional Plan for Tudorza® and will keep this under review with its partner AstraZeneca. The intention is to focus promotional efforts on higher volume prescribers and promote Tudorza® as the primary product in the majority of health care professional (HCP) calls. A dedicated team will also concentrate on selling the product to larger public and private institutions under fixed term contracts.

With regard to its NIOX® franchise, the Group continues to apply increasing resources to sales of the device. By the end of 2016 there were approximately 100 sales representatives selling NIOX® in the United States, representing approximately a fourfold increase in the course of the year. A direct sales team has also been assembled in the UK, alongside the existing commercial teams in China and Germany. Distributor markets are now more closely managed following the appointment of an experienced Director of Distributor Management.

With respect to the Respiratory franchise, the Group's agreement with Mylan contains provisions which offer remedies in the event that insufficient diligence is applied to the marketing of its Flixotide substitute. A joint steering committee oversees this project.

### **Compliance with healthcare regulations**

The Group must comply with complex regulations in relation to the marketing of its device products (and in the future will need to comply with such regulations in relation to its drug products). These regulations are strictly enforced. Failure by the Group (or its commercial partners) to comply with the US False Claims Act, Anti-Kickback Statute and the US Foreign and Corrupt Practices Act and regulations relating to data privacy (amongst others) and similar legislation in countries outside the US may result in criminal and civil proceedings against the Group.

### **Mitigating activities**

The Group has an internal Compliance function which is head by its VP, Global Compliance Officer. The Global Compliance Officer reports to the General Counsel but also has a direct reporting line to the Chair of the Audit and Risk Committee. A Compliance Committee has been formed to oversee activities in this area and this met throughout 2016 on a quarterly basis. The Compliance function works with a network of external advisers in the relevant territories to ensure the local regulations are comprehended and that strategies are in place to support products in development as well as those already approved and sold. Robust processes are in place to ensure that sales compliance requirements are met and any failures or allegations of failure are swiftly investigated. This includes training of employees, ride-alongs with sales representatives, due diligence on distributors and suppliers prior to contracting with them, and audits of distributors and suppliers.

# Risks and risk management continued

## Regulatory approvals

The Group may not obtain regulatory approval for those of its products which are in development. Even where products are approved, subsequent regulatory difficulties may arise, or the conditions relating to the approval may be more onerous or restrictive than the Group expects, or existing approvals might be withdrawn.

The pharmaceutical industry is highly regulated. Regulatory authorities across the world enforce a range of laws and regulations which govern the testing, approval, manufacturing, labelling and marketing of pharmaceutical products. Stringent standards are imposed which relate to the quality, safety and efficacy of these products. These requirements are a major determinant of whether it is commercially feasible to develop a drug substance or medical device given the time, expertise, and expense which must be invested. Moreover, approval in one territory offers no guarantee that regulatory approval will be obtained in any other territory.

In order to obtain regulatory approval for the Group's products, it will be necessary to successfully complete supporting clinical studies. Clinical studies are typically expensive, complex and time-consuming, and have uncertain outcomes. Conditions in which clinical studies are conducted differ, and results achieved in one set of conditions could be different from the results achieved in different conditions or with different subject populations. Regulatory authorities or institutional review boards may suspend or terminate clinical studies at any time if the subjects participating in such studies are being exposed to unacceptable health risks or may require additional studies to be performed. Difficulties or delays in the enrolment of subjects could result in significant delays in the completion of those studies and even in their abandonment.

The Group already holds regulatory approvals for its NIOX MINO® and NIOX VERO® devices in certain key countries such as the United States, Japan, China, and Germany but approvals are still pending for the VERO® in a number of other countries. Delays or complications in any of these regulatory applications could adversely affect the Group's business.

The Group also has an exclusive licence to commercialise Duaklir® in the United States. This product is not yet approved, and is undergoing two clinical trials (AMPLIFY and ACHIEVE), both managed by AstraZeneca, in order to support a filing for a New Drug Application to the FDA. The results of AMPLIFY are expected in H2 2017 and the results of ACHIEVE are expected in H1 2017. If either or both of these studies fail to achieve their endpoints then there is a risk that the product might not be approved by the FDA.

Also, the product Tudorza® which will be promoted by the Group in 2017 as part of its collaboration with AstraZeneca is currently the subject of a cardiovascular safety study (ASCENT), managed by AstraZeneca, the results of which are anticipated before the end of 2017. If the ASCENT study shows that there is a safety signal associated with Tudorza® then that would lead to discussions with the FDA, one possible outcome of which could be that the product would require a black box warning or even be withdrawn from the market.

The Group is currently carrying out clinical trials for a number of respiratory products. The lead respiratory programmes seek to develop substitutes for Seretide® and Spiriva®. However, there can be no guarantee that these trials will meet their endpoints or that the products will ultimately be approved.

The Group relies on third party sub-contractors and service providers for the execution of most aspects of its development programmes. Failure of these third parties to provide services of a suitable quality within acceptable timeframes – for example due to technical reasons or bankruptcy of the provider – may cause the failure or delay of these development programmes.

Even where approval is obtained, regulatory authorities may still impose significant restrictions on the indicated uses or marketing of a product or impose costly, ongoing requirements for post-marketing surveillance or post-approval studies, or may even withdraw the approval if new concerns over safety and efficacy arise.

## Mitigating activities

The Group manages its regulatory risk by employing highly experienced clinical managers and regulatory affairs professionals who, where appropriate, will commission advice from external advisers and consult with the regulatory authorities on the design of the Group's pre-clinical and clinical programmes. These in-house experts ensure that high quality protocols and other documentation are submitted during the regulatory process, and that well-reputed contract research organisations with global capabilities are retained to manage the trials. The clinical studies which are taking place with Tudorza® and Duaklir® are being managed by AstraZeneca which is a global leader in the development of respiratory drugs.

## Unforeseen side effects

Unforeseen side effects may result from the use of the Group's products or product candidates.

There is a risk of adverse reactions with all drugs and there is a risk that the malfunction of a medical diagnostic may have an adverse impact on patients. If any of the Group's products are found to cause adverse reactions or unacceptable side effects or risk of misdiagnosis, then product development may be delayed, additional expenses may be incurred if further studies or product development work are required, and, in extreme circumstances, it may prove necessary to suspend or terminate development. This may occur even after regulatory approval has been obtained, in which case additional trials may be required or the approval may be suspended or withdrawn or additional safety warnings may have to be included on the label.

Adverse events or unforeseen side effects or device malfunction may also potentially lead to product liability claims being raised against the Group as the developer of the products and sponsor of the relevant clinical trials.



### Mitigating activities

The Group conducts extensive pre-clinical and clinical trials which test for and identify adverse side effects of its internally developed novel drug candidates. Its medical diagnostic products are subject to rigorous testing procedures. A robust pharmacovigilance plan is in place to ensure any safety issues are identified and reported. Insurance is in place to cover product liability claims which may arise during the conduct of clinical trials or sales of the Group's NIOX MINO<sup>®</sup> and NIOX VERO<sup>®</sup> products and sales of Tudorza<sup>®</sup>. AstraZeneca will administer the global safety database for Tudorza<sup>®</sup>.

### Supply Chain

The Group relies on third parties for the supply of key materials and services. Problems at these contractors, such as technical issues, contamination, and regulatory actions may lead to delays or even loss of supply or inadequate supply of these materials and services either prior to launch or thereafter. Some materials may only be available from one source, as is currently the case for the NIOX MINO<sup>®</sup> and NIOX VERO<sup>®</sup> devices and the sensors contained in those devices, and regulatory requirements may make substitution costly and time-consuming.

The supply chain for Tudorza<sup>®</sup> will continue to be controlled by AstraZeneca at least until the Group is able to exercise its option to acquire the full rights to the product and AstraZeneca will remain the sole source of supply for this product and for Duaklir<sup>®</sup> if approved.

### Mitigating activities

Audits of sub-contractors are routinely conducted according to procedures set out in the Group's Quality system. Dual sourcing is being investigated where this is practicable. Manufacturing sites are well established FDA-approved facilities. AstraZeneca has an established global supply chain in place for Tudorza<sup>®</sup> and at the point when the Group is able to acquire the full rights to the product an arms'-length supply agreement will be in place.

### Research and development risks

The Group may not be successful in its efforts to build a pipeline of respiratory products. This would have a material impact on the long-term success of the business. Failure of programmes could result from lack of internal resources or capabilities, or from not obtaining the desired pre-clinical and clinical results.

In addition, the Group is dependent upon external collaborators for the development of its NIOX<sup>®</sup> devices. The Group relies upon its collaborations with Panasonic Healthcare Co., Ltd for the development of the devices themselves and upon IT Dr. Gambert GmbH for the development of the sensors contained in those devices.

Research and Development activities associated with Tudorza<sup>®</sup> and Duaklir<sup>®</sup> will continue to be led by AstraZeneca, although the Group will have input through the steering committees which have been formed to govern the collaboration.

### Mitigating activities

The Group has recruited highly experienced R&D executives. Projects are closely monitored against goals and regularly reported to the Senior Management Team and the Board, and external resources are retained where this is deemed appropriate. The development collaborations with Panasonic and AstraZeneca are managed by steering committees which include representatives from the Group. In addition, the Group will seek, through business development activity, to identify opportunities which would expand and diversify its portfolio.

### Intellectual property, know how, and trade secrets

The Group may be subject to challenges relating to the validity of its patents. If these challenges are successful then the Group may be exposed to generic competition. Currently there is an opposition pending against a patent owned by the Group namely a process patent in its particle engineering portfolio (the 'SAX' patent). This patent does not cover products which are currently marketed or which the Group expects to market in the near future.

The Group could also be sued for infringement of third party patent rights. If these actions are successful then it would have to pay substantial damages and potentially remove its products from the market. Such litigation, particularly in the US, involves significant costs and uncertainties.

It is possible that the Group will not be able to secure intellectual property protection, or sufficient protection, in relation to products which are acquired or in development. Similarly, a failure by the Group to maintain or renew key patents would lead to the loss of such protection. In both cases the potential of the Group to earn revenue from its products could be compromised as it would be less difficult for third parties to copy the products.

The Group may rely upon know how and trade secrets to protect its products and maintain a competitive advantage. This may be especially important where patent protection is limited or lacking. Conversely, the Group may be subject to claims that its employees or agents have wrongfully used or disclosed the confidential information of third parties which could lead to damages or injunctions which affect particular products.

The Group licenses certain intellectual property rights from third parties. The rights which are licensed to the Group as part of the collaboration with AstraZeneca relating to Tudorza<sup>®</sup> and Duaklir<sup>®</sup> fall within this category. If the Group fails to comply with its obligations under these licence agreements it may enable the other party to terminate the agreement. This could impair the Group's freedom to operate and potentially lead to third parties preventing it from selling certain of its products.

# Risks and risk management continued

## Mitigating activities

Important products are covered by more than one patent family and attacks on patents are defended using expert external patent attorneys and lawyers. A robust system is in place which ensures patents are renewed on time. Third party patent filings are monitored to ensure the Group continues to have freedom to operate and oppositions are filed where this is considered expedient. Confidential information (both of the Group and belonging to third parties) is protected through use of confidential disclosure agreements with third parties, and suitable provisions relating to confidentiality and intellectual property exist in the Group's employment contracts. Licences are monitored for compliance with their terms.

## Organisational capabilities and capacity

The Group may be unable to successfully implement its plans for growth if it does not attract and retain employees with the requisite capabilities and experience, in appropriate numbers. The Group depends on the skills and experience of its current management team and employees, and is generally subject to competition for, and may fail to retain, skilled personnel.

Existing employees, investigators, consultants and commercial partners may engage in misconduct or improper activities, including non-compliance with regulatory standards and laws.

Where the Group acquires complementary technologies, products, or businesses it may not be able to integrate those acquisitions effectively or realise their expected benefits.

The Group may be vulnerable to disruption and damage as a result of failures of its computer systems.

## Mitigating activities

The Group has budgeted for substantial growth in headcount over the next three years. Remuneration packages are competitive, and incentive plans based on the contingent award of shares, are in place to attract, motivate and retain staff.

Disciplinary and whistleblowing policies exist to address misconduct by employees and officers, and committee structures have been established with the Contract Research Organisations instructed by the Group, to monitor and manage the conduct of the Group's clinical trials.

To address IT and cyber risks, a disaster recovery plan has been developed.

Data is backed up daily on off-site servers and the Group operates from a number of physically separate sites. In addition, the Group maintains up to date anti-virus, anti-malware and anti-spyware software.

## Free float

The UK Listing Authority requires listing issuers to maintain at least 25% free float in their listed shares. At 20 April 2017 the Company had a free float of approximately 16%. If the level of free float cannot be increased to 25% then the UKLA can require the Company to cancel its listing on the premium segment of the Official List. This might adversely affect the ability of new and existing shareholders to buy Ordinary shares and of holders to sell them.

## Mitigating activities

The Company has obtained a derogation from the UKLA in respect of the Free Float requirement for a period of 12 months from 17 March 2017. During this period the Company will: (i) discuss with Shareholders who own more than 5% of the issue share capital of the Company whether any of their holdings can be disaggregated because decisions are being taken by independent investment managers within that Shareholder's organisation; and (ii) discuss with such Shareholders the prospect of reducing their holding below 5%.

## Financial operations

The Group has incurred significant losses since the inception of its various businesses and anticipates that it will continue to do so for some time due to the high level of expenditure required to develop its NIOX<sup>®</sup> business, its respiratory pipeline, and to promote Tudorza<sup>®</sup> and launch Duaklir<sup>®</sup>.

Foreign exchange fluctuations may adversely affect the Group's results and financial condition. The Group records its transactions and prepares its financial statements in pounds sterling, but a significant proportion of its expenditure is in US dollars, Swedish krona, or Euros.

Adverse decisions of regulators, including tax authorities, or changes in tax treaties, laws, or the interpretation of those laws, could reduce or eliminate research and development tax credits which the Group, and its joint venture Adiga Life Sciences Inc. currently receives in the United Kingdom and Canada respectively.

## Mitigating activities

The Group has prepared a detailed forecast for the next 10 years and, if it achieves its objectives, this shows that the current business plan is sufficient to take the Group through to profitability. Forward purchases of foreign currencies are made when exchange rates are favourable to provide for expenditure in those currencies. Markets are constantly monitored and an external commentary is provided by Investec on a daily basis. If tax credits are lost in the future then action would be taken to reduce discretionary expenditure in order to ensure there remained sufficient cash to support the business through to profitability.

## Brexit

At the referendum which was held on 23 June 2016, the UK voted to leave the EU. The Group faces a range of risks associated with this decision. For example, the vote to leave the EU may lead to changes in the regulatory system by which medical devices and pharmaceutical products are approved for use. The Group's NIOX® product is currently CE marked in accordance with European regulations and it is possible that this registration will need to be changed in some way once the UK has left the EU, to permit sales of the device to continue across Europe. The Group will also seek marketing authorisations in respect of its respiratory pipeline products in the future, and the optimal regulatory pathway for the approval of these products after Brexit cannot yet be determined.

Brexit may also result in restrictions on the movement of people which make it harder for the Group to attract the talent it needs to support the business. The general economic uncertainty created by the process may also make it harder to enter into strategic partnerships with European companies.

The announcement of Brexit also caused a significant depreciation in the value of sterling and may lead to further foreign exchange volatility. This may affect the Group as indicated in the more general risk relating to Financial Operations set out above.

## Mitigating activities

The Group continues to monitor developments relating to Brexit and receives updates from its legal and regulatory advisers on a frequent basis. The Group does already have an established subsidiary in Sweden (Circassia AB) and Germany (Circassia AG) and so will still have a corporate presence in the EU even after Brexit comes into effect. The risks relating to currency volatility are mitigated through the actions described above under the Financial Operations risk.

## Viability statement

The Directors have assessed the viability of the Group over a three year period to 31 December 2019, taking account of the Group's current position and the potential impact of the principal risks identified above. Based on this assessment, the Directors have a reasonable expectation that the Group will be able to continue in operation and meet its liabilities as they fall due over the period to 31 December 2019.

In making this statement, the Directors have considered the robustness of the Group, taking account of its current position, potential future developments, the principal risks facing it, and the effectiveness of mitigation plans and controls. Their assessment has encompassed the potential impact of significant credible scenarios on the business model, future performance, solvency and liquidity over the period to 31 December 2019.

The Directors have determined that a three year period is the appropriate length of time over which to provide its viability statement. The Board first considers annually, and on a rolling basis, a detailed annual budget and 10 year plan for the Group and then uses the output from that review to inform its viability statement. For the purposes of the viability statement, the Board's review is limited to three years given the nature of the business and uncertainty. This is built from the bottom up and is stress tested for the following key scenarios:

- Reasonable delays in key product launches
- Reasonable reductions in sales growth targets in combination with the above

In each case, the mitigating actions were robust enough to ensure the solvency and liquidity of the Group through to at least 31 December 2019.

The Group's annual budget and 10 year plan was approved by the Board at its December 2016 meeting.

In addition, after the year end, the Board considered a 10 year plan for the Group which included the collaboration with AstraZeneca. This was built from the bottom up and stress tested for each of the above scenarios. In each case, the mitigating actions were robust enough to ensure the solvency and liquidity of the Group through to at least 31 December 2019 which is the period to which the Board's review is limited for the purpose of the viability statement.

The collaboration agreement includes terms for the payment of deferred consideration of \$100 million which will fall due by 30 June 2019 at the latest. In the event that the Group is unable to raise sufficient funding to meet this obligation, a vendor loan has been agreed with AstraZeneca to borrow up to \$180 million.

The Directors also considered it appropriate to prepare the financial statements on the going concern basis, as explained in the Basis of Preparation paragraph in note 1 to the accounts.

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The Strategic report on pages 02 to 41 has been approved by the Board.

**Steven Harris**  
Chief Executive Officer

25 April 2017

# Board of Directors

## 1 Dr Francesco Granata Chairman

Dr Francesco Granata, joined Circassia as Chairman on 1 September 2013.

He is also Chairman of the Nomination Committee.

Francesco is senior advisor at Warburg Pincus International LLC. Prior to this he was Executive Vice President at Biogen Idec Inc., and before that he was Group Vice President and President responsible for Canada and major European markets at Schering-Plough Corporation. Previously, he served as Regional President for Northern Europe and also Middle East and Africa at Pfizer Inc., and as Managing Director of Pharmacia & Upjohn Inc. in Italy. He is currently a Board member of Italfarmaco SpA, a leading Italian pharmaceutical group that operates in both the pharma and chemical sectors; Prismic Pharmaceuticals Inc., a US based medical food company; Quantia Dialysis Technologies Ltd., a UK company that has developed advanced haemodialysis systems for use in the home and clinic; Helsinn Investment Fund, a venture capital fund focused on healthcare; and a member of the strategic advisory committee at Lupin, a leading Indian global pharmaceutical company. He is also a director and founder of Micromega Limited and Chairman of Kiowa Kirin International plc. Prior to his career in industry, Francesco practised as a medical doctor specialising in cardiology. He holds a degree in medicine and surgery from the University of Pavia, Italy, and was formerly a member of the Board of the European Federation of Pharmaceutical Industry Associations.

## 2 Steven Harris Chief Executive Officer

Steven Harris co-founded Circassia on 19 May 2006 and has led the Company as Chief Executive Officer since then.

Steve has extensive experience of leading specialty pharmaceutical companies. Prior to co-founding Circassia, he was a founding member of the management team that grew Zeneus Pharma Limited into a successful specialty pharmaceutical company and managed its acquisition by Cephalon Inc. (now part of Teva Pharmaceutical Industries Limited). Prior to this he served for seven years as Chief Financial Officer of PowderJect Pharmaceuticals plc and was a key member of the management team which grew the organisation from a private biotechnology company to the world's fifth largest vaccines business, before it was acquired by Chiron Corporation in 2003. He holds a BSc from Southampton University and is a Chartered Accountant and a member of the Institute of Chartered Accountants of England and Wales (ICAEW). Steve is also a non-executive Director of Woodford Patient Capital Trust plc and Chairman of Synchrony Pharma Limited.

## 3 Julien Cotta Chief Financial Officer

Julien Cotta joined Circassia as Chief Financial Officer on 5 January 2012 and was appointed a Director on 26 November 2013.

Julien has significant financial management experience in the healthcare industry. Prior to joining Circassia, he was Chief Financial Officer of the Finnish medical technology company, Inion Oy, and before this Group Financial Controller at Whatman plc (now part of GE Healthcare). Previously, he served as Vice President of Financial Accounting at Chiron Corporation and Group Financial Controller at PowderJect Pharmaceuticals plc (prior to its acquisition by Chiron in 2003).

Before this he held senior financial management roles at Scotia Pharmaceuticals Limited, and Sanofi S.A., having begun his pharmaceutical career as a sales representative at Merck Sharpe & Dohme Corporation. He completed his accountancy training at Coopers & Lybrand (now PricewaterhouseCoopers LLP). Julien holds a BSc (Hons) in Pharmacology from University College London and is a Chartered Accountant and a member of the ICAEW.

## 4 Dr Rod Hafner Director and Senior Vice President Research & Development

Dr Rod Hafner joined Circassia on 1 March 2007 and became Senior Vice President of Research & Development and a Director on 10 March 2008.

Rod has many years of experience at a senior level in the life sciences industry and is a named inventor on numerous granted patents and patent applications. Before joining Circassia, he led the UK operating company of the Scandinavian drug delivery business, OptiNose AS (now OptiNose US Inc.) and prior to that was Director of Programme Management and Vice President of Research & Development Portfolio Management at PowderJect. Other roles have included Head of Project Management at Cortecs International Limited and positions at Wyeth Pharmaceuticals, Inc. (now Pfizer) and The Procter & Gamble Company. Rod has led Circassia's research and development function since joining in 2007. He has a BSc (Hons) in Biochemistry from Edinburgh University and a PhD in Biochemistry from the University of Cambridge.

## 5 Dr Jean-Jacques Garaud Senior Independent Non-Executive Director

Dr Jean-Jacques Garaud, the Senior Independent Non-Executive Director joined Circassia as a Non-Executive Director on 1 November 2012.

He is a Member of the Audit and Risk Committee and the Nomination Committee.

Jean-Jacques has extensive pharmaceutical research and development experience having held senior roles at companies in the United States and Europe. Until recently he was Global Head of Pharma Research and Early Development and a member of the extended corporate executive committee at F Hoffmann-La Roche Inc. having joined the company in 2007 as Global Head of Pharmaceutical Development and Chief Medical Officer. Prior to this he was Global Head of Clinical Research and Development and Global Head of Exploratory Development at Novartis and held roles at Schering-Plough Corporation, Rhone-Poulenc Rorer Limited and Merrell Dow Pharmaceuticals Inc. Before working in industry, Jean-Jacques practised medicine at the Claude Bernard Hospital in Paris, France after gaining his medical degree at the University of Paris. He is a Non-Executive Director at ENYO Pharma SAS and Polyphor Limited. He is the CEO of Inotrem, a biotech company based in Paris.

## 6 Dr Tim Corn Non-Executive Director

Dr Tim Corn joined Circassia as an independent Non-Executive Director on 1 August 2006. He is a Member of the Audit and Risk Committee, the Remuneration Committee, and the Nomination Committee.

Tim was previously Chief Medical Officer at EUSA Pharma (Europe Limited), an international division of Jazz Pharmaceuticals plc. In the course of his career, he has played a key role in the regulatory approval of numerous products in the fields of neurology and oncology. Tim qualified in medicine at King's College Hospital, London, after gaining an MSc in Biochemistry from Imperial College, London. He has been a Fellow of the Faculty of Pharmaceutical Medicine since 1996 and a Fellow of the Royal College of Psychiatrists since 1998.

He is Chairman of the Board of Trustees of the Neuro Foundation and a Non-Executive Director of Reneuron plc, and Laboratoire HRA Pharma SAS. Tim is also a director of the following charitable institutions: The Neurofibromatosis Association, Children with Tumours Ltd, Kids with Tumors Ltd, and Tots with Tumours Ltd.

## 7 Russell Cummings Non-Executive Director

Russell Cummings joined Circassia as a Non-Executive Director on 25 January 2007. He is Chief Executive Officer of Touchstone Innovations plc, having joined as Chief Investment Officer in 2006. From 2003 to 2006, he held roles at the growth equity and venture capital firm Scottish Equity Partners LLP, and prior to this spent 16 years at the international venture capital company 3i Group plc, latterly as a Director in its UK Technology Group. He holds a BSc (Eng) in Mechanical Engineering from Imperial College, London.



**8 Marvin S Samson**  
**Independent Non-Executive Director**

Marvin S Samson joined Circassia as an independent Non-Executive Director on 8 December 2015.

He is Chairman of the Remuneration Committee.

Marvin brings to Circassia 50 years' experience of the specialty pharmaceutical industry, having established and led a number of successful companies. He is the Founder and CEO of Samson Medical Technologies LLC, and was until recently Interim President of the University of the Sciences, Philadelphia. Previously, he was CEO and Chairman of Qualitest Pharmaceuticals, Group Vice President of Injectables at Teva, CEO and President of SICOR, Founder, President and CEO of Marsam Pharmaceuticals and Founder, CEO and President of Elkins-Sinn. He holds a BSc in Chemistry from Temple University, Philadelphia. He is currently Chairman of the board of directors of Heritage Pharmaceuticals Inc., a Non-Executive Director of Antares Pharma Inc, Flynn Pharma Ltd and NanoPass Technologies Ltd. He is also Chairman of the Board of Trustees of the University of the Sciences in Philadelphia and a Board Member of Virtua Health and the Franklin Institute.

**9 Charles Swingland**  
**Non-Executive Director**

Charles Swingland is a Non-Executive Director and co-founder of Circassia.

Charles is Deputy Chairman at Drayson Technologies Limited. He was General Counsel, Company Secretary and Deputy Chairman of Circassia from May 2006 until March 2014. Prior to founding Circassia with Steven Harris, he was a Director and General Counsel at Zeneus Pharma Limited from 2004 to 2006 and before this was Executive Director, General Counsel and Company Secretary at PowderJect Pharmaceuticals plc until it was sold to Chiron in 2003. Before working in industry, Charles practised as a lawyer in the City of London for over 15 years. Charles is a member of the board of advisers of the Earthwatch Institute.

**10 Lota S Zoth**  
**Independent Non-Executive Director**

Lota Zoth joined Circassia as an independent Non-Executive Director on 9 February 2015. She is Chair of the Audit and Risk Committee and a member of the Remuneration Committee.

Lota is an experienced Board member, and has significant financial experience gained in a number of global public companies. Most recently she was CFO at MedImmune, and she previously held senior positions at PSINet, Sodexo Marriott, PepsiCo and Ernst & Young. She is currently a Non-Executive Director at NewLink Genetics Corporation, Orexigen Therapeutics Inc., Spark Therapeutics, and Zymeworks Inc. She is also Chair of Aeras, a non-profit product development organisation focused on tuberculosis and funded by The Bill and Melinda Gates Foundation, and until recently was a Non-Executive Director at privately-held biopharmaceutical company Ikaria Inc. (until February 2014).

Lota has over 30 years' experience as a Certified Public Accountant, and holds a Bachelor of Business Administration from Texas Tech University.



# Corporate governance

## Dear Shareholders

On behalf of the Board, I am pleased to present Circassia's Corporate governance report for the year ended 31 December 2016. It describes how the Board and its Committees apply the principles of good corporate governance set out in the UK Corporate Governance Code issued by the Financial Reporting Council (the "Code").

High standards of corporate governance are fundamental to our business and are implemented and supported through appropriate internal policies and procedures. The responsibility for ensuring this framework is effective lies with the Board, and we are constantly striving to improve standards while building a successful company.

One area on which the Board has focused in particular since Listing relates to its composition. As we explained at the time of Listing, the Board believes that at this critical point in its development the Group benefits from the knowledge and experience of the full range of its Non-Executive Directors but has been looking to increase the proportion of Independent Non-Executive Directors who sit on the Board. Accordingly, in the course of 2015 the Board was strengthened by the appointment of Ms Lota Zoth and Mr Marvin Samson who are both Independent Non-Executive Directors.

There were two additional changes to the Board during 2016. Mr Paul Edick, who served as a Non-Executive Director since 3 April 2013 did not seek re-election at the Company's Annual General Meeting on 18 May 2016 and, following her appointment as Head of European Healthcare at CVC Capital Partners, Ms Cathrin Petty also stepped down from the Board on 16 December 2016. We are very grateful to Paul and Cathrin for their significant contributions.

Since the end of the year, two of our other long-serving Non-Executive Directors, Mr Charles Swingland and Dr Tim Corn have announced that they do not intend to stand for re-election at the Company's 2017 Annual General Meeting.

Maintaining good communication with our Shareholders is extremely important to us. During the year, Steven Harris, our CEO has held a number of meetings with investors and current shareholders, and presented at several conferences which were attended by existing and potential Shareholders. Communications with Shareholders are coordinated by the Head of Corporate Communications, who reports directly to the CEO.

**Dr Francesco Granata**  
Chairman

## Corporate governance report

### Statement of Compliance with the UK Corporate Governance Code

The UK Corporate Governance Code (the "Code") sets out the principles of good practice in relation to corporate governance which should be followed by companies with a listing on the London Stock Exchange. The Code is published by the Financial Reporting Council ("FRC") and the most recent edition (September 2014) can be found on their website ([www.frc.org.uk](http://www.frc.org.uk)).

The principles of the Code are divided into five sections. Each section sets out the main principles relating to Leadership; Effectiveness; Accountability; Remuneration; and Relations with Shareholders.

This report explains how Circassia has applied these principles.

Until September 2016, Circassia was included in the FTSE 350, however, following the fall in its share price after the disappointing cat allergy results in June 2016, this was no longer the case. The Code requires that at least half the Board of FTSE 350 companies should comprise independent Non-Executive Directors. A smaller company, which is defined in the Code as one that is below the FTSE 350 throughout the year immediately prior to the reporting year, should have at least two independent Non-Executive Directors.

The Directors support high standards of corporate governance. However, as is explained below, the Company has not complied with the recommendations of the Code that at least half the Board should comprise independent Non-Executive Directors.

At the beginning of 2016, the Board consisted of twelve members, the Chairman (who was independent on appointment), three Executive Directors, and eight Non-Executive Directors. Of the eight Non-Executive Directors, three were considered by the Board to be independent, namely Lota Zoth, Dr Jean Jacques Garaud and Marvin Samson. The independence ratio of the Board (excluding the Chairman) was therefore 27% at the beginning of the year, but by the end of the year, following the departures of Paul Edick and Cathrin Petty, it had risen to 33%.

Dr Jean-Jacques Garaud had participated in the Company's unapproved share option scheme before the Initial Public Offering of the Company in 2014. However, this scheme is unrelated to performance, such participation was historic, and no further share options will be granted to him. For this reason, Dr Jean Jacques Garaud is considered to be independent. In addition, Dr Garaud will exercise his options following announcement of the Preliminary Results.

Charles Swingland and Dr Tim Corn who are not considered to be independent, will not seek re-election to the Board at the 2017 Annual General Meeting.

Immediately following the 2017 Annual General Meeting, the Board will therefore consist of eight members. These are the Chairman (who was independent on appointment), three Executive Directors, and four Non-Executive Directors. Of the four Non-Executive Directors, three are considered by the Board to be independent, namely Lota Zoth, Dr Jean Jacques Garaud and Marvin Samson. The independence ratio of the Board (excluding the Chairman) will therefore increase to 43% and the Board will meet the requirement that a FTSE Small Cap company should have at least two independent Non-Executive Directors.

The Board believes that at this point in the Group's development it is important that it has access to the expertise and knowledge of its remaining non-independent Non-Executive Director.

The composition of the three Board Committees throughout the year and the extent to which their composition complied with the provisions of the Code, was as follows:

— **Nomination Committee**

The Code requires that a majority of the members of the Committee should be Independent Non-Executive Directors and the Committee should be chaired by the Chairman or an Independent Non-Executive Director. Throughout the year, the Committee was composed of the following members:

Dr Francesco Granata (Chairman and Chair of the Committee); Dr Tim Corn, and Dr Jean-Jacques Garaud. As Dr Jean Jacques Garaud was the only Independent Non-Executive Director, one third of the Committee was therefore made up of Independent Non-Executive Directors, although the Chairman was independent upon appointment. The composition of the Nomination Committee therefore did not comply fully with the recommendations of the Code.

As Dr Tim Corn will not seek re-election at the 2017 Annual General Meeting, his membership of the Nomination Committee will be replaced by an existing Independent Non-Executive Director. Therefore the Nomination Committee is expected to become fully compliant with the recommendations of the Code during 2017.

— **Remuneration Committee**

The Code requires that the Committee should comprise a minimum of three Directors, all of whom should be independent. For the period from 1 January 2016 until 9 February 2016, the Committee members were: Dr Jean-Jacques Garaud (Chair of the Committee); Dr Tim Corn and Ms Lota Zoth. On 9 February 2016 Dr Jean-Jacques Garaud stepped down as Chair of the Committee and was replaced by Mr Marvin Samson. Lota Zoth, Dr Jean Jacques Garaud and Marvin Samson were considered to be independent, however Dr Tim Corn was not considered independent. Therefore, from 1 January 2016 until the end of the year and up to the date of this report, the Committee did not comply with the membership requirements of the Code insofar as they relate to independence.

As Dr Tim Corn will not seek re-election at the 2017 Annual General Meeting, his membership of the Remuneration Committee will be replaced by an existing Independent Non-Executive Director. Therefore the Remuneration Committee is expected to become fully compliant with the recommendations of the Code, as they apply to FTSE 350 companies, during 2017. The Remuneration Committee does currently comply with the smaller company requirement that it consist of at least two independent Non-Executive Directors.

— **Audit and Risk Committee**

The Code requires that the Committee should comprise a minimum of three Directors, all of whom should be independent. For the period from 1 January 2016 up to the date of this report, the Committee was made up of three members: Ms Lota Zoth (Chair of the Committee); Dr Tim Corn; and Dr Jean-Jacques Garaud. Lota Zoth and Dr Jean Jacques Garaud are considered independent, however Dr Tim Corn was not considered independent. Therefore, from 1 January 2016 until the end of the year and up to the date of this report, the membership of the Audit and Risk Committee did not comply with the membership requirements of the Code insofar as they relate to independence.

As Dr Tim Corn will not seek re-election at the 2017 Annual General Meeting, his membership of the Audit and Risk Committee will be replaced by an Independent Non-Executive Director. Therefore the Audit and Risk Committee is expected to become fully compliant with the recommendations of the Code, as they apply to FTSE 350 companies, during 2017. The Audit and Risk Committee does currently comply with the smaller company requirement that it consist of at least two independent Non-Executive Directors.

The Board confirms that in all other respects, the Group has fully complied with the principles of the Code throughout the year to 31 December 2016 and up to the date of this report. Details of Directors' remuneration, as required by the Code and Part 4 to Schedule 8 of the Large- and Medium-sized Companies and Groups (Accounts and Reports) (Amendment) Regulations 2013, are set out in the Remuneration Committee report.

The Group's Auditor, PricewaterhouseCoopers LLP, is required to review whether this Corporate governance statement properly reflects the Group's compliance with certain provisions of the Code and to report any non-compliance. The Group confirms that no report of non-compliance has been made other than in respect of the matters identified above in relation to Board composition.

## **Leadership**

### **The role of the Board**

The Board is responsible for the leadership and long-term success of the business. It has a schedule of matters which are reserved for its review. These include the review and approval of strategic plans, financial statements and budgets, financing, acquisitions and disposals, major capital expenditure, dividend policy, making key risk decisions, monitoring risks and compliance, monitoring health, safety and environmental performance, and Executive remuneration and appointments.

At each meeting, the Board assesses the progress of the Group when measured against its objectives, particularly those which relate to its clinical trials programmes, and reviews financial performance against the budget.

### **Roles and responsibilities**

The Board is currently composed of the Chairman, three Executive Directors, and six Non-Executive Directors. The biographies of the current members of the Board are set out on pages 42 to 43 of this report.

The Executive Directors have direct responsibility for the business operations of the Company. The Non-Executive Directors, by virtue of their wide range of industry experience and skills, bring an informed view to the decision making process.

The roles of the Chairman and Chief Executive Officer are clearly delineated. This division of responsibilities has been set out in writing and approved by the Board.

### **Chairman**

Dr Francesco Granata, Chairman, is responsible for the leadership of the Board and its effectiveness by ensuring that:

- the agenda for meetings is appropriate, and the Board is provided with the information it needs for high quality decision making in a timely fashion;
- the Board plays a full and constructive role in shaping the strategy of the Group;
- the Board environment is productive and utilises the skills and experience of all members;
- the Board complies with the appropriate standards of corporate governance;
- the Committees are properly structured and resourced;
- the performance of the Board, its Committees, and individual Directors are evaluated each year; and
- there is effective communication with Shareholders.

The Chairman and the Non-Executive Directors met in the absence of the Executive Directors at the end of each Board meeting which occurred in 2016.

# Corporate governance continued

## Chief Executive Officer

Steven Harris, Chief Executive Officer, is responsible for the day to day management of the Group and for implementing the strategy which has been reviewed and approved by the Board. He is also responsible for ensuring effective communication with Shareholders, brokers, and analysts.

## Senior Independent Non-Executive Director

Dr Jean-Jacques Garaud has been Senior Independent Non-Executive Director since 21 February 2014. He works closely with the Chairman to resolve any significant issues which may arise and is responsible for the annual evaluation of the Chairman's performance, for leading the other Non-Executive Directors in their oversight of the Chairman, and for ensuring there is a clear division of responsibilities between the Chairman and the Chief Executive Officer. He is available to communicate directly with Shareholders if they have concerns which cannot be resolved through the normal channels of the Chairman, Chief Executive Officer, or Chief Financial Officer.

## Non-Executive Directors

The role of the Non-Executive Directors, and of the Committees of which they are members, is to scrutinise the performance of management, satisfy themselves that the financial and risk control mechanisms are robust, and determine appropriate levels of Executive pay. They have wide ranging experience of industry and bring their judgement to bear in the decision making process of the Board.

Their seniority and range of skills ensure that no one individual can dominate this process.

## Board Committees

The Board has three Committees: the Audit and Risk Committee; the Nomination Committee; and the Remuneration Committee, to which it delegates specific responsibilities. The reports of these Committees and details of their composition form part of the Corporate governance report.

Each Committee has full terms of reference which have been approved by the Board and also appear on the website at [www.circassia.com](http://www.circassia.com). These terms of reference are reviewed annually. The Board provides the Committees with sufficient resources, including access to external advisers, as may be required in order to fulfil their roles.

## Board meetings

The Board aims to meet at least five times during the year. Additional meetings may be arranged where urgent matters arise. These additional meetings may be held by telephone.

The table below sets out the attendance of the Directors, while they were Board members, at scheduled meetings which occurred during the year to 31 December 2016.

	Committee Memberships	Independent status	Board	Nomination Committee	Audit and Risk Committee	Remuneration Committee
<b>Executive Directors</b>						
Steven Harris	n/a	n/a	5 (5)	2 (2) <sup>1</sup>	4 (4) <sup>1</sup>	2 (2) <sup>1</sup>
Julien Cotta	n/a	n/a	5 (5)	2 (2) <sup>2</sup>	4 (4) <sup>2</sup>	2 (2) <sup>2</sup>
Rod Hafner	n/a	n/a	5 (5)	–	–	–
<b>Non-Executive Directors</b>						
Francesco Granata	N (Chair)	Yes	5 (5)	2 (2)	–	–
Jean-Jacques Garaud	A, R (Chair) <sup>3</sup> , N	Yes	5 (5)	2 (2)	4 (4)	1 (1)
Tim Corn	A, R, N	No	5 (5)	2 (2)	4 (4)	2 (2)
Russell Cummings	–	No	5 (5)	–	–	–
Paul R Edick <sup>4</sup>	–	No	2 (2)	–	–	–
Cathrin Petty <sup>5</sup>	–	No	5 (5)	–	–	–
Charles Swingland	–	No	5 (5)	–	–	–
Lota Zoth	A (Chair), R	Yes	5 (5)	–	4 (4)	2 (2)
Marvin Samson	R (Chair) <sup>6</sup>	Yes	4 (5)	–	–	2 (2)

N = Nomination Committee, R = Remuneration Committee, A = Audit Committee

Figures in brackets represent the total number of meetings

1 By invitation

2 In the capacity of Secretary to the Committee

3 Until 9 February 2016 when he was succeeded by Marvin Samson

4 Until 18 May 2016 when he retired from the Board (having not put himself forward for re-election at the AGM)

5 Resigned from the Board on 16 December 2016

6 Appointed to the Committee (as Chair) 9 February 2016



## Board activity

The Board's main activities during the course of the year included:

- Advance planning for the results of the cat allergy treatment phase III clinical trials (both positive and negative scenarios) and detailed consideration of strategy following receipt of the negative results;
- Review of the expansion of the Group's commercial infrastructure and sales of NIOX;
- Reviews of the progress of the Group's other clinical trial programmes for respiratory and allergy products;
- Reviews of the progress of business and corporate development activity and opportunities;
- Compliance training and updates;
- Review of the 10 year financial model for the business;
- Assessment of the financial performance against the budget for FY 2016;
- Approval of the budget for FY 2017;
- Completion of an externally organised Board evaluation exercise.

## Effectiveness Independence

The Board reviews the independence of its Non-Executive Directors each year. For the period 1 January 2016 to 18 May 2016, excluding the Chairman, three of the eleven Board members were Non-Executive Directors who were considered by the Board to be independent.

For the period from 18 May 2016 to 8 December 2016, excluding the Chairman, three out of ten Board members were considered to be Independent Non-Executive Directors and from 8 December 2016 to 31 December 2016, excluding the Chairman, three out of nine Board members were considered to be Independent Non-Executive Directors.

Dr Jean-Jacques Garaud had participated in the Company's unapproved share option scheme before the Initial Public Offering of the Company in 2014. However, this scheme is unrelated to performance, such participation was historic, and no further share options will be granted. The Board has therefore determined that it regards Dr Jean-Jacques Garaud as an Independent Non-Executive Director within the meaning of "independent" as defined in the Code for the period 1 January 2016 to 31 December 2016.

The Board also carefully reviews any actual or potential conflicts of interest that may arise due to the commercial interests of Non-Executive Directors and they are required to make a declaration in respect of any such situations. The Board can confirm that no new conflicts of interest arose in the year. Cathrin Petty was an employee of JP Morgan, an adviser to the Company, during the term of her directorship and accordingly was not considered independent. Russ Cummings is an employee of Touchstone Innovations plc which is a shareholder and is therefore not considered independent. Paul Edick was also considered not to be independent after his wife was appointed as the Group's Chief Commercial Officer on 15 September 2014. Charles Swingland is not considered independent as he previously served as an Executive Director, General Counsel, and Company Secretary of the Company.

Dr Tim Corn is not considered to be independent as he has now served as a Director of the Company for more than nine years.

It is confirmed that none of the Independent Non-Executive Directors have served for a period of more than nine years.

The Board further confirms that Dr Francesco Granata was independent upon his appointment.

## Appointments to the Board

The procedure for appointment of new Directors to the Board is formal, rigorous and transparent. The process is led by the Nomination Committee which comprises the Chairman and Independent Non-Executive Directors. Shortlisted candidates are interviewed by members of the Committee before a recommendation is made to the Board.

## Diversity

The Board recognises the value of diversity at all levels of the Group. The Group has an Equal Treatment, Equal Opportunities and Diversity policy which extends to the Board.

## Induction and training

Upon appointment, each Director receives a comprehensive induction package which includes written materials relevant to their responsibilities. In addition, meetings are organised with other Board members and with members of the Company's management team.

All Directors have direct access to the advice of the Company Secretary. Whenever it is considered necessary, the Company Secretary can arrange the appointment of professional advisers at the Group's expense to assist Board members in their roles.

Directors receive frequent updates on commercial developments affecting the business as well as regulatory and legislative changes. Directors are invited, during the annual evaluation procedure, to identify any training which they feel might benefit them.

## Information

In advance of each Board Meeting, Directors receive a full agenda and a comprehensive set of papers which include commercial and functional reports. A procedure is in place to ensure that these materials are delivered to the Board in a timely fashion. Senior employees of the business regularly attend meetings in order to enhance the Non-Executive Directors' understanding of current issues and give them the opportunity to ask detailed questions.

## Commitment

The Board is satisfied that the other commitments of the Chairman and Non-Executive Directors – which are set out in their biographies – leave them with sufficient time to diligently perform their role for the Group.

## Performance evaluation

Formal Board evaluations are carried out once a year, and informal evaluations are carried out on a continuing basis throughout the year. The formal evaluation commences with the circulation of a written questionnaire which is prepared by the Company Secretary. This invites Directors to rate and comment on the performance of the Board in a number of areas, including the conduct of Board meetings; the standard and timeliness of information; the balance of skills of the members of the Board; the roles and responsibilities of individual Directors; and compliance with good corporate governance practices. A detailed, anonymised analysis of these responses is then prepared by the Company Secretary and reviewed and discussed by the Board.

The Board subjects itself to an external review every third year. No external review occurred in 2014 or 2015. Accordingly an external review was performed in 2016. The review was carried out by a firm named Independent Audit who specialise in the review of Boards and their committees. The Board was required to complete four tailored questionnaires for the Board as a whole and for each of its committees. The results were analysed by Independent Audit and presented as a report to the Board. The findings of the report were debated by the Board and a list of actions agreed.

# Corporate governance continued

## Re-election

All Directors have service contracts which are capable of termination on giving a fixed period of notice. In the case of the Executive Directors this notice period is six months and in the case of the Non-Executive Directors and Chairman it is three months. All Directors are subject to re-election by Shareholders on an annual basis.

## Accountability

The Board acknowledges its duty to present a fair, balanced and understandable view of the Group's position and prospects. A description of the Group's business model is contained in the Strategic report. The Statement of Directors' responsibilities sets out information regarding the Directors' responsibility to prepare financial statements. The Independent Auditors' report includes a statement by the Auditor on its reporting responsibilities.

The role of the Audit and Risk Committee is set out in detail in the Audit and Risk Committee report.

The Board is responsible for determining the significant risks which the Group is prepared to take in order to attain its strategic objectives, and keeps the risk management procedures and internal controls of the business under regular review. The Board confirms that it is satisfied that the current procedures and controls are sufficient to ensure compliance with the Code.

After taking advice from the Audit and Risk Committee, the Board is able to confirm that the Annual report and accounts, taken as a whole is fair, balanced, and understandable and provides the information necessary for Shareholders to judge the Group's strategy, business model, position and performance.

## Viability statement

The Company prepares a 10 year plan which was reviewed and approved by the Board at its meeting on 8 December 2016.

The plan also contains a sensitivity analysis which allows the Board to assess the potential financial impact of certain significant potential scenarios which might arise. This process informs the Viability Statement which the Board gives on page 41 of this report.

## Risk management system

A description of the risk management system is set out in the Strategic report. The system is designed to manage risks, not to eliminate them completely, and can only provide a reasonable degree of assurance against material misstatement or loss. Inherent in the concept of reasonable assurance is the recognition that the cost of a control procedure should not exceed its anticipated benefits. The principal risks facing the Group are set out in the Strategic report.

The Board confirms that it has conducted a review of the Group's risk management and internal controls systems, including financial, operational and compliance controls and has found them to be effective.

## Internal controls

The Audit and Risk Committee reviews the Group's financial controls on an annual basis and makes recommendations to the Board where improvements are required. The efficacy of control systems are reviewed by the full Board as required by the FRC Guidance on Risk Management, Internal Control and Related Financial and Business Reporting.

The Group's primary risk control systems are as follows:

### Management structure

- There is a management structure with clear lines of responsibility and accountability. Employees are recruited when they have the appropriate skills and experience to perform their intended roles.
- The Board sets the overall strategy and reviews the performance of the Group.
- The Group's Senior Management Team, chaired by the Chief Executive Officer, is responsible for day to day operations.
- Other team members comprise the Chief Financial Officer, Senior Vice President R&D, Chief Business Officer, Vice President Human Resources, and General Counsel. This team meets weekly.

### Written policies and procedures

- There are documented quality procedures which ensure regulatory compliance. Regular reviews take place to ensure standards are maintained and the Company is fully prepared for a regulatory inspection. The Vice President, Quality Assurance and her team monitor internal and external (Contract Research Organisation and Contract Manufacturing Organisation) compliance with Good Manufacturing Practice, Good Clinical Practice, and Good Laboratory Practice and organise training for employees.
- The Vice President, Global Compliance Officer and her team maintain policies and deliver training which relate to healthcare compliance, including but not limited to the Group's Whistleblowing policy (which enables employees to communicate concerns regarding improper activity to a trusted individual who is not their line manager or a member of the senior management team), the Group's Anti-Bribery and Anti-Corruption policy, and the Group's privacy and data protection policies.
- There are controls in place which determine how financial information is validated, consolidated and reviewed.
- There are specific controls on expenditure. Material investments or capital expenditure must be approved by the Board. Normal expenditure is controlled by setting limits which are determined by the CEO and CFO within a general framework approved by the Board.
- Detailed management accounts are prepared on a monthly basis and provided to the Board. Accompanying reports will explain any variances between these results and the budget.
- The R&D Committee meets on a weekly basis to review performance of the various clinical trials and implement action plans to prevent delays.
- The Patents Committee meets regularly to assess the scope of protection provided by pending and granted patents, organise the defence of granted patents, and plan new filings where appropriate. This group also manages registered trade marks.
- There are physical and electronic procedures in place to ensure the security and integrity of data and confidential information.
- An established policy exists for share dealing by employees or connected persons. A revised Circassia Group Dealing Policy and Circassia Group Dealing Code was circulated in June 2016 to reflect the coming into force of the Market Abuse Regime in the UK. The format and keeping of insider lists has also been reviewed in the light of the new regulations.
- The Health and Safety Policy is maintained and reviewed by the Health and Safety Committee.

- There is a Disclosure Committee, as required by the Market Abuse Directive, comprising the Chief Financial Officer, General Counsel, and the Head of Corporate Communications. The Chief Business Officer under the direction of this Committee maintains an Insider List recording employees and external parties who may have access to inside information. Individuals are notified of their addition to and removal from the list and are appraised of their responsibilities.

No failure of controls or breach of internal policies was recorded during the year to 31 December 2016 and up to the date of this report.

### Remuneration

The Board has adopted a remuneration policy approved by shareholders at the 2015 AGM which it believes is sufficient to attract, retain, and motivate Directors of the quality required to run the Group successfully, but which does not result in payment of more than is necessary for this purpose. A significant proportion of Executive Directors' pay is linked to corporate and individual performance. Full details of the policy are set out in the Remuneration Committee report.

### Relations with Shareholders

#### Dialogue with Shareholders

The Board maintains regular communication with Shareholders. Meetings between material Shareholders and the Executive Directors take place throughout the year. The Chairman and Senior Independent Non-Executive Director and other Directors are available to meet with major Shareholders on request.

All meetings with Shareholders are held in a manner which ensures price sensitive information which has not been made available to Shareholders generally is protected from disclosure.

The Chief Executive Officer and the Chief Financial Officer give annual and six-monthly presentations to institutional investors, analysts, and the media. These presentations are available on the website. Annual and Interim reports and all press releases are also published on the website as are the terms of reference of the three Board committees. Paper copies of the report and accounts are mailed to those Shareholders who have elected to receive them in hard copy.

The Directors receive a report from the Corporate Communications department at each Board Meeting giving information on material changes in shareholdings and collating feedback from the Company's brokers and investors.

### Annual General Meeting

The AGM provides an opportunity for all Shareholders to meet Board members and have the opportunity to ask about the proposed resolutions and the business in general.

Notice of the AGM is posted to Shareholders not less than 21 clear days prior to the date of the AGM and is also available to Shareholders on the website at [www.circassia.com](http://www.circassia.com). The letter accompanying the Notice will include details of the proposed resolutions and an explanation of their content.

At the AGM the number of proxy votes cast for, against, or abstaining from each resolution will be disclosed. Results of voting are announced to the market and posted on the website as soon as possible after the AGM.

The Group does not currently consider it appropriate to introduce mandatory poll voting on all resolutions put to the Shareholders but will keep this position under review.

### Audit and Risk Committee report

#### Dear Shareholder

On behalf of the Board I am pleased to present Circassia's Audit and Risk Committee report for the year ended 31 December 2016.

The Audit and Risk Committee is the key independent oversight Committee at Circassia. It monitors and reviews the effectiveness of the Group's risk management framework and internal controls.

This report sets out how the Committee has discharged its responsibilities under the UK Corporate Governance Code (the "Code"). It also contains a summary of the activities of the Committee throughout the year.

#### Lota S Zoth

Chair of the Audit and Risk Committee

25 April 2017

### Responsibilities

The Committee has responsibility for monitoring the integrity of the financial statements of the Group, and for reviewing the effectiveness of the Group's internal control systems and risk management systems, including reviewing its risk profile.

Accordingly, the Committee performs a detailed review of the interim and annual financial statements, considering whether the accounting policies have been applied properly and consistently and whether the disclosures made in the Annual report and accounts are compliant with financial reporting standards, and with corporate governance and regulatory requirements.

The Committee also manages the relationship with the external Auditors on behalf of the Board. It monitors the independence of the Auditor and reviews the effectiveness of the audit procedure. The Committee makes recommendations to the Board regarding the appointment of the external Auditors and reviews their terms of engagement. The Committee has access to the services of the external Auditors and, if necessary, may appoint external accounting and legal advisers to assist it with its work.

The Committee also has ultimate responsibility for matters related to healthcare compliance. Following the acquisition of the NIOX franchise, the Group markets approved medical devices to healthcare professionals in a number of markets around the world and from May 2017, following the commencement of the collaboration with AstraZeneca to market Tudorza<sup>®</sup>, the Group will promote an approved drug in the United States. Compliance with healthcare laws and regulations has therefore become and will continue to be a key risk area for the business. The VP, Global Compliance Officer has a direct reporting line to the Chair of the Audit and Risk Committee and provides updates in this area to her.

The Committee's terms of reference are available on the Company's website. They cover issues such as membership and the frequency of meetings, together with requirements for a quorum and the right to attend meetings. The duties of the Committee as set out in the terms of reference include financial and regulatory reporting; internal controls; internal audit; external audit; risk management; and reporting responsibilities.

# Corporate governance continued

## Membership

The names of the members of the Audit and Risk Committee, their dates of appointment, and the number of meetings attended during the year are set out in the table below:

## Financial reporting

During the year to 31 December 2016 and up to the date of this report, the Committee reviewed the Interim report and accounts for the period ended 30 June 2016 and the preliminary announcement and Annual report and accounts for the year ended 31 December 2016.

Member	Date of appointment	Meetings attended (held)
L S Zoth	27 February 2015	4 (4)
T Corn	21 February 2014	4 (4)
J-J Garaud	21 February 2014	4 (4)

The Code provides that all members of the Audit and Risk Committee should be Independent Non-Executive Directors. The Board considers that Lota Zoth and Jean-Jacques Garaud are independent, however as Tim Corn is not independent the recommendation of the Code has not been met.

Ms Zoth has significant recent and relevant financial experience. She is the Board Chair at Aeras. She is a Non-Executive Director, Compensation Committee Member and the Audit Committee Chair at NewLink Genetics Corporation, Orexigen Therapeutics and Zymeworks. She is also a Non-Executive Director and the Audit Committee Chair at Spark Therapeutics. She was also Chief Financial Officer and Senior Vice President at MedImmune, LLC from 2004 to 2007.

The Company Secretary acts as the Secretary to the Committee. The CEO attends Committee meetings at the invitation of the Chair. The Chair of the Committee meets with the external Auditors at least once a year in the absence of management.

A summary of the matters considered by the Committee since the last financial statements is shown in the table below and explained in further detail in the subsequent text:

## Significant accounting matters

The Committee considered the following key accounting issues, judgments and disclosures during the course of the year:

- Impact of cat allergy trial results
- Goodwill and intangibles impairment assessment
- Assessment of going concern

Area of review	Activities undertaken
Financial reporting	Review of the interim and full year results. Consideration of whether the Annual report is fair, balanced, and understandable. Review of the external Auditors' reports on the interim and full year results. Review of significant accounting issues (see below). Review of anticipated changes in accounting standards and their impact. Review of the viability statement and going concern basis of preparation of the financial statements.
External Auditor	Review of external Auditors' independence. Review of Auditors compliance with ethical and professional guidance on audit partner rotation. Assess effectiveness of audit process. Audit tender and recommend re-appointment of Auditors.
Risk management and internal control	Review of risk, risk management systems, internal controls, and anti-corruption and anti-bribery procedures. Review of internal compliance monitoring.
Governance	Review of the Committee's terms of reference.



### Following the negative results of the cat allergy trial, the following assessments resulting in changes were carried out:

- Goodwill and intangibles impairment assessment (which is described further under a separate heading)
- Review of onerous R&D and other contracts: an accrual for expected termination fees was made where required
- Restructuring: a reorganisation was initiated including closure of facilities in Chicago and Solna and associated redundancies together with redundancies within R&D
- Review of the fair value of awards under share options schemes: the fair value of all historic share awards that have cat allergy phase III trial success as part of the non-market conditions have been reduced resulting in a reduction in the expense charged to the income statement

### Goodwill and intangibles impairment assessment

In line with IAS 36 Impairment of Assets, the carrying value of each cash generating unit (CGU) including the allocated goodwill tested for impairment.

Cash generating units are the smallest group of assets that independently generate cash flows and whose cash flow is largely independent of the cash flows generated by other assets. These have been defined as the pre-existing Circassia business (i.e. allergy business) prior to the acquisition of Aerocrine and Prosonix; Aerocrine (NIOX® business) and Prosonix (respiratory business).

Goodwill arising on the acquisition of Aerocrine was allocated to both the pre-existing allergy cash generating unit and the NIOX® cash generating unit. This is because both cash generating units would benefit from the same sales force selling to largely the same customers. The assumptions used in allocation of the goodwill are set out in note 14 to the accounts. This estimate is subject to a high degree of judgement.

Goodwill arising on the acquisition of Prosonix was allocated entirely to respiratory. Goodwill allocated to each cash generating unit is disclosed in note 14 of the financial statements.

Goodwill of £74.5 million which had been allocated to the allergy CGU was fully impaired and intangible assets of £0.3 million which had been allocated to the allergy CGU were also impaired.

### Going concern and cash flow

Following review of Group cash flows over a three year period to 31 December 2019, taking account of the Group's current position and the potential impact of the principal risks identified earlier in this report the Directors have a reasonable expectation that the Group will be able to continue in operation and meet its liabilities as they fall due over the period to 31 December 2019.

In making this statement, the Directors have considered the robustness of the Group, taking account of its current position, potential future developments, the principal risks facing it, and the effectiveness of mitigation plans and controls. Their assessment has encompassed the potential impact of significant credible scenarios on the business model, future performance, solvency and liquidity over the period to 31 December 2019.

The Directors have determined that a three year period is the appropriate length of time over which to provide its viability statement. The Board first considers annually, and on a rolling basis, a detailed annual budget and 10 year plan for the Group and the output from this exercise informs the preparation of the viability statement. For the purposes of the viability statement, the Board's review is limited to three years given the nature of the business and uncertainty. This is built from the bottom up and is stress tested for the following key scenarios:

- Reasonable delays in key product launches

- Reasonable reductions in sales growth targets in combination with the above

In each case, the mitigating actions were robust enough to ensure the solvency and liquidity of the Group through to at least 31 December 2019.

The Group's annual budget and 10 year plan was approved by the Board at its December 2016 meeting.

In addition, after the year end, the Board considered a 10 year plan for the Group which included the collaboration with AstraZeneca. This was built from the bottom up and stress tested for each of the above scenarios. In each case, the mitigating actions were robust enough to ensure the solvency and liquidity of the Group through to at least 31 December 2019 which is the period to which the Board's review is limited for the purpose of the viability statement.

The collaboration agreement includes terms for the payment of deferred consideration of \$100 million which will fall due by 30 June 2019 at the latest. In the event that the Group is unable raise sufficient funding to meet this obligation, a vendor loan has been agreed with AstraZeneca to borrow up to \$180 million.

The Directors also considered it appropriate to prepare the financial statements on the going concern basis, as explained in the Basis of Preparation paragraph in note 1 to the accounts.

### Risk management and internal control

The Board has overall responsibility for the review of the Group's risk management framework and the level of risk which is acceptable in order to achieve its strategic objectives. The Committee, on behalf of the Board, undertakes the detailed monitoring of the risk management framework and system of internal controls and reports to the Board on their suitability and efficacy annually.

In order to discharge its duties in this respect, the Committee receives and reviews reports from the Group's management team.

The Committee continues to assess what is an acceptable level of risk in key areas, and the best strategy for mitigating those risks given the cost and time constraints which exist.

During the year, as is required by the 2014 edition of the Code, the Committee performed a detailed assessment of the principal risks faced by the Group and how these are managed and mitigated. An annual review of the effectiveness of the Group's monitoring and review systems was carried out at the December Committee meeting. In addition, the Board asked the management team to carry out a review of the operations of the Group's representative office in China. The report, prepared with the assistance of PricewaterhouseCoopers' Beijing office was provided to the Board for review.

### Whistleblowing

A confidential whistleblowing procedure exists to enable employees to raise concerns regarding possible improprieties in relation to financial or other matters. This procedure has been communicated to all staff. Reports can be made through an online tool or a telephone helpline operated by a third party provider. The Committee has reviewed these arrangements and is satisfied that the current procedure allows for proportionate and independent investigation of such disclosures, and for appropriate follow up actions to be taken. In accordance with the current policy, concerned employees may raise matters directly with the Vice President, Global Compliance Officer.

### Anti-corruption and anti-bribery

The Group has an anti-corruption and anti-bribery policy which has been communicated to all staff. This policy ensures full compliance with the UK Bribery Act 2010, the US Foreign Corrupt Practices Act and other major anti-corruption legislation. The policy extends to carrying out due diligence on new key business partners who are judged to be acting on behalf of the Group in high risk areas.

# Corporate governance continued

## Internal audit

This year the Committee considered again whether there is a need for an internal audit function and concluded that, given the scale of operations at this time, it is not currently necessary. The Board accepted this recommendation. This decision will be kept under review.

## External audit

The Group's external Auditor, PricewaterhouseCoopers LLP (PwC), is engaged to express its opinion on the Group's financial statements.

## Effectiveness

The effectiveness of the external audit process is reviewed annually by the Committee. This review encompasses an examination of the independence, qualifications, capabilities, and remuneration of the Auditor. If issues are identified which may affect the effectiveness of the process then actions will be agreed. No such issues were identified in the year to 31 December 2016 or up to the date of this report.

As PwC has been Auditor for 10 years, the Board conducted a process inviting a number of firms to tender for the 2017 year end audit. At the end of the process, the Audit and Risk Committee recommended to the Board that PwC be proposed for re-appointment as Auditors.

In addition, at the end of the audit for the year ended 31 December 2016 the Committee formally evaluated the performance of PwC. To conduct this evaluation the Committee completed a questionnaire to assess robustness of the audit process, quality of its delivery, quality of reporting, and quality of the individuals and service. Moreover, the Committee takes into account the quality of its interactions with the Auditor in forming a view on their effectiveness.

## Independence

The Committee is responsible for reviewing the independence and objectivity of the external Auditor. Each year the external Auditor confirms its policies for ensuring its independence and provides the Committee with written confirmation that they continue to be independent.

The Committee pays careful regard to whether non-audit work is carried out by the Auditor so as to ensure that the provision of such additional services does not impair its independence or objectivity.

A formal process exists for approving the use of the Auditor for non-audit work. The Auditor should not be appointed to provide non-audit services which might put the Auditor in the position of auditing its own work or create a mutual interest between the Group and the Auditor or result in the Auditor acting as an advocate, manager, or employee of the Group.

PwC undertook non-audit services for the Group in the course of the year to 31 December 2016 which are summarised in the table below. These services were provided in compliance with the policy outlined above and no conflicts of interest were considered to have arisen.

Committee approval required?	Nature of work	Fees £'000
Yes	Reporting accountant	290
No	Other assurance services	52

The total fees paid to the Auditor are shown in note 8 of the financial statements. Services were provided during the year in connection with corporate advisory services. The Committee believes that the use of PwC for this work was appropriate in the circumstances and that independence was preserved as the nature of the non-audit services was such that the external Auditor was best placed to perform this work due to their skills and experience, and the fees paid were insignificant in the context of the overall revenues earned by PwC.

Other assurance services related mainly to the fees for the review of the operations of the Group's representative office in China.

In summary, the Committee confirms that the Group has received an independent audit service in the year to 31 December 2016 and up to the date of this report.

## Audit partner rotation

PwC adheres to a rotation policy which complies with the ethical standards of the Audit Practices Board (the "APB") and the audit partner is rotated every five years. Simon Ormiston, the current audit partner was appointed for the year ended 31 December 2014 and is not due for rotation until completion of the year ending 31 December 2018.

## Tendering

PwC has been the Company's Auditor since the year ended 31 December 2007. The Committee is actively monitoring developments arising from the EU audit reform framework and the Competition and Markets Authority. In view of those developments, the Committee conducted an audit tender process during the course of 2016 and recommended PwC for re-appointment by shareholders at the 2017 Annual General Meeting.

The Company has complied during the financial year under review and up to the date of this report with the provisions of the Statutory Audit Services for Large Companies Market Investigation (Mandatory use of Competitive Tender Processes and Audit Committee Responsibilities) Order 2014.

## Committee evaluation

An external review of the effectiveness of the Committee was carried out in 2016 as part of the process of evaluating Board effectiveness. The review was carried out by a firm named Independent Audit who specialise in the review of Boards and their committees. The Board was required to complete four tailored questionnaires for the Board as a whole and for each of its committees. The results were analysed by Independent Audit and presented as a report to the Board. The findings of the report were debated by the Board and a list of actions agreed.

## Results of Audit Quality Review

The external audit in respect of the year ended 31 December 2015 was subject to review by the Audit Quality Review (AQR) team of the Financial Reporting Council (FRC) during the year. The Committee received a copy of the report from the FRC and has discussed the matters identified in this report with the audit partner. There were no significant findings identified and the Committee are satisfied that the matters discussed have been appropriately considered as part of the audit of the year ended 31 December 2016.

## Lota S Zoth

Chair of the Audit and Risk Committee

25 April 2017

## Nomination Committee report

### Dear Shareholder

On behalf of the Board, I am pleased to present Circassia's Nomination Committee report for the year ended 31 December 2016. The key objective of the Committee is to ensure the Board is made up of a range of individuals who together have the appropriate mixture of skills and experience to lead the Group.

In the course of the year, Mr Paul Edick and Ms Cathrin Petty both departed from the Board. Their contributions have been greatly appreciated. However, the Committee did not feel it necessary to replace them at this stage given the breadth of expertise provided by the remaining Board members.

A summary of the activities of the Committee is set out below.

### Dr Francesco Granata

Chairman of the Nomination Committee

25 April 2017

### Responsibilities

The Committee must review the size, structure, and composition of the Board and the Committees evaluating the balance of skills, experience, independence, and diversity of the Board as a whole. On the basis of this evaluation it will then make recommendations to the Board on any appointments. As part of this process, the Committee will prepare a description of the skills, experience and other characteristics required, and identify through a transparent procedure, individuals who are capable of filling those roles.

The Committee also plans for the orderly succession of Directors to the Board and recommends to the Board the membership and chairmanship of the Audit and Remuneration Committees.

The full terms of reference of the Committee can be found on the website.

### Membership and meetings

Throughout the year the Committee comprised Dr Tim Corn, Dr Jean-Jacques Garaud, and Dr Francesco Granata, the Chairman. Dr Jean-Jacques Garaud was considered by the Board to be Independent. However, Dr Tim Corn was not considered to be Independent. As Dr Jean-Jacques Garaud was the only Independent Non-Executive Director, one third of the Committee was therefore made up of Independent Non-Executive Directors, although the Chairman was independent upon appointment. The composition of the Nomination Committee therefore did not comply fully with the recommendations of the Code.

As Dr Tim Corn will not stand for re-election at the Annual General Meeting, he will be replaced by an existing independent Non-Executive Director. The Committee is therefore expected to comply with the Code in respect of its composition of independent Non-Executive Directors during 2017.

The Committee met twice during the year ended 31 December 2016 and all members, except for Dr Jean-Jacques Garaud were present at each meeting. A summary of the composition and attendance of the Committee is as follows:

Member	Date of appointment	Meetings attended (held)
Dr Francesco Granata	21 February 2014	2 (2)
Dr Tim Corn	21 February 2014	2 (2)
Dr Jean-Jacques Garaud	21 February 2014	1 (2)

The Company Secretary acts as Secretary to the Committee. The Chief Executive Officer may attend meetings by invitation.

The Committee is empowered to obtain external professional advice to assist in the performance of its duties. However, during the year the Committee did not require any external services except for the external evaluation of Board effectiveness.

### Activities

The principal activities during the year were:

- Review of the structure, size and composition of the Board (including skills, experience, independence, knowledge and diversity); and
- Annual performance evaluation of the Board, its members and its Committees.

### Appointment procedure

There is a formal and transparent procedure by which new Directors are appointed to the Board. Suitable candidates are proposed either by existing Board members or by an external search firm. The Committee will then assess whether the candidate has the requisite skills and experience for the role, sufficient time to perform it, and that their appointment will preserve or improve the balance of skills, experience and knowledge of the Board.

No Board appointments were made in the course of the year or up to the date of this report.

### Diversity

The Company has an Equal Treatment, Equal Opportunities and Diversity policy which extends to the Board. Any appointments are carried out in full compliance with this policy.

### Succession Planning

The Board is satisfied that appropriate planning has taken place for the orderly succession of Directors and senior management.

### Chairman's commitments

In accordance with provision B.3.1 of the Code, it is confirmed that the Chairman's other significant commitments are as disclosed in the biography which appears in the Corporate governance report.

### Committee evaluation

An external review of the effectiveness of the Committee was carried out in December 2016 as part of the process of evaluating Board effectiveness. This was performed by Independent Audit who specialise in the review of Boards and their committees. The Board was required to complete four tailored questionnaires for the Board and for each of its committees. The results were analysed by Independent Audit and presented as a report to the Board. The findings of the report were debated by the Board and a list of actions agreed.

### Dr Francesco Granata

Chairman of the Nomination Committee

25 April 2017

# Corporate governance continued

## Annual statement

### Dear Shareholder

On behalf of the Board, I am pleased to present Circassia's Remuneration Committee report for the year ended 31 December 2016. This report will be presented for the consideration and approval of Shareholders at the Annual General Meeting on 26 May 2017.

This report complies with the regime set out in Part 4 to Schedule 8 of the Large- and Medium-sized Companies and Groups (Accounts and Reports) Regulations 2008 (as amended) (the Regulations), the UK Corporate Governance Code ('the Code') and the Listing Rules. Accordingly it consists of three parts: (i) an Annual statement which summarises the key issues and explains the business context in which the Committee's main decisions were taken; (ii) an unaudited Directors' remuneration policy report which describes the current and future executive remuneration policy, and which was approved by 99.57% of Shareholders at the AGM on 20 May 2015; and (iii) the Annual report on remuneration which sets out details of and rationale for the remuneration provided to the Group's Directors during the 2016 financial year. This latter report is subject to an advisory vote at the AGM.

### Remuneration policy

The remuneration policy which was approved by the Shareholders at the 2015 AGM, promotes the long-term sustainable success of the Group. It aims to reward Executive Directors for performance, and for delivery of Shareholder value judged against transparent and demanding criteria. As part of this policy a significant proportion of potential remuneration is linked to the achievement of corporate and individual performance indicators.

The annual bonus plan for Executive Directors and management at Senior Vice President level includes an element being deferred into shares for three years and subject to forfeiture.

Share incentive arrangements have been in effect since 2014 and are intended to closely align the interests of the Executive Directors with those of Shareholders. The earliest date of vesting under these schemes falls three years after grant subject to the achievement of performance conditions. Details of the awards made under these schemes to the Executive Directors are set out in the Annual report on remuneration. In addition, the Company operates shareholding guidelines for Executive Directors and Senior Vice Presidents to further increase alignment with Shareholders.

The Committee believes that the emphasis on performance-related pay, the use of bonus deferral, annual long-term incentive awards and mandatory share ownership guidelines, creates a clear focus on sustainable performance, avoids paying more than is necessary and maintains an ongoing alignment between Executive Directors and Shareholders.

### Performance and reward

The bonus arrangements for 2016 provided for an award of up to 100% of salary linked to the achievement of annual developmental and operational goals. As described in the Strategic report, although the Group made significant progress in developing its NIOX business, building its commercial infrastructure, and progressing its respiratory pipeline it suffered a significant setback when the phase III results for its cat allergy treatment proved negative. As a result, even though a number of the corporate objectives set by the Board were in fact achieved, given the material decline in the share price suffered by Shareholders, the Executive Directors and the Board felt it appropriate not to award any bonus to the Executive Directors or Senior Vice Presidents for the year ended 2016.

No long-term incentives were due to vest in relation to performance ending in 2016.

### Application of policy for 2017

The Remuneration policy set out in this report was approved by Shareholders at the Annual General Meeting on 20 May 2015 and will be applied without changes in 2017.

The salaries of the Executive Directors were reviewed with effect from 1 January 2017 and increased in line with increases to the general workforce of 3%.

The annual fee for the Chairman, Dr Francesco Granata, will increase from £134,400 to £138,400.

We welcome Shareholder feedback on these matters and hope that you will be able to support our policy and its application at the forthcoming AGM.

### Marvin S Samson

Remuneration Committee Chairman

25 April 2017

## Directors' remuneration policy report (DRP)

The present policy was approved by a binding Shareholder vote at the AGM on 20 May 2015 and is therefore expected to remain in force until the AGM in 2018. There is no requirement to vote again on the policy this year as no changes are being proposed at this time, but the full policy has been included again this year for information only. The bar charts on page 61 have, however, been updated to reflect possible scenarios for remuneration in 2017.

### Remuneration philosophy

The potential levels of remuneration have been set so that they are competitive against those comparator companies with which the Group will compete for talented individuals.

The Committee's goal is to design and implement a remuneration policy which will support and reward Executive Directors for delivering the Group's strategic objectives and ultimately creating value for Shareholders, whilst adhering to good corporate governance and reflecting best practice. To achieve this, the balance of remuneration is focused on variable performance-related pay. In particular, to reflect the long-term nature of the Group's development pipeline, variable pay is more heavily weighted towards long-term sustainable value creation through the use of share incentive plans. When combined with share ownership guidelines, this creates an alignment between Executive Directors and Shareholders with a longer-term view.

The Committee annually reviews the operation of the variable incentive plans to ensure they are operating within an acceptable risk profile and that they do not inadvertently encourage any economic, social or governance issues.

### Remuneration policy

The total remuneration for each Executive Director is made up of the following elements:

- Salary;
- Benefits;
- Annual bonus;
- Long-term incentive awards; and
- Pension.

Recovery and withholding provisions will apply to the bonus and long-term incentive arrangements in specific circumstances as determined appropriate by the Remuneration Committee.



# Remuneration committee report

Salary	Benefits	Annual bonus
<p><b>Purpose and link to strategy</b> Provides fixed remuneration in line with market rates that reflects the responsibilities of the role undertaken and the experience of the individual.</p>	<p><b>Purpose and link to strategy</b> Provides market competitive, yet cost-effective employment benefits.</p>	<p><b>Purpose and link to strategy</b> To incentivise and recognise execution of the business strategy and personal objectives on an annual basis.</p>
<p><b>Operation</b> Set at an approximately mid-market level and reviewed annually taking into account individual responsibilities, performance, inflation, and market rates. The Committee will also consider the pay and employment conditions in the wider workforce when determining Executive Directors' salaries. Salary increases are normally effective from 1 January each year.</p> <p>Salaries are periodically benchmarked against a relevant peer group of UK listed companies with similar market capitalisation and operations.</p>	<p><b>Operation</b> For Executive Directors this includes private medical insurance and life insurance.</p> <p>Other employment benefits may be provided from time to time on similar terms as those of other employees.</p> <p>If the Company introduces an all-employee share plan, Executive Directors will be eligible to participate on the same terms as other employees.</p> <p>If an Executive Director is based outside the UK additional benefits and assistance with relocation may be provided which reflect local market norms or legislation.</p>	<p><b>Operation</b> Annual bonus performance targets are set at the start of the year by the Board and performance against objectives is assessed by the Remuneration Committee.</p> <p>Bonuses will be paid as a mix of cash and deferred shares. Until the share ownership guidelines are reached, the bonus will be payable as 50% cash and 50% shares.</p> <p>Thereafter, the bonus will be payable as 75% cash and 25% shares.</p> <p>Bonus shares are deferred for three years from the date of the award and are subject to forfeiture.</p> <p>Recovery and withholding provisions will apply in the event of misstatement of results, error in performance calculation or gross misconduct.</p> <p>A dividend equivalent, if payable, will be payable in cash when the shares vest.</p>
<p><b>Maximum potential value</b> The current base salaries are set out in the implementation of policy section of the Annual report on remuneration.</p> <p>There is no formal maximum limit, but increases are generally in line with those of the wider workforce.</p> <p>Larger increases may be permitted to reflect a change in responsibilities or a significant increase in the scale or complexity of the role.</p>	<p><b>Maximum potential value</b> There is no formal maximum limit as the value of insured benefits will vary from year to year based on the cost from third-party providers.</p>	<p><b>Maximum potential value</b> The maximum payable for all Executive Directors is 100% of salary.</p>
<p><b>Performance metrics</b> The overall performance of the individual and Company is a key determinant for salary increases.</p>	<p><b>Performance metrics</b> None.</p>	<p><b>Performance metrics</b> Research and development, business development, financial and operational targets are set at the start of the year by the Board. The weighting for each performance measure is determined by the Remuneration Committee and may vary for each Executive Director according to their role and reflecting their objectives for the year.</p> <p>Details of the performance measures for the current year are provided in the Annual report on remuneration.</p>

## Remuneration committee report continued

<p><b>Performance share plan (PSP)</b></p>	<p><b>Pension</b></p>
<p><b>Purpose and link to strategy</b> To align the interests of management with Shareholder interests and to enhance retention of staff.</p> <p>To incentivise and recognise achievement of longer-term business objectives and sustained superior Shareholder value creation.</p>	<p><b>Purpose and link to strategy</b> To provide a competitive and cost-effective level of retirement provision.</p>
<p><b>Operation</b> Conditional awards or options from the Performance Share Plan are granted annually. The awards vest provided certain performance conditions, which have been approved by the Board, are achieved over a period of at least three years.</p> <p>Performance targets are set at the start of each performance period. Recovery and withholding provisions apply for reasons of misstatement of results, error in performance calculation or gross misconduct.</p>	<p><b>Operation</b> Executive Directors are eligible to join a defined contribution pension scheme.</p> <p>Alternatively a cash supplement (or a combination of contribution and cash) can be made.</p>
<p><b>Maximum potential value</b> Annual awards of up to the following percentage each year are granted to Executive Directors:</p> <ul style="list-style-type: none"> <li>— Chief Executive Officer, 150% of salary</li> <li>— Other Executive Directors, 125% of salary</li> </ul> <p>In special circumstances (such as a recruitment) an award of up to 300% of salary is permitted.</p> <p>Dividend equivalents may be payable on vested awards.</p>	<p><b>Maximum potential value</b> The maximum contribution, cash supplement (or combination thereof) payable by the Company is 15% of salary.</p>
<p><b>Performance metrics</b> Awards are currently subject to a combination of relative Total Shareholder Return (TSR) and clinical progression timelines for Executive Directors.</p> <p>No more than 25% of the maximum award will vest for achieving the threshold performance level.</p> <p>The weighting of these performance measures, the choice of comparators for relative Total Shareholder Return (TSR) and/or the inclusion of additional performance measures will be reviewed annually by the Committee, reflecting the strategic objectives and priorities of the following three year performance period.</p> <p>If the Committee determines a material change to the performance measures used for future awards is required to reflect a change in strategy, this would only be made following appropriate dialogue with the Company's major Shareholders.</p>	<p><b>Performance metrics</b> None.</p>

<b>Share ownership guidelines</b>
<p><b>Purpose and link to strategy</b> To align Executives with Shareholders and provide an ongoing incentive for continued performance.</p>
<p><b>Operation</b> Only shares which are fully owned with no outstanding vesting criteria count towards the shareholding guideline. Executive Directors will be required to retain half of any post-tax awards which vest under long-term incentive plans, until the share ownership guideline has been satisfied.</p>
<p><b>Maximum potential value</b> Executive Directors are required to build and maintain the following minimum level of shareholding:</p> <ul style="list-style-type: none"> <li>– Chief Executive Officer, 150% of salary</li> <li>– Other Executive Directors, 100% of salary</li> </ul>
<p><b>Performance metrics</b> None.</p>

The Committee operates the annual bonus and Performance Share Plan (PSP), in accordance with their rules, and where relevant, the Listing Rules. To maintain an efficient administrative process, the Committee retains the following discretions relating to remuneration:

- a. the eligibility to participate in the plans;
- b. the timing of grant of awards and any payments;
- c. the size of awards and payments (subject to the maximum limits set out in the policy table above and the respective plan rules);
- d. the determination of whether the performance conditions have been met;
- e. determining a good or bad leaver under the terms of the plan;
- f. dealing with a change of control or restructuring of the Group;
- g. adjustments required in certain capital events such as rights issues, corporate restructuring, events and special dividends; and
- h. the annual review of performance conditions for the annual bonus plan and PSP.

In certain exceptional circumstances, such as a material acquisition/divestment of a Group business, which mean the original performance conditions are no longer appropriate, the Committee may adjust the targets, alter weightings or set different measures as necessary, to ensure the conditions achieve their original purpose and are not materially less difficult to satisfy.

#### Historical awards

Awards which were granted prior to the Company's IPO are set out in the Annual report on remuneration (ARR).

These awards remain eligible to vest, based on their original terms and will be disclosed in the relevant ARR as required.

# Remuneration committee report continued

## Performance measures

The rationale behind each performance measure currently used in the Performance Share Plan and how it is calculated is as follows:

Performance measure	Rationale
Relative TSR performance	<b>Recognises outperformance and delivery of relative value to Shareholders</b> Relative total Shareholder return is currently measured against the FTSE 250 (excluding Investment trusts (the 'Index')). This was chosen as a comparator group because it represents similar sized companies, is subject to less volatility than a smaller peer comparator group and is transparent for both Shareholders and participants. The Committee will review on an annual basis the continued appropriateness of the comparator group.
Key strategic business objectives	<b>Recognises the importance of both revenue growth and clinical progress</b> The growth of the Company and therefore delivery of value to investors is dependent on achievement of certain key commercial and clinical objectives.

The annual bonus is designed to drive the achievement of the Company's strategic business targets. These targets are agreed by the Board and selected because of their importance in value creation for Shareholders. Objectives are weighted for Executives in proportion to the degree of responsibility for control and achievement of that objective. The weightings are agreed by the Remuneration Committee.

## Remuneration on recruitment

The Remuneration Committee determines the remuneration package of new Executive Directors. Each element of an Executive Director's remuneration is set out below:

Salary	Base salary will be determined based on the role, experience of the individual and the current market rate. It may be considered necessary to appoint a new Executive Director on a below market salary (e.g. to reflect limited plc board experience). In such circumstances phased increases above those of the wider workforce may be required over an appropriate time period, to bring the salary to the desired market level, subject to the continued development in the role.
Benefits	Benefits provided would be in line with those of current Executive Directors. Where required to meet business needs, reasonable relocation support will be provided. In addition if it becomes necessary to appoint a new Executive Director from outside the UK, additional benefits may be provided to reflect local market norms or legislation.
Annual bonus	The ongoing annual bonus maximum will be in line with that outlined in the policy table for existing Executive Directors, pro-rated to reflect the period of service. Depending on the timing or nature of an appointment it may be necessary to set different initial performance measures and targets for the first year of appointment.
Long-term incentive awards	PSP awards are granted in line with the policy outlined for existing Executives. Any ongoing annual award is limited to that of the current Chief Executive Officer. An award may be made shortly following an appointment (provided the Company is not in a prohibited period). For internal appointments, existing awards will continue on their original terms.
Pension	A company contribution or cash supplement up to the maximum as outlined for current Executive Directors.
Buy-out awards	To enable the recruitment of exceptional talent, the Committee may determine that the buy-out of remuneration forfeit from a prior employer is necessary. Where possible, any replacement remuneration will be offered on a like-for-like basis with the forfeited awards and may be in the form of cash or shares and depending whether the award forgone has similar performance conditions, may or may not be subject to performance conditions. The value of any buy-out will be limited to the value of remuneration forfeit. Where appropriate, such awards will be granted under existing share plans, however, the Remuneration Committee will have discretion to make use of the flexibility to make awards under exemptions in the Listing Rules.

Fee levels for the Chairman and Non-Executive Directors will be set at a level that is consistent with those of existing Non-Executive Directors.



### Exit payment policy

The Group does not have a policy of fixed term employment contracts, however, all Directors put themselves forward for re-election at the Annual General Meeting. Notice periods for Executive Directors' employment contracts are six months and three months for the Chairman's and Non-Executive Directors' letters of appointment from either party.

The following policies and payments apply in the event that an Executive Director's employment is terminated.

Remuneration element	Exit payment policy
Current service contracts	<p>Termination by notice: six months.</p> <p>Redundancy: six months annual salary payable (reduced accordingly if part of the notice period is worked).</p> <p>Retirement, death and ill-health, injury or disability: no termination payment.</p>
Future service contracts	<p>Termination by notice: up to 12 months' notice, with a provision to make a payment in lieu of notice for base salary and benefits only. Any payment will be phased on a monthly basis and would be subject to mitigation, whereby the payment made can be reduced (including to zero) if appropriate alternative employment is found.</p> <p>Redundancy: annual salary payable for the relevant notice period (reduced accordingly if part of the notice period is worked).</p> <p>Retirement, death and ill-health, injury or disability: no termination payment.</p>
Long-term incentives and deferred bonuses	<p>PSP awards are governed by the Plan Rules as approved by Shareholders. Likewise, the deferred bonus awards are subject to the same leaver provisions. These are summarised below.</p> <p>Termination by notice: unvested awards lapse on cessation.</p> <p>Redundancy, retirement, ill health, injury or disability, transfer of employment outside of the Group or change of control, or any other reason the Committee determines: unvested awards will vest either on the normal vesting date or if the Board decides, immediately on the participant ceasing to be in employment. Awards will vest subject to the extent the performance condition has been met, as determined by the Remuneration Committee. Awards will be pro-rated for time, unless the Committee determines otherwise.</p> <p>Death: unvested awards will vest on the date of death. Awards will be pro-rated, unless the Committee determines otherwise.</p> <p>Change of control: unvested awards will vest on the date of the takeover. Awards will vest subject to the extent the performance condition has been met, as determined by the Remuneration Committee. Awards will be pro-rated, unless the Committee determines otherwise.</p>
Annual bonus	<p>Termination by notice by individual: if an individual serves notice and the termination date falls before 31 December, the bonus is forfeited. If notice is served between 1 January following the year in which the bonus was earned and the payment date, the employee may (as determined by the Remuneration Committee) receive the entire bonus payable in cash, subject to malus and clawback provisions.</p> <p>Redundancy, retirement, death and ill-health, or any other reason the Committee determines: if the termination date falls during the financial year, pro-rated for service rendered and subject to performance; if it falls after the end of the financial year the bonus is payable in cash based on actual results on the normal bonus payment date.</p> <p>Termination by notice: not normally paid, however, at the Committee's discretion, if the termination date falls during the financial year, a bonus may be paid pro-rata for service rendered and subject to performance over the full financial year and normally paid on the normal payment date: if it falls after the end of the financial year a bonus is payable based on actual results on the normal bonus payment date.</p>
Benefits	These will normally continue to apply until the termination date.
Pension	Contributions by the Company will normally continue to apply until the termination date.
Additional payments	<p>The Committee will make payment of any statutory entitlements as necessary. In addition the Committee will retain the discretion to make settlement or to compromise a claim in connection with a termination of any Executive Directors as necessary.</p> <p>Reasonable legal and outplacement costs will be met if deemed necessary.</p>

# Remuneration committee report continued

## Service contracts

The following Executive Directors have service agreements with the Company which were effective from 18 March 2014 as follows:

Name	Position	Date of joining
Steven Harris	Chief Executive Officer	19 May 2006
Rod Hafner	Senior VP of R&D	1 March 2007
Julien Cotta	Chief Financial Officer	5 January 2012

The notice period for each Executive Director is 6 months and all Executive and Non-Executive Directors put themselves forward for re-election at the Annual General Meeting.

The Board believes that it may be beneficial to the Group for executives to hold non-executive directorships outside the Group. Any such appointments are subject to approval by the Board and the director may retain any fees received. Steven Harris received fees of £Nil for being on the Board of Synchrony Pharma Limited during the year to 31 December 2016 (2015: £Nil) and £30,000 for being on the Board of Woodford Patient Capital Trust during the year to 31 December 2016 (2015: £22,318).

The key terms for the Letters of Appointment for Non-Executive Directors are set out below:

Name	Notice period	Date of joining
Dr Francesco Granata	3 months	1 September 2013
Dr Tim Corn	3 months	1 August 2006
Russell Cummings	3 months	25 January 2007
Paul Edick <sup>1</sup>	3 months	3 April 2013
Dr Jean-Jacques Garaud	3 months	1 November 2012
Cathrin Petty <sup>2</sup>	3 months	8 March 2010
Charles Swingland	3 months	31 May 2006
Lota Zoth	3 months	9 February 2015
Marvin Samson	3 months	8 December 2015

<sup>1</sup> Retired from the Board 18 May 2016.

<sup>2</sup> Resigned from the Board 16 December 2016.

Copies of the service contracts and letters of appointment are available for inspection at the registered office.

## Statement of consideration of employees' pay and remuneration conditions elsewhere in the Group

The Company does not formally consult with employees on the matters of Executive Director remuneration. However, the Committee is made aware of employment conditions in the wider Group.

The same broad principles apply to the remuneration policy for both Executive Directors and the wider employee population. However, the remuneration for Executive Directors has a stronger emphasis on performance-related pay than for other employees. In particular the following approach is used:

- Salaries, benefits and pensions are compared to appropriate market rates and set at approximately mid-market level with allowance for role, responsibilities and experience.
- When setting salary levels for the Executive Directors, the Committee considers the salary increases provided to other employees and in particular those based in the UK.
- An annual bonus plan is available to all employees and is based on business and individual performance.

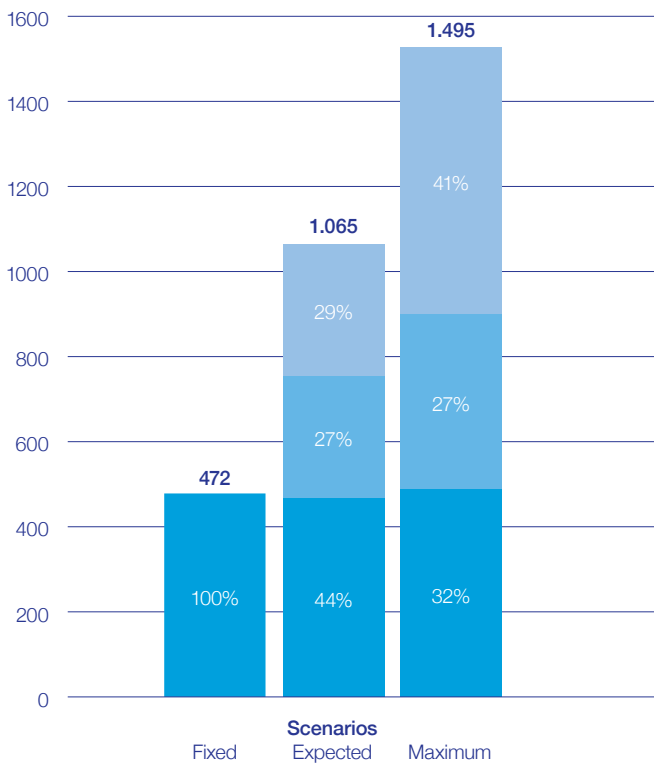
## Scenarios

The charts set out for illustrative purposes only, what annual remuneration the Company expects the Directors to obtain if performance levels are below threshold, meet expectations or exceed the maximum targets.

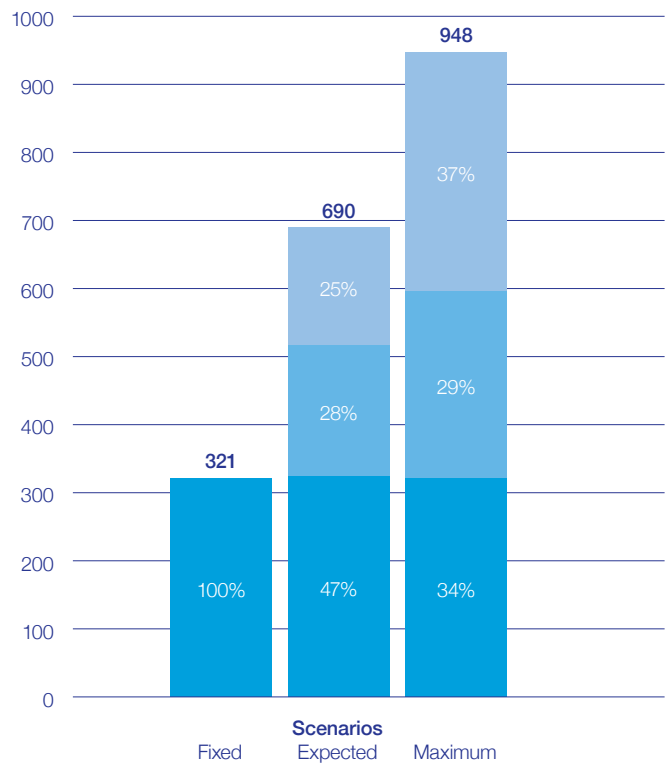
The assumptions used in the calculations are set out below:

- Fixed pay: this includes salary, pension and benefits.
- Base salary effective 1 January 2017 and expected pension contribution has been used.
- The actual monetary value of benefits received in 2016 have been used.
- Expected: this includes salary, pension, benefits, annual bonus and PSP. This assumes that 70% of the annual bonus maximum will be payable for each of the Directors and 50% of PSP awards will vest.
- Maximum: It is assumed that the maximum annual bonus would be payable and that the awards under the PSP vest in full.
- No share price growth has been assumed.

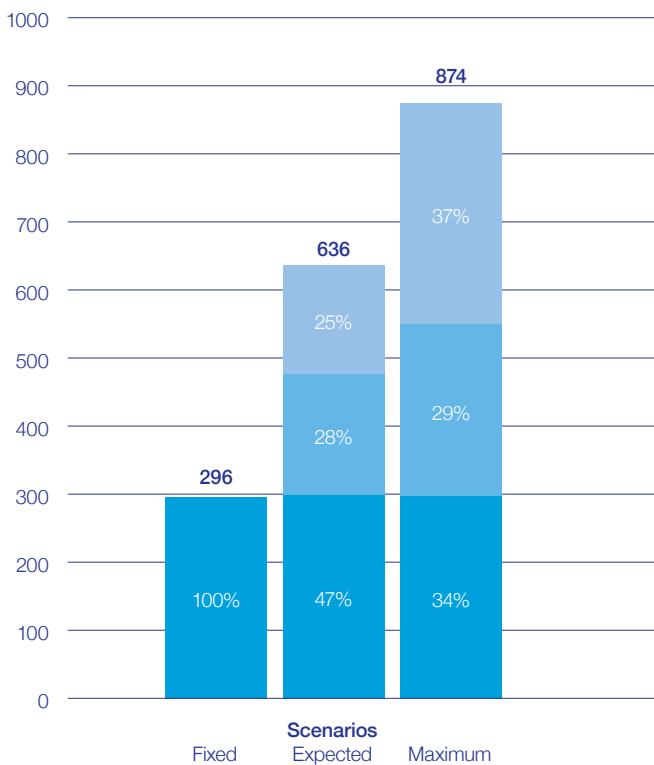
**CEO**  
£'000



**Senior VP R&D**  
£'000



**CFO**  
£'000



- Fixed
- Annual bonus
- Long-term variable remuneration

## Remuneration committee report continued

### Remuneration policy for Non-Executive Directors

The Remuneration Committee is responsible for evaluating and making recommendations to the Board on fees payable to the Chairman. The Chairman does not participate in discussions in respect of fees. The Chairman and CEO are responsible for evaluating and making recommendations to the Board on the fees payable to the Company's Non-Executive Directors.

Remuneration element	Purpose and link to strategy	Operation and maximum
Chairman's fee	To attract and retain a high calibre individual with the requisite experience and knowledge.	<p>The current fee is set out in the implementation of policy section of the Annual report on remuneration. There is no formal maximum.</p> <p>Fees are reviewed on a periodic basis against those in similar sized companies to ensure they remain competitive and adequately reflect the time commitments and scope of the role.</p> <p>Any increase in fee levels may be above that of the wider workforce in a particular year to reflect the periodic nature of any review and/or any change in responsibilities/time commitments.</p> <p>The Chairman may also receive limited travel and/or hospitality related benefits in connection with the role.</p>
Non-Executive Director fee	To attract and retain high calibre individuals with the requisite experience and knowledge.	<p>The current fee levels are set out in the implementation of policy section of the Annual report on remuneration. There is no formal maximum.</p> <p>Fees are reviewed on a periodic basis against those in similar sized companies to ensure they remain competitive and adequately reflect the time commitments and scope of the role.</p> <p>A Board fee is paid to each Non-Executive Director. Supplemental fees are paid to the Senior Independent Director and for the Chairing and membership of Committees to recognise the additional time commitments and responsibilities of these roles.</p> <p>Any increase in fee levels may be above that of the wider workforce in a particular year to reflect the periodic nature of any review and/or any change in responsibilities/time commitments.</p> <p>Non-Executive Directors may also receive limited travel and/or hospitality related benefits in connection with the role.</p>

### Statement of consideration of Shareholders' views

The Remuneration Committee will consider any Shareholder feedback received at the AGM and at meetings throughout the year, when reviewing the overall remuneration policy each year. The guidance from shareholder representative bodies is also considered on an ongoing basis.

More specifically the Committee will consult with major Shareholders when proposing any significant changes to the policy in the future.



## Annual report on remuneration

This section of the Remuneration Committee report has been prepared in accordance with Part 3 of the Regulations as amended, and 9.8.6R of the Listing Rules. The Annual report on remuneration will be put to an advisory Shareholder vote at the AGM on 26 May 2017.

### Composition

From 1 January 2016 to 9 February 2016, the Committee was made up of Dr Jean-Jacques Garaud (Chairman), Dr Tim Corn, and Ms Lota Zoth. Dr Jean-Jacques Garaud and Lota Zoth are both considered independent by the Board. Tim Corn is considered not to be independent. The Committee therefore did not comply with the requirement of the Code that all members of the Remuneration Committee be Independent Non-Executive Directors. On 9 February 2016 Dr Garaud was succeeded by Mr Marvin Samson as Chairman of the Committee. Mr Samson is also considered to be an Independent Non-Executive Director. There have been no further changes to the Committee up to the date of this report. The terms of reference of the Committee appear on the Company's website. The Committee met twice during the year ended 31 December 2016. Each meeting was fully attended.

### Responsibilities

The Committee is responsible for the following matters:

- setting a remuneration strategy which is designed to promote the long-term success of the Company;
- ensuring that the remuneration of the Executive Directors and senior employees reflects performance and delivery of Shareholder value;
- agreeing the design and targets of share incentive plans which require Shareholder approval and monitoring the achievement of those targets;
- deciding on the remuneration of the Executive Directors and senior employees, including any specific recruitment or retention terms;
- making a recommendation to the Board in relation to the Chairman's fees;
- appointing external advisers where necessary.

### Activities

A summary of the matters considered by the Committee in the course of the year ended 31 December 2016 is as follows:

Meeting	Agenda items
February	Review of the salary levels and annual bonus plan for the Executive Directors. Review of remuneration for the Chairman. Review of performance targets for annual PSP awards.
May	Review of PSP plan vesting criteria. Approval of option awards for new employees.
December	The review and approval of annual bonus targets for 2017 for Executive Directors and Senior Vice Presidents which is usually considered at the December meeting was postponed until February 2017

### Advisers

The Committee appointed New Bridge Street (NBS) (part of Aon plc) to advise it on aspects of the Group's remuneration policy. NBS is a signatory to the Remuneration Consultants' Group Code of Conduct which sets out guidelines to ensure that its advice is independent and free from undue influence. The fees to NBS in 2016 were £39,150 (2015: £18,216), which were mainly charged on the basis of hourly rates. The Committee reviews the performance and independence of its advisers on an annual basis.

# Remuneration committee report continued

## Committee evaluation

An external review of the effectiveness of the Committee was carried out in December 2016 as part of the process of evaluating Board effectiveness.

## Audited information

### Total remuneration – year ended 31 December 2016

The total remuneration of the individual Directors who served during the year is set out in the table below. Total remuneration is the sum of emoluments plus pension contributions and the value of long-term incentive awards vesting by reference to performance in the year ended 31 December 2016.

		Salary or fees <sup>4</sup> £'000	Benefits <sup>5</sup> £'000	Bonus <sup>6</sup> £'000	Long-term incentives <sup>7</sup> £'000	Pension <sup>8</sup> remuneration £'000	Total £'000
<b>Executive Directors</b>							
Steven Harris	2016	398	1	–	–	60	459
	2015	386	1	386	–	58	831
Julien Cotta	2016	249	1	–	–	37	287
	2015	242	1	242	–	36	521
Rod Hafner	2016	270	1	–	–	41	312
	2015	263	1	263	–	39	566
<b>Non-Executive Directors</b>							
Francesco Granata	2016	142	–	–	–	–	142
	2015	138	–	–	–	–	138
Tim Corn	2016	60	–	–	–	–	60
	2015	59	–	–	–	–	59
Russell Cummings	2016 <sup>1</sup>	42	–	–	–	–	42
	2015 <sup>1</sup>	42	–	–	–	–	42
Paul R Edick	2016 <sup>2</sup>	17	–	–	–	–	17
	2015 <sup>2</sup>	43	–	–	–	–	43
Jean-Jacques Garaud	2016	63	–	–	–	–	63
	2015	71	–	–	–	–	71
Cathrin Petty	2016 <sup>3</sup>	45	–	–	–	–	45
	2015 <sup>3</sup>	45	–	–	–	–	45
Lota Zoth	2016	60	–	–	–	–	60
	2015	54	–	–	–	–	54
Marvin Samson	2016	54	–	–	–	–	54
	2015	3	–	–	–	–	3
Charles Swingland	2016	45	–	–	–	–	45
	2015	43	–	–	–	–	43
<b>Total 2016</b>		<b>1,445</b>	<b>3</b>	<b>–</b>	<b>–</b>	<b>138</b>	<b>1,586</b>
Total 2015		1,389	3	891	–	133	2,416

1 All fees for Russell Cummings are paid to Touchstone Innovations Limited

2 Retired from the Board on 18 May 2016 having not submitted himself for re-election.

3 Resigned from the Board on 16 December 2016.

4 This is the amount earned as salary or fees in the financial year

5 This is the taxable value of benefits paid in respect of the financial year. The majority of these benefits consist of medical insurance and life assurance

6 This is the value of the total bonus earned during the financial year and comprises the annual bonus paid in respect of performance against goals for 2015. Where the requisite shareholding requirement has not been met by an Executive Director then 50% of the annual bonus will be paid in shares. Where the requirement has been met then 25% will be paid in shares.

7 The amount shown relates to the gain, being the market value on date of exercise less exercise price, on EMI share option awards that vested during the year

8 UK tax legislation imposes penalty taxes on annual pension contributions where prescribed maximum limits are exceeded. The Committee has previously determined that Executive Directors affected by this legislation would receive pension benefits limited by the prescribed maximum amounts and an additional taxable supplementary cash payment equal to the cost to the Company of the benefit foregone. The amount of this supplementary allowance is set so that there is no additional cost to the Company as a result of the implementation of this arrangement. In 2016 Steven Harris received £59,625 of this pension amount as supplementary cash (2015: £40,114). In 2016 Rod Hafner received £30,417 of this pension amount as supplementary cash (2015: £nil).

## Annual bonus for the year to 31 December 2016

For the year ended 31 December 2016, bonuses up to a maximum of 100% of base salary for Executive Directors and Senior Vice Presidents could be earned for performance against annual operational and development goals.

Performance objectives are agreed by the Board at the beginning of the year and the Remuneration Committee determines the proportion of bonus payable to each Director and Senior Vice President in the event that the objective is achieved. The Remuneration Committee determines at the beginning of the year following the bonus year, the extent to which the objective has been achieved and the proportion of the bonus earned. The bonus is calculated on base salary.

Notwithstanding the achievement of certain objectives in the course of 2016, the Committee agreed to the proposal put forward by the Executive Directors, that in view of the negative phase III allergy clinical trial results received in June 2016, and the consequent impact on the share price, not to award any bonus to the Executive Directors for 2016.

For completeness, the annual performance objectives previously agreed for 2016 are set out below together with the % achievement

Objective	Potential bonus			Achieved bonus			Commentary
	Steven Harris	Rod Hafner	Julien Cotta	Steven Harris	Rod Hafner	Julien Cotta	
<b>1 Cat SPIRE</b> File cat allergy product for approval in US and EU Prepare cat allergy product for launch	5%	15%	5%	0%	0%	0%	Phase III trial results missed primary endpoint.
<b>2 Seriveo®</b> Enable product filing in UK in 2017	5%	10%	5%	0%	0%	0%	Further formulation optimisation required; filing not possible in 2017.
<b>3 Sales</b> Sales target £23.6 million	15%	5%	15%	10%	3%	10%	2016 revenues £23.1 million
<b>4 Commercial</b> Agree and implement optimal commercial approach for EU and US including: – Grow US sales organisation – Grow German sales organisation, establish direct sales in UK and France and other markets as appropriate. – Establish manufacturing & supply networks for Seriveo® and cat SPIRE plus distribution for NIOX® and Nanopass device distribution.	5%	–	5%	5%	–	5%	US sales territories grown to 99  German organisation grown but sales team not expanded. UK sales organisation established. France and other markets focused on high performing local distributors.  Networks established or progressed as appropriate prior to negative cat allergy phase III results.
<b>5 Ragweed SPIRE</b> Complete ragweed allergy phase IIb study Initiate recruitment for ragweed SPIRE field study assuming positive results for phase IIb study	5%	5%	5%	5%	5%	5%	Phase IIb results announced in preliminary announcement on 11 March 2016.  Activity halted following cat SPIRE phase III results.
<b>6 Grass SPIRE</b> Initiate grass registration study	5%	15%	5%	5%	15%	5%	Grass study initiated. Study halted post cat SPIRE phase III results.
<b>7 New products</b> Initiate development of at least three further products.	5%	15%	5%	3%	10%	3%	Spiriva substitute® plus two COPD products added to pipeline; development activities on one programme initiated after target date.

## Remuneration committee report continued

Objective	Potential bonus			Achieved bonus			Commentary
	Steven Harris	Rod Hafner	Julien Cotta	Steven Harris	Rod Hafner	Julien Cotta	
8 <b>Acquisitions</b> Board approval to pursue at least three acquisition/licensing opportunities; target source and process weightings applied.	20%	10%	20%	12%	6%	12%	Multiple opportunities reviewed with Board approval to progress two issued.
9 Attract, recruit, retain and develop required workforce for timely and effective delivery of business objectives.	5%	5%	5%	5%	5%	5%	Recruitment of all open positions in 2016, with an in-house recruiter substantially reducing costs. Following cat SPIRE results re-assessed resource requirements and restructured quickly, reducing headcount in R&D.  Developed Learning and Development Programme to assess training needs.
10 <b>Quality</b> Establish systems required post cat SPIRE approval.	5%	5%	5%	0%	0%	0%	Activities halted following cat SPIRE phase III results.
11 <b>Compliance</b> Maintain and manage global system to ensure Group is fully compliant with all applicable laws	5%	5%	5%	3%	3%	3%	Key activities performed: (i) Compliance Committee established; (ii) global Code of Conduct implemented; (iii) transparency reporting for 2015 completed; (iv) key policies updated and web-based whistleblowing tool introduced; (v) compliance training delivered to commercial/medial affairs teams; (vi) monitoring and auditing performed in US; (vii) preparation of distributor Code of Conduct; (ix) EU/US data privacy shield adopted. Objective not complete due to process improvement requirements.
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>56%</b>	<b>52%</b>	<b>56%</b>	

Deferred share bonus awards are structured as conditional awards over shares which vest after three years. The level of deferral is linked to the achievement of the Company's shareholding guidelines as set out in the policy report. Where the guidelines have been met in full, 75% of bonuses are paid in cash and 25% in shares. Both Steven Harris and Rod Hafner have met their shareholding guidelines and therefore 75% of their 2015 bonus was paid in cash. Julien Cotta has not yet met the shareholding guidelines and so 50% of his 2015 bonus was paid in cash and 50% in shares. As no bonuses were awarded for 2016, no deferred share bonus awards have been made in respect of 2016.



### Long-term incentive plan (LTIP) awards made during the year

On 19 May 2016 the following awards under the Circassia Pharmaceuticals plc Performance Share Plan (the "PSP") were made to the Executive Directors.

Executive Director	Type of award	Basis of award granted	Share price at date of grant	Number of shares over which award was granted	% of shares granted that vest at threshold performance	Face value of shares over which award originally granted £'000	Vesting determined by performance over
Steven Harris	Nominal cost option	150% of salary of £397,500	£2.66	212,946	12.5%	£596	3 years from date of grant
Julien Cotta	Nominal cost option	125% of salary of £249,250	£2.66	111,272	12.5%	£312	3 years from date of grant
Rod Hafner	Nominal cost option	125% of salary of £270,375	£2.66	120,703	12.5%	£338	3 years from date of grant

The number of options in the 2016 PSP that ultimately vest will be determined according to the following performance criteria:

#### Criterion 1: Relative TSR

For options granted in 2016, up to 50% of the total award will vest subject to achievement of the performance criterion.

% vesting of the total award	Relative TSR ranking against the FTSE 250 Index (as at Relative TSR ranking against the FTSE 250 Index) (as at the date of grant) for a period of three years from the date of grant. <sup>1</sup>
0%	Below median
12.5%	Median and above
50%	Upper quartile

<sup>1</sup> In respect of criterion 1, vesting occurs on a straight line basis between the median and upper quartile points

#### Criterion 2: Strategic business objectives

For options granted in 2016, up to 50% of the total award will vest subject to achievement of the performance criterion.

The strategic business objectives referred to in criterion 2 are as follows. Percentages in brackets relate to the percentage of the total award:

- First filing of cat SPIRE by 2017 (12.5%);
- Establishment of country-specific sales and sales operations infrastructures including US sales force by end of 2017 (12.5%);
- File one additional product by end of 2018 (12.5%);
- Average sales growth for 2016 – 2018 greater than 20% per annum (12.5%).

# Remuneration committee report continued

## Long-term incentive plan (LTIP) awards made in previous years

The number of options in the 2014 PSP that ultimately vest will be determined according to the following performance criteria:

### Criterion 1: Relative TSR

For options granted in 2014, up to 70% of the total award will vest subject to achievement of the performance criterion.

% vesting of the total award	Relative TSR ranking against the FTSE 250 Index (as at the date of grant) for a period of three years from the date of grant. <sup>1</sup>
0%	Median and below
25%	Above median
70%	Upper quartile

<sup>1</sup> In respect of criterion 1, vesting occurs on a straight line basis between the median and upper quartile points

### Criterion 2: Clinical and strategic business objectives

For options granted in 2014, between 0% and 30% of the total award will vest subject to achievement of the performance criterion.

The clinical and strategic business objectives referred to in criterion 2 are as follows. Percentages in brackets relate to the percentage of the total award:

- Cat allergy phase III results (CP007) by 30 Sept 2016 (9%);
- Ragweed allergy – phase II results (TR006) by 31 December 2015 (3%);
- Ragweed allergy – regulatory and IRB approval for commencement of phase III study by 31 March 2016 (3%);
- HDM allergy – phase II study fully recruited by 31 March 2016 (6%);
- Grass allergy – end of phase II meeting by 31 December 2015 (3%);
- Regulatory and IRB approval for commencement of new clinical programme by 31 March 2017 (3%);
- Signed agreement for out-licensing deal/partnership for development and commercialisation by end 31 December 2016 (3%).

The number of options in the 2015 PSP that ultimately vest will be determined according to the following performance criteria:

### Criterion 1: Relative TSR

For options granted in 2015, up to 50% of the total award will vest subject to achievement of the performance criterion.

% vesting of the total award	Relative TSR ranking against the FTSE 250 Index (as at the date of grant) for a period of three years from the date of grant. <sup>1</sup>
0%	Median and below
25%	Above median
50%	Upper quartile

<sup>1</sup> In respect of criterion 1, vesting occurs on a straight line basis between the median and upper quartile points

### Criterion 2: Clinical and strategic business objectives

For options granted in 2015, up to 50% of the total award will vest subject to achievement of the performance criterion.

The clinical and strategic business objectives referred to in criterion 2 are as follows. Percentages in brackets relate to the percentage of the total award:

- First filing of cat SPIRE by 2017 (12.5%);
- Establishment of country-specific sales and sales operations infrastructures including US sales force by end of 2017 (12.5%);
- File one additional product by end of 2018 (12.5%);
- Average sales growth for 2016 – 2018 greater than 20% per annum (12.5%).

### Deferred bonus share awards made during the year

On 17 March 2016 the following awards under the Circassia Pharmaceuticals plc Deferred Share Bonus Plan (the DSBP) were made to the Executive Directors in respect of the deferred portion of their 2015 bonus. Awards will vest after three years, subject to continued service only.

Director	Type of award	Vesting date	Face value of shares over which award granted £'000's	Share price at date of grant	Number of shares over which award granted
Steven Harris	Conditional award	17 March 2019	97	£2.64	36,562
Julien Cotta	Conditional award	17 March 2019	121	£2.64	45,845
Rod Hafner	Conditional award	17 March 2019	66	£2.64	24,864

### Directors' pensions

For the financial year ended 31 December 2016 the Company contributed £137,568 to defined contribution money purchase pension schemes for the Directors. As was explained in the remuneration table, Executive Directors may also receive a supplementary cash payment in lieu of pension contributions where statutory limits have been exceeded. During the financial year ended 31 December 2016, a total of £59,625 (2015: £40,114) was paid to Steven Harris as supplementary cash due to him exceeding such a statutory limit. During the financial year ended 31 December 2016, a total of £30,417 (2015: £nil) was paid to Rod Hafner as supplementary cash due to him exceeding such a statutory limit.

### Statement of Directors' shareholding and share interests (audited information)

The Directors who have held office during the year ended 31 December 2016 and their interests (in respect of which transactions must be notified to the Company) in the share capital of the Company are shown in the following tables.

There was no change in the Directors' interests between 31 December 2016 and the date of this report.

Directors holding office at 31 December 2016 with LTIP awards and options outstanding over Ordinary shares of 0.08p were as follows:

## Remuneration committee report continued

Plan	Date of grant	Awards granted and options held as at 1 January 2016 <sup>1</sup>	Awards and options granted (exercised, lapsed, or cancelled) during year	Awards and options held at 31 December 2016 and at the date of this report
<b>Executive Directors</b>				
<b>S Harris</b>				
2007 EMI Scheme	2 August 2007	317,500	–	317,500
2007 EMI Scheme	15 August 2011	217,875	–	217,875
2014 PSP	12 March 2014	251,125	–	251,125
2015 PSP	26 February 2015	214,444	–	214,444
2016 PSP	19 May 2016	–	212,946	212,946
<b>Total</b>		<b>1,000,944</b>	<b>212,946</b>	<b>1,213,890</b>
<b>J Cotta</b>				
2013 Unapproved Scheme	22 October 2013	149,250	–	149,250
2014 PSP	12 March 2014	131,125	–	131,125
2015 PSP	26 February 2015	112,037	–	112,037
2016 PSP	19 May 2016	–	111,272	111,272
<b>2015 PSP</b>		<b>392,412</b>	<b>111,272</b>	<b>503,684</b>
<b>R Hafner</b>				
2014 PSP	12 March 2014	204,750	–	204,750
2015 PSP	26 February 2015	121,528	–	121,528
2016 PSP	19 May 2016	–	120,703	120,703
<b>Total</b>		<b>326,278</b>	<b>120,703</b>	<b>446,981</b>
<b>Non-Executive Directors</b>				
<b>T Corn</b>				
2007 Unapproved Scheme	23 February 2010	62,500	–	62,500
2007 Unapproved Scheme	15 August 2011	16,750	–	16,750
<b>Total</b>		<b>79,250</b>	<b>–</b>	<b>79,250</b>
<b>JJ Garaud</b>				
2007 Unapproved Scheme	12 November 2012	77,500	–	77,500

Vesting during year	Vested as at year end	Unvested as at year end	Exercise price (p)	Date from which first exercisable	Expiry date
–	317,500	–	0.08	2 August 2010	1 August 2017
–	217,875	–	0.08	18 March 2014	14 August 2021
–	–	251,125	nil	12 March 2017	11 March 2024
–	–	214,444	0.08	26 February 2018	25 February 2025
–	–	212,946	0.08	19 May 2019	18 May 2026
<b>–</b>	<b>535,375</b>	<b>678,515</b>			
149,250	149,250	–	242	22 October 2016	21 October 2023
–	–	131,125	nil	12 March 2017	11 March 2024
–	–	112,037	0.08	26 February 2018	25 February 2025
–	–	111,272	0.08	19 May 2019	18 May 2026
<b>149,250</b>	<b>149,250</b>	<b>354,434</b>			
–	–	204,750	nil	12 March 2017	11 March 2024
–	–	121,528	0.08	26 February 2018	25 February 2025
–	–	120,703	0.08	19 May 2019	18 May 2026
<b>–</b>	<b>–</b>	<b>446,981</b>			
–	62,500	–	0.08	23 February 2013	22 February 2020
–	16,750	–	0.08	15 August 2014	14 August 2021
<b>–</b>	<b>79,250</b>	<b>–</b>			
–	77,500	–	0.08	12 November 2015	11 November 2022



## Remuneration committee report continued

With regard to the PSP, the number of shares released to Directors at the end of the three year performance period is dependent upon satisfying the criteria relating to TSR and clinical and strategic milestones which are set out in the section of this report relating to the PSP.

DSBP awards will vest on the third anniversary of the date of grant, provided the Executive Director remains an officer or employee of the Group.

Executive Directors hold options under the Circassia Holdings Limited EMI Share Option Scheme 2007 (the "EMI Scheme"); the Circassia Holdings Limited Unapproved Share Option Scheme 2007 (the "2007 Unapproved Scheme"); and the Circassia Holdings Limited Unapproved Share Option Scheme 2013 (the "2013 Unapproved Scheme"). Historically, no performance conditions have been attached to the options granted under these schemes. The exercise price is equal to the market value of the Company's shares at the time the options are granted.

It was explained in the Corporate governance section of this report that the Group granted certain Non-Executive Directors share options in the past, when it was a private company. No further options have been granted since the IPO in 2014 and no awards will be made in the future.

Mr Paul Edick holds options under the 2007 Unapproved Scheme. Mr Edick retired from the Board on 18 May 2016. Mr Edick has been granted by the Board a 12 month period following retirement in which to exercise his options. This period ends on 18 May 2017.

### Gain on exercise of share options

No Directors exercised share options in the financial year ended 31 December 2016.

### Directors' interests in shares (including shares held as Restricted shares)

As was noted earlier in this report, the Company has implemented guidelines which require the Executive Directors and key senior employees to build up and maintain an interest in the Ordinary shares of the Company which is equal in value to their annual base salary. For the purpose of assessing compliance with these guidelines, the value of the shareholding is calculated using the higher of the share price on 31 December 2016 (94p) and the acquisition price of the shares. The value as a percentage of salary has been calculated using base salary as at 31 December 2016.

The following table shows the number of Ordinary shares beneficially owned by the Directors who served during the financial year which are not subject to any restrictions on transfer or to forfeiture.

	Shares beneficially owned as at 31 December 2016	Value of owned shares as a % of salary	Shareholding requirement met
<b>Executive Directors</b>			
S Harris	5,423,677	1283%	Yes
J Cotta	46,875	18%	No
R Hafner	900,544	313%	Yes
<b>Non-Executive Directors</b>			
F Granata	312,500	n/a	n/a
T Corn	62,500	n/a	n/a
C Petty	188,875	n/a	n/a
C Swingland	3,728,129	n/a	n/a

The following table shows the interests in Restricted shares of the Directors who served during the year. These are subject to restrictions on transfer or to forfeiture.

	Date of grant of Restricted shares	b/f as at 1 January 2016	Vesting	c/f as at 31 December 2016	Value of owned shares as a % of salary
<b>Executive Directors</b>					
S Harris	7 March 2013	125,000	(125,000)	–	–
J Cotta	7 March 2013 4 March 2014	12,500 9,375	(12,500)	– 9,375	– 4%
R Hafner	7 March 2013 4 March 2014	75,000 29,500	(75,000)	– 29,500	– 10%
<b>Non-Executive Directors</b>					
F Granata	1 September 2013	312,500	(312,500)	–	n/a
C Swingland	7 March 2013	75,000	(75,000)	–	n/a

No further restricted shares were awarded in the year.

Restricted shares have been subscribed for or purchased at a price of 10p per Ordinary share and, under the terms of their acquisition, are subject to certain restrictions on transfer and forfeiture. The restrictions lift on the earlier of a sale of the Company and the expiry of a vesting period of between two and three years (depending on the date of award of the Restricted shares). The Ordinary shares may be forfeited if the participant ceases to be employed or be an officer of the Company prior to the vesting of the shares other than by reason of: death; resignation; permanent incapacity; redundancy; retirement; non-renewal of a fixed term contract or consultancy.

Directors are not permitted to hold their shares in hedging arrangements or as collateral for loans without the express permission of the Board. None of the Directors currently holds or has held their shares in such an arrangement.

## Unaudited information

### Percentage increase in the remuneration of the CEO

	% change between 31 December 2015 and 31 December 2016
<b>CEO</b>	
Salary	3% increase
Benefits	nil
Bonus	100% decrease
<b>Average per employee</b>	
Salary	3% increase
Benefits	nil
Bonus	40% decrease

### Total shareholder return

The performance of the Company's Ordinary shares compared with the FTSE 250 (excluding Investment trusts) (the "Index") for the period from its IPO on 18 March 2014 up to 31 December 2016 is shown in the graph below:

The Company has chosen the Index as its benchmark of share price performance as it believes that this gives Shareholders a reasonable comparison with the total shareholder return of other equity investments in companies of a broadly similar size across all sectors. The TSR performance has been measured by JPMorgan Cazenove.

The mid-market price of an Ordinary share on 31 December 2016 was 94p. From 1 January 2016 to 31 December 2016 the share price ranged from a high of 323p to a low of 80p.

### Total shareholder return

18 March 2014 – 31 December 2016



# Remuneration committee report continued

## Total remuneration for the CEO over time

		2016	2015	2014
Total remuneration	(£'000)	2,817	2,359	1,528
Bonus awarded	(%)	Nil	100%	93%
LTIP vesting	(%)	n/a	n/a	100%

The table above shows the total remuneration of the Chief Executive Officer during the financial years in which the Company has been constituted as a public company. The total remuneration figure includes the annual bonus and LTIP awards which vested based on performance during those years. The annual bonus and PSP percentages show the amount paid out for each year as a percentage of the maximum.

## Relative importance of expenditure on pay

The table below shows the expenditure by the Company on remuneration paid to all employees of the Group and distributions to Shareholders for the financial period.

	2016 £m	2015 £m
Overall expenditure on pay	29.3	13.7
Dividend plus share buyback	Nil	Nil

## Application of remuneration policy to 2017 salary review

The Executive Directors' salaries were reviewed in January 2014 as part of the IPO process and were set at a level which the Committee regarded as broadly mid-market when compared with other companies of a similar size operating within the same sector. New Bridge Street provided advice to the Committee on this process. Further salary reviews have taken place on 9 February 2015, 10 February 2016, and 8 February 2017 and a 3% increase was applied effective 1 January 2015, 2016, and 2017 respectively. This increase is in line with the average salary increase awarded to UK employees.

	Salary as at 1 January 2017	Salary as at 1 January 2016	% Increase
Steven Harris	409,400	397,500	3
Julien Cotta	256,700	249,250	3
Rod Hafner	278,450	270,375	3

## Performance targets for 2017 bonus and PSP awards

For the financial year 2017, the annual bonus will continue to be based on corporate objectives analogous to those set out in the Remuneration Policy. The maximum bonus opportunity will be 100% of salary for Executive Directors in line with the ongoing remuneration policy.

The Committee has decided not to disclose the detailed nature of these performance targets as they comprise commercially sensitive information. Retrospective disclosure of the targets and performance against them will be made in the 2017 Remuneration Committee report.

The measures applicable to awards made under the Performance Share Plan will be as follows:

### Criterion 1: Relative TSR

For options granted in 2017, up to 50% of the total award will vest subject to achievement of the relative TSR performance criterion.

% vesting of the total award	Relative TSR ranking against the FTSE 250 Index (as at the date of grant) for a period of three years from the date of grant. <sup>1</sup>
0%	Below median
12.5%	Median and above
50%	Upper quartile

<sup>1</sup> In respect of criterion 1, vesting occurs on a straight line basis between the median and upper quartile points

### Criterion 2: Strategic business objectives

For options granted in 2017, up to 50% of the total award will vest subject to achievement of certain strategic business performance criteria.

Award levels for 2017 will be in accordance with the remuneration policy.

### Other remuneration components

Pension and benefits will be in line with the remuneration policy.

### Non-Executive Director remuneration

The fees for the Chairman and Non-Executive Directors have been increased by 3% effective 1 January 2017. This increase is in line with the average salary increase awarded to UK employees. The fees paid to the Non-Executive Directors in 2016 and the fees proposed to be paid in 2017 are set out below:

	From 1 January 2016 (£)	From 1 January 2017 (£)	Increase %
Chairman	134,400	138,400	3
Non-Executive Director	44,550	45,850	3
Senior Independent Non-Executive Director Fee	51,450	52,950	3
Remuneration and Audit Committee Chairmanship Fee	10,600	10,900	3
Nomination Committee Chair	7,950	8,150	3
Committee Memberships	5,300	5,450	3

### Shareholder voting at the Annual General Meeting on 18 May 2016

The Annual Report on Remuneration was approved by Shareholders at last year's AGM held on 18 May 2016 with the following votes cast for and against.

Voting results at 2016 AGM	For (%)	Against (%)	Withheld (votes)
To approve the Annual report on remuneration	80.47	19.53	107,401

### Shareholder voting at the Annual General Meeting on 16 May 2015

The Directors' remuneration policy report was approved by Shareholders at the AGM held on 16 May 2015 with the following votes cast for and against.

Voting results at 2015 AGM	For (%)	Against (%)	Withheld (votes)
To approve the Directors' remuneration policy report	99.57	0.43	1,901,524

A vote withheld is not a vote in law and is therefore not included in the percentages shown above.

### Approval

This report was approved by the Board on 25 April 2017

### Marvin Samson

Chairman of the Remuneration Committee

# Directors' report

## Directors' report

In accordance with the Companies Act 2006, the Directors present their report together with the financial statements and the Independent Auditors' report for the year ended 31 December 2016.

## Information included in Strategic Report

The Company's Strategic Report is on pages 02 to 41 and includes the following information that would otherwise be required to be disclosed in this Directors' report:

Subject matter	Page reference
Likely future developments in the business	22 to 28
Research and development	22 to 28
Employee involvement	34
Disclosures concerning greenhouse gas emissions	35

## Corporate governance statement

The information that fulfils the requirements of the Corporate Governance Statement can be found in the Corporate Governance Report on pages 44 to 45 and the Strategic Report on pages 36 to 41 (and is incorporated into this Directors' Report by reference), with the exception of the information referred to in DTR 7.2.6, which is located in this Directors' Report.

## Results and dividend

The results for the year and the financial position as at 31 December 2016 are shown in the Consolidated statement of comprehensive income and the Consolidated statement of financial position. The results of the Group are explained in more detail in the Financial review.

The Directors do not recommend the payment of a dividend for the year to 31 December 2016 (2015: £nil).

## Directors and Directors' interests

The Directors of the Company at the date of this report, together with their biographical details and dates of appointment are set out in the Corporate governance report and the Board of Directors section.

The named Directors served throughout the year and up to the date of this report with the exception of Paul Edick and Cathrin Petty who left the Board on 18 May 2016 and 16 December 2016 respectively.

The Board confirms that each of the Directors who served during the year has been formally appraised during this period with the exception of Paul Edick who left before the Board evaluation took place in December 2016. In accordance with the Code, all Directors of the Company will stand for re-election on an annual basis. At the 2017 Annual General Meeting, Dr Tim Corn and Charles Swingland will not stand for re-election.

Information on the Directors' remuneration and their interests in the share capital of the Company are set out in the Remuneration report. None of the Directors has a commercial interest in any material contract entered into by the Company.

As is permitted by sections 232 to 235 Companies Act 2006, and consistent with the Company's Articles of Association, the Company has maintained insurance cover for its Directors and Officers under a

Directors' and Officers' Liability Policy. Further, the Company has granted an indemnity to its Directors against liability which arises due to claims brought by third parties.

The Directors may exercise their powers pursuant to the Articles of Association, the Companies Act 2006 and related legislation, and any resolution of the Shareholders. The Articles are available for review at the registered office.

## Share capital and Shareholders

### Share capital

At 20 April 2017 the Company had a total of 141 Ordinary Shareholders and 332,244,588 Ordinary shares in issue.

There were no changes in the share capital of the Company during the year to 31 December 2016. The share capital of the Company increased by 47,355,417 Ordinary shares on 12 April 2017 as a result of the admission of shares issued pursuant to the collaboration with and securing of rights to Tudorza® and Duaklir® from AstraZeneca.

The Company has only one class of shares which carry no right to fixed Income. Each share carries the right to one vote at general meetings of the Company. There are no restrictions on voting rights or on the holding or transfer of these securities.

Details of employee share schemes are set out in note 25 to the financial statements. The Circassia Pharmaceuticals plc Employee Benefit Trust abstains from voting on the shares held by it. 156,035 shares were acquired by the Employee Benefit Trust during the year (2015: 110,845) and the balance of shares held at 31 December 2016 was therefore 266,880 (2015: 110,845).

Pursuant to the Articles of Association and vote of Shareholders at the AGM which took place on 18 May 2016 the Company was granted authority to allot shares for cash up to a maximum nominal amount of £22,791 on a non-pre-emptive basis. This nominal amount represents approximately 10% of the issued share capital of the Company as at 10 March 2016. No such allotments were made during the year to 31 December 2016 or up to the date of this report. At the General Meeting which took place on 3 April 2017 the Company was granted authority to allot shares in the Company up to an aggregate nominal amount of £49,925.74 pursuant to the issue of Consideration Shares to AstraZeneca as part of the collaboration and securing of rights relating to Tudorza® and Duaklir® although ultimately, under the terms of the collaboration shares with an aggregate nominal value of £37,868.33 were allotted.

### Lock up arrangements

There are currently no lock-up arrangements relating to the shares of the Company.

### Share price

From 1 January 2016 to 31 December 2016 the share price ranged from a high of 323p to a low of 80p. The average price for the period was 202p. The mid-market price of an Ordinary share on 31 December 2016 was 94p.

### Significant shareholdings

As at 20 April 2017 the Company had been notified of the following interests, held, directly or indirectly, in 3% or more of the Company's issued share capital.

	Number of shares	% of shares
The Bank of New York (Nominees) Limited	99,654,807	30.0%
Nortrust Nominees Limited	47,789,431	14.4%
AstraZeneca UK Limited	47,355,417	14.3%
State Street Nominees Limited	34,548,967	10.4%
PH Nominees Limited	26,693,711	8.0%
Chase Nominees Limited	23,185,617	7.0%
Chase (GA Group) Nominees Limited	13,534,518	4.1%



The Board confirms that, in accordance with LR 9.2.2AR(2)(a) Relationship Agreements were put in place on 12 March 2014 between the Company and Invesco Asset Management Limited, and the Company and Touchstone Innovations LLP and their affiliates.

Invesco holds more than 20% of the voting rights attached to the issued share capital of Touchstone Innovations and accordingly there is a presumption (which has not been rebutted) that Invesco and Touchstone Innovations are acting in concert in relation to their shareholdings in the Company. At the date of this report, Invesco and Touchstone Innovations together held 44.4% of the voting rights attached to the issued share capital of the Company.

#### [Invesco relationship agreement](#)

The principal purpose of the relationship agreement is to ensure that the Company will be capable of carrying on its business independently of Invesco for so long as Invesco, together with its concert parties, holds a controlling interest.

Pursuant to these agreements, and for so long as Invesco holds a controlling interest:

- The parties shall procure that all transactions and relationships between the Company and any other member of the Group and Invesco (or any of its associates) are conducted at arms-length and on normal commercial terms; and
- Invesco shall not (and shall procure that each of its associates shall not) take any action that would prevent the Company from complying with its obligations under the Listing Rules and shall not propose or procure the proposal of any Shareholder resolution which is intended to or appears to be intended to circumvent the proper application of the Listing Rules.

#### [Touchstone Innovations relationship agreement](#)

The principal purpose of the Relationship Agreement is to ensure that the Company will be capable of carrying on its business independently of Touchstone Innovations for so long as Touchstone Innovations with its concert parties, holds a controlling interest.

Pursuant to these agreements, and for so long as Touchstone Innovations together with Invesco holds a controlling interest:

- The parties shall procure that all transactions and relationships between the Company and any other member of the Group and Touchstone Innovations (or any of its associates) are conducted at arms-length and on normal commercial terms; and
- Touchstone Innovations shall not (and shall procure that each of its associates shall not) take any action that would prevent the Company from complying with its obligations under the Listing Rules and shall not propose or procure the proposal of any Shareholder resolution which is intended to or appears to be intended to circumvent the proper application of the Listing Rules.

The Board confirms that the Company has complied with the independence provisions under the relationship agreements referred to above and, that so far as it is aware, the controlling Shareholders have complied with the independence provisions and, so far as it is aware, the controlling Shareholders have complied with the procurement obligation.

### **Disclosures required under Listing Rule 9.8.4R**

The information that fulfils the reporting requirements relating to the following matters can be found on the pages identified.

<b>Subject matter</b>	<b>Page reference</b>
<b>Statement by the board on relationship agreements with controlling shareholders</b>	<b>77 (Directors' report)</b>

#### **Treasury management**

The Company's policy on the use of financial instruments and the management of financial risks is set out in note 2 to the financial statements.

#### **Going concern**

The accounts have been prepared on a going concern basis. The budget is prepared annually and the 10 year plan is updated annually. These are built from the bottom up and presented to the Board each year for review and approval. The Directors have reviewed the current and projected financial position of the Company, taking into account existing cash balances and available financial facilities. On the basis of this review, the Directors have not identified any material uncertainties to the Group's ability to continue to adopt the going concern basis of accounting for a period of at least 12 months from the date of approval of the financial statements.

#### **Employment and environment**

The Company's policies on health and safety, the environment, and employee-related matters are disclosed in the Strategic report. Greenhouse gas emissions have been calculated as carbon dioxide equivalents.

#### **Political and charitable donations**

There were no charitable or political donations in the year to 31 December 2016.

#### **Auditor**

Following a tender process which was conducted in Q4 2016 for 2017 onwards, PricewaterhouseCoopers LLP has been appointed as auditor and a resolution to appoint PwC will be put to the members at the forthcoming Annual General Meeting.

The Directors who held office at the date of approval of this report confirm that, so far as they are each aware, there is no relevant audit information of which the Company's Auditor is unaware, and each Director has taken all the steps a Director ought to have taken to make themselves aware of relevant audit information and to establish that the Auditor is aware of that information.

#### **Annual General Meeting**

The Annual General Meeting will be held at the offices of Circassia Pharmaceuticals plc on 26 May 2017 at 9:30 a.m. Details of the business to be transacted at the forthcoming AGM will be given in a separate circular to Shareholders.

By order of the Board

**Julien Cotta**  
Company Secretary

25 April 2017

# Statement of Directors' responsibilities

## In respect of the Annual report and accounts and financial statements for the year ended 31 December 2016

The Directors are responsible for preparing the Annual report and the financial statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare Group and parent Company financial statements for each financial year. Under that law they are required to prepare the Group financial statements in accordance with IFRSs as adopted by the EU and applicable law and have elected to prepare the parent company financial statements on the same basis.

Under company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and parent Company and of their profit or loss for that period. In preparing each of the Group and parent financial statements the Directors are required to:

- properly select and consistently apply accounting policies;
- make prudent and reasonable accounting estimates and judgements;
- state whether they have been prepared in accordance with IFRSs as adopted by the EU; and
- make an assessment of the Company's ability to continue as a going concern.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company and enable them to ensure that the financial statements and Directors Remuneration Report comply with the Companies Act 2006 and, as regards the Group financial statements, Article 4 of the IAS Regulation. They are also responsible for safeguarding the assets of the Group and for taking reasonable steps to prevent and detect fraud and other irregularities.

The Directors are responsible for the maintenance and integrity of the corporate and financial information included on the website. Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

## Directors' responsibility statement

We confirm that to the best of our knowledge:

- the financial statements, prepared in accordance with IFRS as adopted by the EU give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and the undertakings included in the consolidation taken as a whole;
- the Strategic report includes a fair review of the development and performance of the business and the position of the Company and the undertakings included in the consolidation taken as a whole, together with a description of the principal risks and uncertainties which they face; and
- the Annual report and the financial statements, taken as a whole, are fair, balanced and understandable and provide the information necessary for Shareholders to assess the Group's position, performance, business model and strategy.

The Directors' report, including those sections of the Annual report which are referred to in it, has been approved by the Board and is signed on its behalf by:

**Julien Cotta**  
Director

25 April 2017

# Independent Auditors' report to the members of Circassia Pharmaceuticals plc

## Report on the financial statements

### Our opinion

#### In our opinion:

- Circassia Pharmaceuticals Plc's group financial statements and parent company financial statements (the "financial statements") give a true and fair view of the state of the group's and of the parent company's affairs as at 31 December 2016 and of the group's loss and the group's and the parent company's cash flows for the year then ended;
- the group financial statements have been properly prepared in accordance with International Financial Reporting Standards ("IFRSs") as adopted by the European Union;
- the parent company financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006 and, as regards the group financial statements, Article 4 of the IAS Regulation.

### What we have audited

The financial statements, included within the Annual report and accounts (the "Annual Report"), comprise:

- the Consolidated and parent company statements of financial position as at 31 December 2016;
- the Consolidated statement of comprehensive income for the year then ended;
- the Consolidated and parent company statement of cash flows for the year then ended;
- the Consolidated and parent company statements of changes in equity for the year then ended; and
- the notes to the financial statements, which include a summary of significant accounting policies and other explanatory information.

The financial reporting framework that has been applied in the preparation of the financial statements is IFRSs as adopted by the European Union and, as regards the parent company financial statements, as applied in accordance with the provisions of the Companies Act 2006, and applicable law.

## Our audit approach

### Overview

- Overall group materiality: £3.25 million which represents 5% of loss before tax and exceptional items
- Impact of CatSPIRE results on the carrying value of assets and recording costs
- Impairment of goodwill and intangibles

### The scope of our audit and our areas of focus

We conducted our audit in accordance with International Standards on Auditing (UK and Ireland) ("ISAs (UK & Ireland)").

We designed our audit by determining materiality and assessing the risks of material misstatement in the financial statements. In particular, we looked at where the directors made subjective judgements, for example in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits we also addressed the risk of management override of internal controls, including evaluating whether there was evidence of bias by the directors that represented a risk of material misstatement due to fraud.

The risks of material misstatement that had the greatest effect on our audit, including the allocation of our resources and effort, are identified as "areas of focus" in the table below. We have also set out how we tailored our audit to address these specific areas in order to provide an opinion on the financial statements as a whole, and any comments we make on the results of our procedures should be read in this context. This is not a complete list of all risks identified by our audit.

# Independent Auditors' report to the members of Circassia Pharmaceuticals plc continued

Area of focus	How our audit addressed the area of focus
<p><b>Impact of CatSPIRE results on the carrying value of assets and recording costs</b></p> <p>We have focused on this area, as the results of the cat allergy clinical trials have resulted in changes to the Group's strategy, with potential implications for the carrying value of certain assets (particularly goodwill and intangible assets) and the recording of certain costs (including, potentially, costs in relation to onerous R&amp;D contracts, onerous leases, redundancies and share-based payments).</p> <p>Goodwill and intangible assets in the Allergy cash generating unit (totalling £74.5m and £0.3m respectively) have been fully impaired.</p> <p>Refer to page 49 (Audit Committee Report), page 90 (Critical accounting estimates and judgements), and page 99 in the notes.</p>	<p>We considered the impact of the clinical trial results and management's future plans for the Group's allergy programmes on the carrying value of the goodwill and intangible assets in the Allergy cash generating unit. We concurred that management's decision to fully impair these balances was appropriate.</p> <p>We reviewed management's assessment of contractual R&amp;D obligations relating to the allergy programme. We reviewed management's calculations of commitments and agreed these back to supporting contracts or invoices.</p> <p>We obtained management's calculations in relation to onerous leases at two premises which are not now expected to be utilised following the Group's change in strategy. We tested the mathematical accuracy of the provisions recorded and considered the reasonableness of the judgements made, e.g. in relation to assumed sub-let income.</p> <p>We reviewed the Group's redundancy plans and assessed whether the related costs were recorded in the same period as the relevant communications to employees.</p> <p>For those share schemes with conditions relating to the Cat-SPIRE programme, we considered whether the number of shares expected to vest (and therefore the share-based payment charge) had been appropriately adjusted to reflect the outcome of the clinical trial.</p> <p>No material exceptions arose from our testing.</p>
<p><b>Impairment of goodwill and intangibles</b></p> <p>IAS 36 requires at least annual impairment assessments in relation to goodwill, indefinite-lived intangible assets and intangible assets that are not yet ready for use, with more regular assessment should an impairment trigger be identified. The results of the Cat-SPIRE clinical trial were considered an impairment trigger in relation to the Allergy cash-generating unit (CGU), resulting in full impairment of goodwill and intangible assets relating to this CGU (see above).</p> <p>Goodwill of £84.2m and intangible assets of £167.1m in relation to the NIOX and Respiratory CGU's are significant balances, and judgement is required in the impairment assessment, specifically in forecasting the future results of both marketed and in-development products. Judgement is also required in determining the discount rates to be applied to future cash flows. Management have utilised a model based on fair value less costs of disposal in relation to the NIOX CGU and a value-in-use model for the Respiratory CGU.</p> <p>Refer to page 49 (Audit Committee Report), page 90 (Critical accounting estimates and judgements), and pages 101–103 in the notes.</p>	<p>We obtained management's impairment analyses and gained an understanding of the key assumptions and judgements underlying the assessment. We assessed the appropriateness of the methodology applied and tested the mathematical accuracy of the models.</p> <p>We assessed the key assumptions, including:</p> <p>Future revenue streams: We compared forecast revenues to the Group's business plan, obtained an understanding of the stage of product development and management's expected timelines for product launches, including updates on the achievement of expected milestones. We specifically considered the reasonableness of:</p> <ul style="list-style-type: none"> <li>(i) revenue growth rates in respect of NIOX (taking into account latest forecasts and historical growth rates); and</li> <li>(ii) forecasts for sales of new products, including assessing projected peak sales of in-development Respiratory products.</li> </ul> <p>Expenses and overheads: We reviewed historical forecasting accuracy and assessed the appropriateness of key assumptions, including in relation to the future sales force utilisation.</p> <p>Discount rate: We used experts to recalculate management's discount rates and benchmark the rates against companies of a similar nature.</p> <p>We found the assumptions utilised to be supportable.</p> <p>We also obtained management's sensitivity analysis and performed our own sensitivities (reflecting what we believed to be a range of reasonably possible alternative outcomes) over the forecasted cash flows and discount rates, the results of which did not indicate an impairment to goodwill.</p>

### How we tailored the audit scope

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole, taking into account the geographic structure of the group, the accounting processes and controls, and the industry in which the group operates.

### Materiality

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and on the financial statements as a whole.

Based on our professional judgement, we determined materiality for the financial statements as a whole as follows:

<b>Overall group materiality</b>	£3.25 million (2015: £0.7m).
<b>How we determined it</b> <b>Rationale for benchmark applied</b>	5% of loss before tax and exceptional items.  Profit/loss before tax is often used as a benchmark for calculating the materiality of a profit-orientated business, and, since the Group is now generating revenue, we consider that the profit/loss before tax benchmark is now appropriate for Circassia. For the prior year audit, we used a benchmark of 1% of total expenses, as we considered that users were previously focused on expenditure as a key metric, in the absence of recurring revenues.
<b>Component materiality</b>	For each component in our audit scope, we allocated a materiality that is less than our overall group materiality. The range of materiality allocated across components was For each component in our audit scope, we allocated a materiality that is less than our overall group materiality. The range of materiality allocated across components was between £0.74m and £3.0m. Certain components were audited to a local statutory audit materiality that was also less than our overall Group materiality. Certain components were audited to a local statutory audit materiality that was also less than our overall group materiality.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above £162,000 (2015: £36,000) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

### Going concern

Under the Listing Rules we are required to review the directors' statement, set out on page 77, in relation to going concern. We have nothing to report having performed our review.

Under ISAs (UK & Ireland) we are required to report to you if we have anything material to add or to draw attention to in relation to the directors' statement about whether they considered it appropriate to adopt the going concern basis in preparing the financial statements. We have nothing material to add or to draw attention to.

As noted in the directors' statement, the directors have concluded that it is appropriate to adopt the going concern basis in preparing the financial statements. The going concern basis presumes that the group and parent company have adequate resources to remain in operation, and that the directors intend them to do so, for at least one year from the date the financial statements were signed. As part of our audit we have concluded that the directors' use of the going concern basis is appropriate. However, because not all future events or conditions can be predicted, these statements are not a guarantee as to the group's and parent company's ability to continue as a going concern.



# Independent Auditors' report to the members of Circassia Pharmaceuticals plc continued

## Other required reporting

### Consistency of other information and compliance with applicable requirements

#### Companies Act 2006 reporting

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the Strategic Report and the Directors' Report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the Strategic Report and the Directors' Report have been prepared in accordance with applicable legal requirements.

In addition, in light of the knowledge and understanding of the group, the parent company and their environment obtained in the course of the audit, we are required to report if we have identified any material misstatements in the Strategic Report and the Directors' Report. We have nothing to report in this respect.

#### ISAs (UK & Ireland) reporting

Under ISAs (UK & Ireland) we are required to report to you if, in our opinion:	
information in the Annual Report is: — materially inconsistent with the information in the audited financial statements; or — apparently materially incorrect based on, or materially inconsistent with, our knowledge of the group and parent company acquired in the course of performing our audit; or — otherwise misleading.	We have no exceptions to report.
the statement given by the directors on page 76, in accordance with provision C.1.1 of the UK Corporate Governance Code (the "Code"), that they consider the Annual Report taken as a whole to be fair, balanced and understandable and provides the information necessary for members to assess the group's and parent company's position and performance, business model and strategy is materially inconsistent with our knowledge of the group and parent company acquired in the course of performing our audit.	We have no exceptions to report.
the section of the Annual Report on page 45, as required by provision C.3.8 of the Code, describing the work of the Audit Committee does not appropriately address matters communicated by us to the Audit Committee.	We have no exceptions to report.

## The directors' assessment of the prospects of the group and of the principal risks that would threaten the solvency or liquidity of the group

Under ISAs (UK & Ireland) we are required to report to you if we have anything material to add or to draw attention to in relation to:	
the directors' confirmation on page 48 of the Annual Report, in accordance with provision C.2.1 of the Code, that they have carried out a robust assessment of the principal risks facing the group, including those that would threaten its business model, future performance, solvency or liquidity.	We have nothing material to add or to draw attention to.
the disclosures in the Annual Report that describe those risks and explain how they are being managed or mitigated.	We have nothing material to add or to draw attention to.
the directors' explanation on page 41 of the Annual Report, in accordance with provision C.2.2 of the Code, as to how they have assessed the prospects of the group, over what period they have done so and why they consider that period to be appropriate, and their statement as to whether they have a reasonable expectation that the group will be able to continue in operation and meet its liabilities as they fall due over the period of their assessment, including any related disclosures drawing attention to any necessary qualifications or assumptions.	We have nothing material to add or to draw attention to.
Under the Listing Rules we are required to review the directors' statement that they have carried out a robust assessment of the principal risks facing the group and the directors' statement in relation to the longer-term viability of the group. Our review was substantially less in scope than an audit and only consisted of making inquiries and considering the directors' process supporting their statements; checking that the statements are in alignment with the relevant provisions of the Code; and considering whether the statements are consistent with the knowledge acquired by us in the course of performing our audit. We have nothing to report having performed our review.	

### **Adequacy of accounting records and information and explanations received**

Under the Companies Act 2006 we are required to report to you if, in our opinion:

- we have not received all the information and explanations we require for our audit; or
- adequate accounting records have not been kept by the parent company, or returns adequate for our audit have not been received from branches not visited by us; or
- the parent company financial statements and the part of the Directors' Remuneration Report to be audited are not in agreement with the accounting records and returns.

We have no exceptions to report arising from this responsibility.

### **Directors' remuneration**

#### **Directors' remuneration report - Companies Act 2006 opinion**

In our opinion, the part of the Directors' Remuneration Report to be audited has been properly prepared in accordance with the Companies Act 2006.

#### **Other Companies Act 2006 reporting**

Under the Companies Act 2006 we are required to report to you if, in our opinion, certain disclosures of directors' remuneration specified by law are not made. We have no exceptions to report arising from this responsibility.

### **Corporate governance statement**

Under the Listing Rules we are required to review the part of the Corporate Governance Statement relating to ten further provisions of the Code. We have nothing to report having performed our review.

### **Responsibilities for the financial statements and the audit Our responsibilities and those of the directors**

As explained more fully in the Statement of Directors' Responsibilities set out on page 78, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

Our responsibility is to audit and express an opinion on the financial statements in accordance with applicable law and ISAs (UK & Ireland). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

This report, including the opinions, has been prepared for and only for the parent company's members as a body in accordance with Chapter 3 of Part 16 of the Companies Act 2006 and for no other purpose. We do not, in giving these opinions, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

### **What an audit of financial statements involves**

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of:

- whether the accounting policies are appropriate to the group's and the parent company's circumstances and have been consistently applied and adequately disclosed;
- the reasonableness of significant accounting estimates made by the directors; and
- the overall presentation of the financial statements.

We primarily focus our work in these areas by assessing the directors' judgements against available evidence, forming our own judgements, and evaluating the disclosures in the financial statements.

We test and examine information, using sampling and other auditing techniques, to the extent we consider necessary to provide a reasonable basis for us to draw conclusions. We obtain audit evidence through testing the effectiveness of controls, substantive procedures or a combination of both.

In addition, we read all the financial and non-financial information in the Annual Report to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report. With respect to the Strategic Report and Directors' Report, we consider whether those reports include the disclosures required by applicable legal requirements.

**Simon Ormiston (Senior Statutory Auditor)**  
for and on behalf of PricewaterhouseCoopers LLP  
Chartered Accountants and Statutory Auditors  
Cambridge

25 April 2017

# Consolidated statement of comprehensive income for the year ended 31 December 2016

				2016	2015
	Notes	Underlying operations £m	Non-underlying items (note 10) £m	Total £m	Total £m
Revenue	4	23.1	–	23.1	10.8
Cost of sales		(8.0)	–	(8.0)	(4.3)
<b>Gross profit</b>		<b>15.1</b>	<b>–</b>	<b>15.1</b>	<b>6.5</b>
Research and development costs		(42.3)	(3.9)	(46.2)	(46.8)
Sales and marketing		(28.9)	(75.8)	(104.7)	(13.5)
Administrative expenses		(15.4)	(0.3)	(15.7)	(13.7)
Other gains	9	–	–	–	1.1
<b>Operating loss</b>	7	<b>(71.5)</b>	<b>(80.0)</b>	<b>(151.5)</b>	<b>(66.4)</b>
Finance costs	6	(0.1)	–	(0.1)	–
Finance income	6	6.1	–	6.1	3.5
Share of profit of joint venture	17	0.6	–	0.6	0.1
<b>Loss before tax</b>		<b>(64.9)</b>	<b>(80.0)</b>	<b>(144.9)</b>	<b>(62.8)</b>
Taxation	11	7.5	–	7.5	12.8
<b>Loss for the financial year</b>		<b>(57.4)</b>	<b>(80.0)</b>	<b>(137.4)</b>	<b>(50.0)</b>
Loss attributable to:					
Owners of Circassia Pharmaceuticals plc		(57.3)	(80.0)	(137.3)	(49.9)
Non-controlling interests		(0.1)	–	(0.1)	(0.1)
<b>Loss for the financial year</b>		<b>(57.4)</b>	<b>(80.0)</b>	<b>(137.4)</b>	<b>(50.0)</b>
Items that may be subsequently reclassified to profit or loss					
Share of other comprehensive income of joint venture	17	0.1	–	0.1	–
Currency translation differences	28	9.8	(0.1)	9.7	3.1
<b>Total other comprehensive income/(expense) for the year</b>		<b>9.9</b>	<b>(0.1)</b>	<b>9.8</b>	<b>3.1</b>
<b>Total comprehensive expense for the year</b>		<b>(47.5)</b>	<b>(80.1)</b>	<b>(127.6)</b>	<b>(46.9)</b>
<b>Total comprehensive expense attributable to:</b>					
Owners of Circassia Pharmaceuticals plc		(47.4)	(80.1)	(127.5)	(46.8)
Non-controlling interests		(0.1)	–	(0.1)	(0.1)
<b>Total comprehensive expense for the year</b>		<b>(47.5)</b>	<b>(80.1)</b>	<b>(127.6)</b>	<b>(46.9)</b>

## Loss per share attributable to owners of the parent during the year (expressed in £ per share)

		£	£
<b>Basic and diluted loss per share</b>			
Loss per share from continuing operations	12	(0.48)	(0.20)

The results for the financial years above are derived entirely from continuing operations.

The Company has elected to take the exemption under section 408 of the Companies Act 2006 not to present the parent company profit and loss account.

The profit for the parent company for the year was £2.4 million (2015: loss £3.2 million).

The notes on pages 90 to 114 are an integral part of these consolidated financial statements.

# Consolidated statement of financial position as at 31 December 2016

	Notes	2016 £m	2015 £m
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	13	1.4	1.3
Goodwill	14	9.7	81.2
Intangible assets	15	167.1	165.6
Deferred tax assets	23	16.6	17.2
Investment in joint venture	17	0.9	0.2
		<b>195.7</b>	265.5
<b>Current assets</b>			
Inventories	18	4.6	3.0
Trade and other receivables	19	7.7	5.1
Current tax assets	11	8.7	11.8
Short-term bank deposits	20	20.0	37.8
Cash and cash equivalents	20	97.4	166.0
		<b>138.4</b>	223.7
<b>Total assets</b>		<b>334.1</b>	489.2
<b>Equity and liabilities</b>			
Ordinary shares	24	0.2	0.2
Share premium	26	563.8	564.0
Other reserves	28	12.5	2.8
Accumulated losses	27	(295.8)	(158.5)
		<b>280.7</b>	408.5
<b>Non-controlling interests</b>		–	1.2
<b>Total equity</b>		<b>280.7</b>	409.7
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Deferred tax liabilities	23	31.9	31.2
		<b>31.9</b>	31.2
<b>Current liabilities</b>			
Trade and other payables	21	21.5	48.3
		<b>21.5</b>	48.3
<b>Total liabilities</b>		<b>53.4</b>	79.5
<b>Total equity and liabilities</b>		<b>334.1</b>	489.2

The notes on pages 90 to 114 are an integral part of these consolidated financial statements.

The financial statements on pages 84 to 114 were authorised for issue by the Board of Directors on 25 April 2017 and were signed on its behalf by

**Steven Harris**  
Chief Executive Officer  
Circassia Pharmaceuticals plc

**Julien Cotta**  
Chief Financial Officer  
Circassia Pharmaceuticals plc

Registered number: 05822706

# Parent Company statement of financial position as at 31 December 2016

	Notes	2016 £m	2015 £m
<b>Assets</b>			
<b>Non-current assets</b>			
Investments in subsidiaries	16	262.0	242.6
		<b>262.0</b>	242.6
<b>Current assets</b>			
Trade and other receivables	19	220.9	185.0
Short-term bank deposits	20	20.0	37.8
Cash and cash equivalents	20	73.0	130.7
		<b>313.9</b>	353.5
<b>Total assets</b>		<b>575.9</b>	596.1
<b>Equity and liabilities</b>			
<b>Equity attributable to the owners of the Company</b>			
Ordinary shares	24	0.2	0.2
Share premium	26	563.8	564.0
Other reserves	28	6.1	3.7
Retained earnings/(accumulated losses)	27	0.4	(2.0)
<b>Total equity</b>		<b>570.5</b>	565.9
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	21	5.4	30.2
		<b>5.4</b>	30.2
<b>Total equity and liabilities</b>		<b>575.9</b>	596.1

The notes on pages 90 to 114 are an integral part of these financial statements.

The financial statements on pages 84 to 114 were authorised for issue by the Board of Directors on 25 April 2017 and were signed on its behalf by

**Steven Harris**

Chief Executive Officer

Circassia Pharmaceuticals plc

**Julien Cotta**

Chief Financial Officer

Circassia Pharmaceuticals plc

Registered number: 05822706



# Consolidated and parent Company statement of cash flows for the year ended 31 December 2016

	Notes	Group		Company	
		2016 £m	2015 £m	2016 £m	2015 £m
<b>Cash flows from operating activities</b>					
Cash used in operations	29	(68.4)	(64.9)	1.9	(5.8)
Cash (used in)/generated from operations		(0.1)	–	(0.1)	–
Tax credit received		11.8	9.1	–	–
Net cash (used in)/generated from operating activities		(56.7)	(55.8)	1.8	(5.8)
<b>Cash flows from investing activities</b>					
Acquisition of subsidiaries, net of cash acquired		(0.2)	(161.9)	(19.0)	(206.8)
Purchases of property, plant and equipment	13	(0.7)	(0.2)	–	–
Contingent consideration payment	21	(30.0)	–	(30.0)	–
Purchases of intangible assets	15	–	(0.1)	–	–
Interest received		0.7	3.0	0.7	2.9
Receipt on maturity of forward contract		–	1.1	–	–
Repayment of borrowings		–	(28.1)	–	–
Loans granted to subsidiary undertakings		–	–	(29.0)	(63.5)
Decrease in short-term bank deposits		17.8	119.1	17.8	119.1
Net cash used in investing activities		(12.4)	(67.1)	(59.5)	(148.3)
<b>Cash flows from financing activities</b>					
Proceeds from issue of ordinary shares	24	–	266.1	–	266.1
Purchase of treasury shares	33	(0.4)	(0.3)	–	–
Transactions with non-controlling interests	28	(3.2)	(7.2)	–	–
Net cash (used in)/generated from financing activities		(3.6)	258.6	–	266.1
<b>Net (decrease)/increase in cash and cash equivalents</b>					
Cash and cash equivalents at 1 January	20	166.0	29.7	130.7	18.8
Exchange gains/(losses) on cash and cash equivalents		4.1	0.6	–	(0.1)
<b>Cash and cash equivalents at 31 December</b>	20	<b>97.4</b>	<b>166.0</b>	<b>73.0</b>	<b>130.7</b>

The notes on pages 90 to 114 are an integral part of these consolidated financial statements.

# Consolidated statement of changes in equity for the year ended 31 December 2016

	Notes	Share capital £m	Share premium £m	Other <sup>1</sup> reserves £m	Accumulated losses £m	Total £m	Non- controlling interests £m	Total equity £m
At 1 January 2015	24, 26, 27, 28	0.2	297.9	1.3	(108.6)	190.8	–	190.8
Loss for the financial year		–	–	–	(49.9)	(49.9)	(0.1)	(50.0)
Other comprehensive income								
Currency translation differences	28	–	–	3.1	–	3.1	–	3.1
Total comprehensive expense	27, 28	–	–	3.1	(49.9)	(46.8)	(0.1)	(46.9)
Transactions with owners:								
Issue of ordinary shares	24	–	266.1	–	–	266.1	–	266.1
Purchase of own shares	28	–	–	(0.3)	–	(0.3)	–	(0.3)
Employee share option scheme	28	–	–	2.7	–	2.7	–	2.7
Non-controlling interests on acquisition of subsidiary	28	–	–	–	–	–	4.5	4.5
Transactions with non-controlling interests	28	–	–	(4.0)	–	(4.0)	(3.2)	(7.2)
<b>At 31 December 2015</b>	24, 26, 27, 28	<b>0.2</b>	<b>564.0</b>	<b>2.8</b>	<b>(158.5)</b>	<b>408.5</b>	<b>1.2</b>	<b>409.7</b>
<b>At 1 January 2016</b>	24, 26, 27, 28	<b>0.2</b>	<b>564.0</b>	<b>2.8</b>	<b>(158.5)</b>	<b>408.5</b>	<b>1.2</b>	<b>409.7</b>
Loss for the financial year		–	–	–	(137.3)	(137.3)	(0.1)	(137.4)
Other comprehensive income								
Share of other comprehensive income of joint venture		–	–	0.1	–	0.1	–	0.1
Currency translation differences	28	–	–	9.7	–	9.7	–	9.7
Total comprehensive expense	27, 28	–	–	9.8	(137.3)	(127.5)	(0.1)	(127.6)
Transactions with owners:								
Purchase of own shares	28	–	–	(0.4)	–	(0.4)	–	(0.4)
Employee share option scheme	28	–	–	2.4	–	2.4	–	2.4
Expenses offset against share premium	26	–	(0.2)	–	–	(0.2)	–	(0.2)
Transactions with non-controlling interests	28	–	–	(2.1)	–	(2.1)	(1.1)	(3.2)
<b>At 31 December 2016</b>	24, 26, 27, 28	<b>0.2</b>	<b>563.8</b>	<b>12.5</b>	<b>(295.8)</b>	<b>280.7</b>	<b>–</b>	<b>280.7</b>

<sup>1</sup> Other reserves include share option reserve, translation reserve, treasury shares reserve, and transactions with NCI reserve.

The notes on pages 90 to 114 are an integral part of these consolidated financial statements.

## Parent Company statement of changes in equity for the year ended 31 December 2016

	Notes	Share capital £m	Share premium £m	Share option reserve £m	Retained earnings/ (Accumulated losses) £m	Total equity £m
<b>At 1 January 2015</b>	24, 26, 27, 28	0.2	297.9	1.3	1.2	300.6
Loss and total comprehensive expense	27	–	–	–	(3.2)	(3.2)
Transactions with owners:						
Issue of ordinary shares	24	–	266.1	–	–	266.1
Employee share option scheme	28	–	–	2.4	–	2.4
<b>At 31 December 2015</b>	24, 26, 27, 28	<b>0.2</b>	<b>564.0</b>	<b>3.7</b>	<b>(2.0)</b>	<b>565.9</b>
<b>At 1 January 2016</b>	24, 26, 27, 28	0.2	564.0	3.7	(2.0)	565.9
Profit and total comprehensive income	27	–	–	–	2.4	2.4
Transactions with owners:						
Expenses offset against share premium	26	–	(0.2)	–	–	(0.2)
Employee share option scheme	28	–	–	2.4	–	2.4
<b>At 31 December 2016</b>	24, 26, 27, 28	<b>0.2</b>	<b>563.8</b>	<b>6.1</b>	<b>0.4</b>	<b>570.5</b>

The notes on pages 90 to 114 are an integral part of these financial statements.

# Notes to the financial statements

## 1. Summary of significant accounting policies

### General information

The Group is a specialty pharmaceutical group focused on the development and commercialisation of a range of asthma and respiratory products.

Circassia Pharmaceuticals plc is a public limited company which is listed on the London Stock Exchange and incorporated and domiciled in England and Wales. The Company is resident in England and the registered office is The Magdalen Centre, Robert Robinson Avenue, Oxford Science Park, Oxford, Oxfordshire, England, OX4 4GA.

The principal accounting policies adopted in the preparation of this financial information are set out below. These policies have been consistently applied to all the financial years presented, unless otherwise stated.

### Basis of preparation

The financial information has been prepared in accordance with International Financial Reporting Standards as adopted by the European Union ('IFRS'), IFRS Interpretations Committee ('IFRS IC') interpretations endorsed by the European Union and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS. The financial statements have been prepared using the historical cost convention modified by the revaluation of certain items, as stated in the accounting policies, and on a going concern basis.

### Going concern

Though the Group continues to make losses, the Directors have reviewed the current and projected financial position of the Group, taking into account existing cash balances. On the basis of this review, the Directors have not identified any material uncertainties to the Group's ability to continue to adopt the going concern basis of accounting for a period of at least 12 months from the date of approval of the financial statements.

### Changes in accounting policy and disclosures

- a) The following new standards and amendments to standards were mandatory for the first time for the financial year beginning 1 January 2016 but had no significant impact on the Group:
  - Annual improvements to IFRS 2012–2014 cycle;
  - Accounting for acquisition of interests in joint operations – amendments to IFRS 11;
  - Clarification of acceptable methods of depreciation and amortisation – amendments to IAS 16 and IAS 38;
  - Equity method in separate financial statements – amendments to IAS 27;
  - Disclosure initiative – amendments to IAS 1; and
  - Investment entities: applying the consolidation exception – amendments to IFRS 10, IFRS 12 and IAS 28.
- b) Standards, amendments and interpretations to existing standards that are not yet effective (and in some cases, had not yet been adopted by the EU) and have not been early adopted by the Group:

IFRS 9 'Financial instruments', on 'Classification and measurement' (effective 1 January 2018). This is the first part of a new standard on classification and measurement of financial assets that will replace IAS 39. IFRS 9 has two measurement categories: amortised cost and fair value. All equity instruments are measured at fair value.

A debt instrument is at amortised cost only if the entity is holding it to collect contractual cash flows and the cash flows represent principal and interest. Otherwise it is at fair value through profit or loss. Amortised cost accounting will also be applicable for most financial liabilities, with bifurcation of embedded derivatives.

The main change is that in cases where the fair value option is taken for financial liabilities, the part of a fair value change due to an entity's own credit risk is recorded in other comprehensive income rather than the income statement, unless this creates an accounting mismatch. The Group is yet to assess the impact of IFRS 9 on its financial information. The Group will also consider the impact of the remaining phases of IFRS 9.

IFRS 15 'Revenue from contract with customers' (effective 1 January 2018) supersedes current revenue recognition guidance including IAS 18 'Revenue' and specifies how and when entities recognise revenue as well as requiring such entities to provide users of financial statements with more informative, relevant disclosures. The standard provides a single, principles based five-step model to be applied to all contracts with customers. The impact on the Group's financial statements is currently being assessed.

IFRS 16 'Leases' (effective 1 January 2019) removes the current distinction between an operating and finance lease, introducing consistent requirements for all leases similar to the current finance lease accounting. The impact on the Group's financial statements is currently being assessed and it is anticipated that the standard will be adopted in the Group's financial statements in line with the effective date stated above.

There are no other IFRSs or IFRIC interpretations that are not yet effective that would be expected to have a material impact on the Group.

### Use of estimates and assumptions

The preparation of financial information in conformity with IFRS requires the use of certain critical accounting estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial information and the reported amounts of revenues and expenses during the reporting period. Estimates and judgements are continually made and are based on historic experience and other factors, including expectations of future events that are believed to be reasonable in the circumstances.

#### Critical accounting estimates and assumptions

Where the Group makes estimates and assumptions concerning the future, the resulting accounting estimates will seldom exactly match actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are addressed below.

#### Fair value of acquired assets

##### Intangibles – Technology

In estimating the fair value of Technology, a variation of the Income Approach called the Relief from Royalty Method is used. This methodology is considered the standard and preferred technique to value assets such as trademark, core technology and patents.

##### Intangibles – Customer Relationships and IPR&D

The Customer Relationships and IPR&D have been valued based on the Excess Earnings Method. This valuation method is based on discounting the cash flows that can be attributed to the intangible asset, after taking into account the contribution of other assets.

#### Deferred tax

Deferred tax assets have been recognised in relation to tax losses carried forward in Aerocrine and Prosonix, but only to the extent of deferred tax liabilities arising in the same jurisdictions as the brought forward losses. Management have concluded that it is not yet probable that taxable profits will be available in the relevant jurisdictions to utilise brought forward losses in excess of deferred tax liabilities. Judgement is required in making this determination. Management anticipate that taxable profits will be considered probable for the purposes of recognising deferred tax assets under IAS 12 only when there is a stable history of profitability in those tax jurisdictions.

### Share issue costs

In June 2015 the Group completed an offer and placement of new shares to finance the acquisitions of Aerocrine and Prosonix. Under IFRS incremental costs that are directly attributable to an equity transaction that otherwise would have been avoided had the equity instruments not been issued are accounted for through equity. Any acquisition related costs (for example due diligence) must be expensed in the income statement. There is a level of judgement in determining which costs meet the criteria of an equity transaction.

### Goodwill and other intangible assets

Goodwill and other intangible assets impairment reviews are undertaken annually or more frequently if events or changes in circumstances indicate a potential impairment. Judgements and estimates are made in respect of the carrying value of the cash generating units (CGU) containing the goodwill taking into account key assumptions (see note 14) about the product candidates. If the Group is unable to obtain regulatory approval or to commercialise its product candidates, or experiences significant delays in doing so, this could result in an impairment of the related goodwill and intellectual property rights.

### Share based payments

Options were valued using the Black Scholes option pricing model or the Monte Carlo Simulation depending on the type of option issued. For each relevant option grant, individual valuation assumptions were assessed based upon conditions at the date of grant. The range of assumptions in the calculation of share based payments is given in note 25.

### Non-underlying items

The Group presents certain items of income and expense as non-underlying in the Consolidated Statement of Comprehensive Income. The determination that an item should be presented as non-underlying is a judgement of the management. The management considers whether providing separate disclosure is helpful in understanding the underlying performance of the business, based on the nature and size of the items and infrequency of the events giving rise to them.

### Business combinations

The Group accounts for all business combinations under the acquisition method. Under the acquisition method, the identifiable assets acquired and liabilities and contingent liabilities assumed are measured at their fair value at the acquisition date. Judgements are made in determining the basis on which goodwill arising on business combinations is allocated to CGUs. Estimates are made in relation to the cash flow forecasts, probability factors and discount rates used for this purpose.

## Consolidation

### Subsidiaries

Subsidiaries are all entities (including structured entities) over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases. Inter-company transactions, balances and unrealised gains on transactions between Group companies are eliminated. Accounting policies of subsidiaries are consistent with the policies adopted by the Group.

### Joint arrangements

The Group applies IFRS 11 to all joint arrangements. Under IFRS 11 investments in joint arrangements are classified as either joint operations or joint ventures depending on the contractual rights and obligations of each investor. Circassia Pharmaceuticals plc has assessed the nature of its joint arrangements and determined them to be joint ventures. Joint ventures are accounted for using the equity method.

Under the equity method of accounting, interests in joint ventures are initially recognised at cost and adjusted thereafter to recognise the Group's share of the post-acquisition profits or losses and movements in other comprehensive income. When the Group's share of losses in a joint venture equals or exceeds its interests in the joint ventures (which includes any long-term interests that, in substance, form part of the Group's net investment in the joint ventures), the Group does not recognise further losses, unless it has incurred obligations or made payments on behalf of the joint ventures.

Unrealised gains on transactions between the Group and its joint ventures are eliminated to the extent of the Group's interest in the joint ventures. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred. Accounting policies of the joint ventures have been changed where necessary to ensure consistency with the policies adopted by the Group.

### Segmental reporting

The Group had three business segments during 2016, Allergy, Respiratory and NIOX®. This is consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance, has been identified as the Executive Directors, who make strategic decisions.

### Clinical study expenses

Where payments to clinical study sites are made in advance for the purchase of stocks of materials for use in clinical studies, the relevant costs are included in receivables as prepaid clinical study expenses. Expenses are charged to the income statement as clinical study services are carried out by third party suppliers, or clinical study materials are received.

### Financial instruments

The Group's financial instruments comprise cash and cash equivalents, short-term bank deposits, receivables and payables arising directly from operations.

Cash and cash equivalents comprise cash in hand and short-term deposits which have an original maturity of three months or less and are readily convertible into known amounts of cash. Such assets are classified as current, where management intend to dispose of the asset within 12 months of the end of the reporting period. Bank deposits with maturity of more than 12 months after the end of the reporting period are classified as non-current assets.

Where derivatives exist in the financial year, they are initially recognised at fair value on the date a derivative contract is entered into and are subsequently re-measured at their fair value at each reporting date, with any resulting gain or loss recognised through profit or loss.

The Group does not have any committed borrowing facilities, as its cash, cash equivalents and short-term deposits are sufficient to finance its current operations. Cash balances are mainly held on short- and medium-term deposits with quality financial institutions, in line with the Group's policy to minimise the risk of loss. The main risks associated with the Group's financial instruments relate to interest rate risk and foreign currency risk (note 2).



# Notes to the financial statements continued

## Leases

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases (net of any incentives received from the lessor) are charged to the income statement on a straight line basis over the period of the lease.

## Goodwill and Intangible assets

Intangible fixed assets, relating to goodwill, customer relationships, technology and intellectual property rights acquired through licensing or assigning patents and know-how are carried at historic cost, less accumulated amortisation, where the useful economic life of the asset is finite and the asset will probably generate economic benefits exceeding costs.

Amortisation is calculated using the straight line method to allocate the cost of intangible assets over their estimated useful lives, as follows:

Intangible asset	Estimated useful lives
IPR&D	5 – 10 years
Customer Relationships	18 years
Technology	15 – 20 years
Software	5 years

Goodwill arising on the acquisition of subsidiaries represents the excess of the consideration transferred, the amount of any non-controlling interests in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the identifiable net assets acquired.

For the purpose of impairment testing, goodwill acquired in a business combination is allocated to each of the CGUs, or groups of CGUs, that are expected to benefit from the synergies of the combination. Each unit or group of units to which the goodwill is allocated represents the lowest level within the entity at which the goodwill is monitored for internal management purposes. Goodwill is monitored at the operating segment level.

Goodwill impairment reviews are undertaken annually or more frequently if events or changes in circumstances indicate a potential impairment. The carrying value of the CGU containing the goodwill is compared to the recoverable amount, which is the higher of value in use and the fair value less costs of disposal. Any impairment is recognised immediately as an expense and is not subsequently reversed.

Where an acquired intangible asset is not yet available for use in the manner intended by management, the asset is tested annually for impairment by allocating the assets to the CGUs to which they relate. Amortisation would commence when product candidates underpinned by the intellectual property rights become available for commercial use. Amortisation would be calculated on a straight line basis over the shorter of the remaining useful life of the intellectual property or the estimated sales life of the product candidates.

Expenditure on product development is capitalised as an intangible asset and amortised over the expected useful economic life of the product candidate concerned. Capitalisation commences from the point at which technical feasibility and commercial viability of the product candidate can be demonstrated and the Group is satisfied that it is probable that future economic benefits will result from the product candidate once completed. Capitalisation ceases when the product candidate receives regulatory approval for launch. No such costs have been capitalised to date.

Expenditure on research and development activities that do not meet the above criteria, including ongoing costs associated with acquired intellectual property rights and intellectual property rights generated internally by the Group, is charged to the income statement as incurred. Intellectual property and in-process research and development from acquisitions are recognised as intangible assets at fair value. Any residual excess of consideration over the fair value of net assets in an acquisition is recognised as goodwill in the financial statements.

## Computer Software

Expenditure on software costs are capitalised as an intangible asset and amortised over the expected useful economic life of the software. Until such an asset is fully developed, the costs are capitalised and classified within intangibles assets as 'Software in development'. These costs are not amortised until the software has been fully developed and operational, at which point the total cost of the software development is amortised over its estimated useful life.

## Investments

Investments in subsidiary companies are recognised and carried at cost less any identified impairment losses at the end of each reporting period. Investments are impaired where there is objective evidence that the estimated future cash flows of the investment have been affected.

## Inventories

Inventories are valued at the lower of the acquisition cost and the net realisable value. The FIFO (first in, first out) principle is used to calculate the value of inventories. Inventories mainly comprise products for sale and stocks of components for the service activities in Sweden and the US. The acquisition value comprises all expenses for purchases. The net realisable value is the expected sale price less expected costs for preparation and selling.

## Impairment of non-financial assets

Assets that have an indefinite useful life, for example goodwill or intangible assets not ready for use, are not subject to amortisation and are tested annually for impairment. Assets that are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Non-financial assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at each reporting date. Charges or credits for impairment are passed through the income statement.

## Property, plant and equipment

Property, plant and equipment is stated at historical cost less depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items. Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of replaced parts is derecognised. All other repairs and maintenance are charged to the income statement during the financial period in which they are incurred.

Depreciation is calculated using the straight line method to allocate the cost of assets over their estimated useful lives, as follows:

Property, plant and equipment	Depreciation rate
	Over the life of the unbreakable
Leasehold improvements	portion of the lease
Plant and equipment	10% – 33%
Fixtures and fittings	20%

Individually significant tangible assets that are intended to be held by the Group for use in the production or supply of goods and services or for administrative purposes and that are expected to provide economic benefit for more than one year are capitalised. All other assets of insignificant value are charged to the income statement in the year of acquisition.

Costs incurred relating to an asset that is not yet complete are capitalised and held as Assets under construction until they are brought into use. The asset is then transferred to the appropriate asset class and depreciated in line with the policy above.

#### Trade and other receivables

Trade receivables are carried at original invoice amount less any provisions for doubtful debts. Provisions are made where there is evidence of a risk of non-payment, taking into account ageing, previous experience and general economic conditions. When a trade receivable is determined to be uncollectable, it is written off, firstly against any provision available and then to the income statement. Subsequent recoveries of amounts previously provided for are credited to the income statement. Other receivables are recognised initially at fair value and subsequently measured at amortised cost, using the effective interest method, less provision for impairment. A provision for impairment of other receivables is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of the receivables.

#### Trade payables

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. They are initially recognised at fair value and subsequently held at amortised cost. Accounts payable are classified as current liabilities if payment is due within one year or less. If not, they are presented as non-current liabilities.

#### Provisions

Provisions are recognised when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. If the amounts involved are significant, provisions are determined by discounting the expected future cash flows at a pre-tax rate which reflects the current market assessment of the time value of money and, when appropriate, the risks specific to the liability.

Where a leasehold property substantially ceases to be used for the Group's business, or a commitment is entered into which would cause this to occur, provision is made to the extent that the recoverable amount of the interest in the property is expected to be insufficient to cover the future obligations relating to the lease.

A charge for restructuring costs is taken to the income statement when the Group has approved a detailed and formal restructuring plan, and the restructuring has either commenced or the Group has a constructive obligation, for example having made an announcement publicly to the employee or the Group as a whole.

#### Cash and cash equivalents

In the consolidated statement of cash flows, cash and cash equivalents include cash in hand, deposits held on call with banks, and other short-term highly liquid investments with original maturities of three months or less from the date of original investment.

#### Share capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

#### Employee benefit costs

The Group makes contributions to defined contribution personal pension schemes for its Directors and employees. The pension cost charge recognised in the year represents amounts payable by the Group to the funds. The Group has no further payment obligations once the contributions have been paid. The contributions are recognised as employee benefit expense when they are due.

#### Share based payments

The Group operates a number of equity-settled, share based compensation plans, under which the entity receives services from employees as consideration for equity instruments (options) of the Group. The fair value of the employee services received in exchange for the grant of the options is recognised as an expense. The total amount to be expensed is determined by reference to the fair value of the options granted:

- including the effect of any market performance conditions (for example, an entity's share price);
- excluding the impact of any service and non-market performance vesting conditions (for example, profitability, sales growth targets and remaining an employee of the entity over a specified time period); and
- including the impact of any non-vesting conditions (for example, the requirement for employees to save).

Non-market performance and service conditions are included in assumptions about the number of options that are expected to vest. The total expense is recognised over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied.

The grant by the Company of options over its equity instruments to the employees of subsidiary undertakings in the Group is treated as a capital contribution. The fair value of employee services received, measured by reference to the grant date fair value, is recognised over the vesting period as an increase to investment in subsidiary undertakings, with a corresponding credit to equity in the parent entity financial statements.

The Group's employees participate in various share option schemes as disclosed in note 25. Equity settled share based payments are measured at fair value at the date of grant and expensed on a straight line basis over the vesting period of the award. At the end of each reporting period the Group revises its estimate of the number of options that are expected to become exercisable. The financial consequences of revisions to the original estimates, if any, are recognised in the income statement, with a corresponding adjustment to equity.

The fair value of share options is measured using either the Black Scholes option pricing model or the Monte Carlo Simulation. This is dependent on the conditions attached to each of the issued options. Where conditions are non-market based the Black Scholes option pricing model is used. Where market based conditions are attached to options, the fair value is determined using the Monte Carlo Simulation.

# Notes to the financial statements continued

## Other employee benefits

The expected cost of compensated short-term absence (e.g. holidays) is recognised when employees render services that increase their entitlement. An accrual is made for holidays earned but not taken, and prepayments recognised for holidays taken in excess of days earned.

## Revenue

Revenue comprises the fair value of consideration received or receivable for the sale of goods and services in the ordinary course of the Group's activities. Revenue is shown net of value added tax and trade discounts and after elimination of intra-Group sales. Income is reported as follows:

### Sale of goods

The Group sells medical technology equipment that enables inflammation of the airways to be measured as well as consumable items and spare parts. Sales are reported as income when the significant risks and benefits have transferred to the buyer and the seller no longer has any significant control over the goods. The Group provides 12 month guarantees for certain products and includes a provision for estimated future claims.

### Licence income

Technology and product licensing revenue represents amounts earned for licences granted under licensing agreements, including up-front payments, milestone payments and technology access fees. Revenues are recognised when this income becomes non-refundable under the terms of the licence and where the Group's obligations related to the revenues have been completed. Refundable licensing revenue is treated as deferred until such time that it is no longer refundable. In general, up-front payments are deferred and amortised in line with the period of development. Milestone payments relating to defined project achievements are recognised as income when the milestone is accomplished.

Royalty revenue is recognised on an accrued basis and represents income earned as a percentage of product sales in accordance with the relevant agreement net of any amounts contractually payable to others under the terms of the relevant royalty agreement.

## Foreign currency translation

Monetary assets and liabilities in foreign currencies are translated into Sterling at the rates of exchange ruling at the end of the financial year. Transactions in foreign currencies are translated into Sterling at the rates of exchange ruling at the date of the transaction. Foreign exchange differences are taken to the income statement in the year in which they arise and presented within 'Finance costs or income'.

Foreign exchange differences on translation of foreign operations into the Group presentational currency, are recognised as a separate element of other comprehensive income. Cumulative exchange differences are presented in a separate component of equity entitled Translation reserve.

## Taxation including deferred tax

The charge for current tax is based on the results for the year, adjusted for items which are non-assessable or disallowed. It is calculated using tax rates that have been enacted or substantively enacted at the end of each reporting period.

The Group is entitled to claim tax credits in the United Kingdom for certain research and development expenditure. The amount included in the financial statements at the year end represents the credit receivable by the Group for the year and adjustments to prior years.

Deferred tax is accounted for using the liability method in respect of temporary differences arising from differences between the carrying amount of assets and liabilities in the financial information and the corresponding tax bases used in the computation of taxable profit. In principle, deferred tax liabilities are recognised for all taxable temporary differences and deferred tax assets are recognised to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilised.

Deferred tax liabilities are recognised for taxable temporary differences arising on investments in subsidiaries and joint ventures, except where the Group is able to control the reversal of the temporary difference and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred tax is calculated at the average tax rates that are expected to apply to the period when the asset is realised or the liability is settled. Deferred tax is charged or credited in the statement of comprehensive income, except when it relates to items credited or charged directly to equity, in which case the deferred tax is also dealt with in equity.

## 2. Financial and capital risk management

### Capital risk management

The Group's objectives when managing capital are to safeguard the ability to continue as a going concern and ensure that sufficient capital is in place to fund the Group's activities. The Group's principal method of adjusting the capital available has been through issuing new shares. During 2015, the Company issued 95,469,537 Ordinary shares which funded the acquisitions of Aerocrine and Prosonix. The shares were offered at 288.05p each, raising gross proceeds of £275.0 million. The Group's capital is comprised of share capital and share premium, which are disclosed in notes 24 and 26 respectively. The Group monitors the availability of capital with regard to its forecast future expenditure on an ongoing basis.

### Transaction and translation risk

Foreign exchange fluctuations may adversely affect the Group's results and financial condition. The Group prepares its financial statements in pounds sterling, but a significant proportion of its expenditure and subsidiary results are in various currencies including US dollars, Swedish krona and Euros. The Group does not currently hedge against translation risk.

### Financial risk factors

The Group's simple structure and the lack of external debt financing reduces the range of financial risks to which it is exposed. Monitoring of financial risk is part of the Board's ongoing risk management, the effectiveness of which is reviewed annually. The Group's agreed policies are implemented by the Chief Executive Officer, who submits periodic reports to the Board.

### Foreign exchange risk

The majority of operating costs are denominated in Sterling, United States dollars, Euro or Swedish krona. Foreign exchange risk arises from future commercial transactions and recognised assets and liabilities. The nature or level of risk that the Group is exposed to has changed during 2016 as a result of the UK referendum decision to leave the European Union. It is considered that it is too early to quantify the exact impact for the Group and the Directors will keep the situation under review and act to mitigate any increased risks accordingly.

In relation to foreign currency risk, the Group's policy is to hold the majority of its funds in Sterling, and to use short-medium-term currency purchase options (including spot purchases and forward contracts) and interest-bearing foreign currency deposits to manage short-medium-term fluctuations in exchange rates.

The change in foreign exchange rates that is assessed to be reasonably likely for each currency in 2016 is 15% (2015: 5%).

At 31 December 2016, if the Euro had weakened/strengthened by 15% against Sterling with all other variables held constant, the post tax loss for the year would have been £1.6 million (2015: £0.5 million) lower/higher, as a result of net foreign exchange gains/losses on translation of Euro-denominated payables, receivables and foreign exchange losses/gains on translation of Euro-denominated bank balances.

The impact on post tax loss at 31 December 2016 of a 15% weakening/strengthening of the US dollar against Sterling with all other variables held constant would have been a decrease/increase of £0.6 million (2015: £1.3 million).

The impact on post tax loss at 31 December 2016 of a 15% weakening/strengthening of the Swedish krona against Sterling with all other variables held constant would have been a decrease/increase of £0.3 million (2015: £1.1 million).

The Group is also exposed to currency translation risk in respect of the foreign currency denominated assets and liabilities of its overseas subsidiaries. At present, the Group does not consider this to be a significant risk since the Group does not intend to move assets between Group companies.

#### Interest rate risk

The Group's policy in relation to interest rate risk is to monitor short- and medium-term interest rates and to place cash on deposit for periods that optimise the amount of interest earned while maintaining access to sufficient funds to meet day to day cash requirements.

The Group does not have any committed external borrowing facilities, as its cash and cash equivalents and short-term deposit balances are sufficient to finance its current operations. Consequently, there is no material exposure to interest rate risk in respect of interest payable.

If interest rates had been 10 basis points higher/lower the impact on net loss in 2016 would have been an increase/decrease of £0.1 million (2015: £0.2 million) due to changes in the amount of interest receivable.

#### Credit risk

The Group's policy following Admission to the London Stock Exchange is to place funds with financial institutions which have a minimum credit rating with Fitch IBCA of A- long-term/F1 short-term. During 2016 the Group placed funds on deposit with 7 banks (2015: 10 banks). The Group does not allocate a quota to individual institutions but seeks to diversify its investments, where this is consistent with achieving competitive rates of return. It is the Group's policy to place not more than £35 million (or the equivalent in other currencies) with any one counterparty.

The value of financial instruments held represents the maximum exposure that the Group has to them. There is no collateral held for this type of credit risk.

No credit limits were exceeded during any of the periods reported, and management does not expect any material losses from non-performance by these counterparties.

#### Cash flow and liquidity risk

Funds are generally placed on deposit with the maturity profile of investments being structured to ensure that sufficient liquid funds are available to meet operating requirements. The Directors do not consider that there is presently a material cash flow or liquidity risk.

The table below analyses the Group's financial liabilities into relevant maturity groupings based on the remaining period at the balance sheet date to the contractual maturity date. There were no financial liabilities outstanding for periods greater than one year. The amounts disclosed in the table are the contracted undiscounted cash flows:

At 31 December	Less than 1 year 2016 £m	Less than 1 year 2015 £m
Trade and other payables	21.5	48.3
<b>Total</b>	<b>21.5</b>	<b>48.3</b>

#### Derivative financial instruments and hedging

There were no derivatives at 31 December 2016 or 31 December 2015.

#### 3. Operating segments

The chief operating decision-maker (the Executive Directors) is responsible for making key operating decisions in the Group. Assessment of performance and decisions regarding the allocation of resources are made by operating segment. The 2016 operating segments are identified within the Group by product portfolios:

- Allergy: relates to a range of immunotherapy development products.
- NIOX® relates to the portfolio of products used to improve asthma diagnosis and management by measuring fractional exhaled nitric oxide (FeNO) and
- Respiratory relates to the portfolio of asthma and chronic obstructive pulmonary disease product candidates.

The table below presents information regarding the Group's operating segments for the years ended 31 December 2016 and 2015. During 2016 the Aerocrine and Prosonix businesses acquired in June 2015 have been further integrated into the Group resulting in consolidation of some operations (mainly support functions). Hence some costs are now shared between the segments and are not allocated to individual segments for decision making purposes.

# Notes to the financial statements continued

## Segment operating loss

	Allergy £m	NIOX® £m	Respiratory £m	Unallocated £m	Total £m
<b>Year ended 31 December 2016</b>					
<b>Revenue (from external customers by country, based on the destination of the customer)</b>					
US	–	7.8	–	–	7.8
EU	–	7.8	–	–	7.8
Other countries	–	7.5	–	–	7.5
<b>Total segment revenue</b>	<b>–</b>	<b>23.1</b>	<b>–</b>	<b>–</b>	<b>23.1</b>
Research and development	(25.4)	(7.7)	(6.8)	(4.3)	(44.2)
Sales and marketing	–	(28.3)	–	–	(28.3)
Administrative expenses	–	(4.2)	–	(9.8)	(14.0)
Depreciation, amortisation and impairment <sup>1</sup>	(74.8)	(4.4)	(0.4)	(0.5)	(80.1)
Other	–	(8.0)	–	–	(8.0)
<b>Operating loss</b>	<b>(100.2)</b>	<b>(29.5)</b>	<b>(7.2)</b>	<b>(14.6)</b>	<b>(151.5)</b>
<b>Year ended 31 December 2015</b>					
<b>Revenue (from external customers by country, based on the destination of the customer)</b>					
US	–	3.6	0.3	–	3.9
EU	–	3.9	0.2	–	4.1
Other countries	–	2.8	–	–	2.8
<b>Total segment revenue</b>	<b>–</b>	<b>10.3</b>	<b>0.5</b>	<b>–</b>	<b>10.8</b>
Research and development	(37.3)	(2.0)	(5.5)	–	(44.8)
Sales and marketing	(5.2)	(7.5)	–	–	(12.7)
Administrative expenses	(10.6)	(2.2)	(0.9)	–	(13.7)
Depreciation and amortisation <sup>1</sup>	(0.1)	(2.2)	(0.6)	–	(2.9)
Other	1.1	(4.1)	(0.1)	–	(3.1)
<b>Operating loss</b>	<b>(52.1)</b>	<b>(7.7)</b>	<b>(6.6)</b>	<b>–</b>	<b>(66.4)</b>

<sup>1</sup> Depreciation, amortisation and impairment is included on the face of the statement of comprehensive income within 'Research and development costs', 'Sales and marketing' and 'Administrative expenses'

## Assets by segment

	Allergy £m	NIOX® £m	Respiratory £m	Unallocated £m	Total £m
<b>As at 31 December 2016</b>					
Cash, cash equivalents and short-term deposits	–	7.3	3.5	106.6	117.4
Property, plant and equipment	–	–	–	1.4	1.4
Goodwill	–	5.3	4.4	–	9.7
Intangible assets	–	59.5	107.6	–	167.1
Deferred tax assets	–	–	–	16.6	16.6
Investment in joint venture	–	–	–	0.9	0.9
Inventories	–	–	–	4.6	4.6
Trade and other receivables	–	–	–	7.7	7.7
Current tax assets	–	–	–	8.7	8.7
<b>Total assets</b>	<b>–</b>	<b>72.1</b>	<b>115.5</b>	<b>146.5</b>	<b>334.1</b>
<b>As at 31 December 2015</b>					
Cash, cash equivalents and short-term deposits	200.4	0.4	3.0	–	203.8
Property, plant and equipment	–	–	–	1.3	1.3
Goodwill	72.1	4.7	4.4	–	81.2
Intangible assets	0.4	57.7	107.5	–	165.6
Deferred tax assets	–	–	–	17.2	17.2
Investment in joint venture	–	–	–	0.2	0.2
Inventories	–	–	–	3.0	3.0
Trade and other receivables	–	–	–	5.1	5.1
Current tax assets	–	–	–	11.8	11.8
<b>Total assets</b>	<b>272.9</b>	<b>62.8</b>	<b>114.9</b>	<b>38.6</b>	<b>489.2</b>



Following the cat allergy immunotherapy phase III study results in 2016, the Allergy portfolio value has been fully written down resulting in the goodwill impairment charge of £74.5 million. In addition, related licences and patents have been fully impaired resulting in £0.3 million impairment charge to Allergy intangible assets.

#### 4. Revenue

The Group derives the following types of revenue:

	2016 £m	2015 £m
Sale of goods	23.0	10.3
Licence and milestone revenue	0.1	0.5
<b>Total revenue</b>	<b>23.1</b>	<b>10.8</b>

#### 5. Employees and directors

The average monthly number of persons (including Executive Directors) employed by the Group during the year was:

By activity	2016 Number	2015 Number
Office and management	46	49
Sales and marketing	138	67
Research and development	107	88
<b>Total average headcount</b>	<b>291</b>	<b>204</b>

The average number of administration staff employed by the Company during the year, including Executive Directors, was 2 (2015: 2). For 2015 medical affairs staff was reclassified from sales and marketing to research and development to align reporting with 2016.

	Group		Company	
	2016 £m	2015 £m	2016 £m	2015 £m
<b>Employee benefit costs</b>				
Wages and salaries	28.1	13.2	1.1	1.5
Social security costs	2.8	2.2	0.2	0.1
Other pension costs	1.2	0.5	0.1	0.1
Share options expense	2.4	2.7	–	–
<b>Total employee benefit costs</b>	<b>34.5</b>	<b>18.6</b>	<b>1.4</b>	<b>1.7</b>

The Group contributes to defined contribution pension schemes for its Executive Directors and employees. Contributions of £101,236 (included in other payables) were payable to the funds at the year end (2015: £52,979).

The details of Directors of the Group who received emoluments from the Group during the year are shown in the Annual report on remuneration in the Remuneration Committee report.

#### Key management personnel

Key management personnel during the year included Directors (Executive and Non-executive), the Chief Commercial Officer, the General Counsel, VP of Human Resources and the Chief Business Officer. The compensation paid or payable to key management is set out below.

	2016 £m	2015 £m
Short-term employee benefits (including bonus)	2.3	3.4
Post-employment benefits	0.2	0.2
Share based payment	1.5	1.1
<b>Total</b>	<b>4.0</b>	<b>4.7</b>

# Notes to the financial statements continued

## 6. Finance income and costs

	2016 £m	2015 £m
<b>Finance costs:</b>		
Bank charges and interest payable	(0.1)	–
<b>Total finance costs</b>	<b>(0.1)</b>	<b>–</b>
<b>Finance income:</b>		
Bank interest receivable	0.9	1.7
Net gain on foreign exchange	5.2	1.8
<b>Total finance income</b>	<b>6.1</b>	<b>3.5</b>

## 7. Operating expenses

Operating loss is stated after charging the following:

	2016 £m	2015 £m
Employee benefit costs (note 5)	34.5	18.6
Externally contracted research & development	27.6	36.4
Legal and professional fees including patent costs	5.1	6.8
Depreciation <sup>1</sup>	0.7	0.5
Amortisation <sup>1</sup>	4.6	2.4
Impairment of goodwill and other intangible assets	74.8	–
Operating lease	1.6	0.8

<sup>1</sup> Depreciation and amortisation is included on the face of the statement of comprehensive income within 'Research and development costs' and 'Sales and marketing'

## 8. Auditors' remuneration

### Services provided by the Group's auditors and their associates

During the year the Group obtained services from the auditors as detailed below:

	2016 £m	2015 £m
Fees payable to the Group's auditors and their associates for the audit of the parent company and consolidated financial statements	0.2	0.2
Fees payable to the Group's auditors and their associates for other services:		
The audit of the Company's subsidiaries	0.1	0.1
Other assurance services <sup>1</sup>	0.3	0.2
<b>Total</b>	<b>0.6</b>	<b>0.5</b>

<sup>1</sup> Other assurance services in 2016 mainly relate to due diligence services performed on perspective acquisitions. In 2015 the costs related to services performed in respect of the acquisition of Aerocrine and Prosonix. 2015 costs were offset against the share premium reserve.

## 9. Other gains

	2016 £m	2015 £m
Forward contract foreign exchange gain	–	1.1

## 10. Non-underlying items

Non-underlying items charged to loss for the year comprise significant non-recurring items. Management considers that providing separate disclosure of such items is helpful in understanding the underlying performance of the business.

The following non-underlying items have been recognised in the income statement for the year:

	2016 £m	2015 £m
<b>Charged to research and development costs</b>		
Onerous contract costs	2.4	–
Restructuring costs	1.2	–
Intangible assets impairment	0.3	–
	<b>3.9</b>	–
<b>Charged to sales and marketing costs</b>		
Restructuring costs	1.3	–
Goodwill impairment	74.5	–
	<b>75.8</b>	–
<b>Charged to administrative expenses</b>		
Restructuring costs	0.3	–
	<b>0.3</b>	–
<b>Total</b>	<b>80.0</b>	–

### Onerous contract costs

Following the negative result from the cat allergy phase III study, management has reassessed R&D expenditure in line with the updated strategy resulting in termination of some trial batch manufacturing contracts.

### Restructuring costs

Restructuring costs comprise cost optimisation initiatives including severance payments, compensation for loss of office, property and other contract termination costs.

### Goodwill and other intangible assets impairment

Impairments totalling £74.8 million (2015: £nil) were recognised in the year following the negative result from the cat allergy phase III study. Further disclosures are given in notes 14 and 15.

## 11. Taxation

The Group is entitled to claim tax credits in the United Kingdom for certain research and development expenditure. The amount included in the financial statements for the years ended 31 December 2016 and 2015 represents the credit receivable by the Group for the year and adjustments to prior years. The 2016 amounts have not yet been agreed with the relevant tax authorities.

	2016 £m	2015 £m
<b>Current tax</b>		
United Kingdom corporation tax research and development credit	(8.6)	(10.3)
Adjustments in respect of prior year	(0.2)	(0.3)
<b>Total current tax</b>	<b>(8.8)</b>	<b>(10.6)</b>
<b>Deferred tax</b>		
(Increase)/decrease in deferred tax assets	(0.8)	0.5
Increase/(decrease) in deferred tax liabilities	0.6	(2.7)
Adjustments in respect of prior year	1.5	–
<b>Total deferred tax</b>	<b>1.3</b>	<b>(2.2)</b>
<b>Total tax</b>	<b>(7.5)</b>	<b>(12.8)</b>

## Notes to the financial statements continued

The tax credit for the year is lower (2015: higher) than the standard rate of corporation tax in the UK of 20% (2015: 20.25%). The differences are explained below:

	2016 £m	2015 £m
Loss on ordinary activities before tax	(144.9)	(62.8)
Loss on ordinary activities before tax multiplied by the standard rate of corporation tax in the UK of 20% (2015: 20.25%)	(29.0)	(12.7)
Expenses not deductible for tax purposes (permanent differences)	15.6	0.8
Temporary timing differences on employee share options	0.2	–
Research & development relief uplift	(3.5)	(4.0)
Utilisation of losses not previously recognised	–	(0.2)
Adjustments in respect of prior year	1.3	(0.3)
Tax losses for which no deferred income tax asset was recognised	7.9	3.6
<b>Tax credit for the year</b>	<b>(7.5)</b>	<b>(12.8)</b>

At 31 December 2016, the Group has tax losses to be carried forward of approximately £292.8 million (2015: £223.3 million).

At 31 December 2016, the Group has current tax assets arising from tax credits in the United Kingdom for certain research and development expenditure of £8.7 million (2015: £11.8 million).

A reduction in the rate of UK corporation tax to 19% from 1 April 2017 and to 17% from 1 April 2020 has been substantively enacted. UK deferred tax assets and liabilities are recognised at a rate of 17% (2015: 18%).

### 12. Loss per share

Basic loss per share is calculated by dividing the loss attributable to ordinary equity holders of the Company by the weighted average number of Ordinary shares in issue during the year.

	2016 Underlying operations	2016 Non-underlying items	2016 Total	2015 Total
Loss from continuing operations attributable to ordinary equity owners of the parent company (£m)	(57.3)	(80.0)	(137.3)	(49.9)
Weighted average number of Ordinary shares in issue (Number)	284,889,171	284,889,171	284,889,171	249,578,520
<b>Loss per share</b>	<b>£(0.20)</b>	<b>£(0.28)</b>	<b>£(0.48)</b>	<b>£(0.20)</b>

As net losses from continuing operations were recorded in 2016 and 2015, the dilutive potential shares are anti-dilutive and therefore were excluded from the earnings per share calculation.

### 13. Property, plant and equipment

Group	Leasehold improvements £m	Fixtures and fittings £m	Plant and machinery £m	Assets under construction £m	Total property, plant and equipment £m
<b>At 1 January 2015</b>					
Cost	0.3	–	–	–	0.3
Accumulated depreciation	–	–	–	–	–
<b>Net book amount</b>	<b>0.3</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>0.3</b>
<b>Year ended 31 December 2015</b>					
Opening net book amount	0.3	–	–	–	0.3
Acquisition of subsidiaries	0.2	0.1	0.5	0.5	1.3
Additions	–	–	0.1	0.1	0.2
Depreciation	(0.2)	–	(0.3)	–	(0.5)
Transfers	–	–	0.6	(0.6)	–
<b>Closing net book amount</b>	<b>0.3</b>	<b>0.1</b>	<b>0.9</b>	<b>–</b>	<b>1.3</b>
<b>At 31 December 2015</b>					
Cost	0.5	0.1	1.2	–	1.8
Accumulated depreciation	(0.2)	–	(0.3)	–	(0.5)
<b>Net book amount</b>	<b>0.3</b>	<b>0.1</b>	<b>0.9</b>	<b>–</b>	<b>1.3</b>
<b>Year ended 31 December 2016</b>					
Opening net book amount	0.3	0.1	0.9	–	1.3
Additions	0.1	0.1	0.5	–	0.7
Depreciation	(0.2)	(0.1)	(0.4)	–	(0.7)
Exchange differences	–	0.1	–	–	0.1
<b>Closing net book amount</b>	<b>0.2</b>	<b>0.2</b>	<b>1.0</b>	<b>–</b>	<b>1.4</b>
<b>At 31 December 2016</b>					
Cost	0.6	0.3	1.7	–	2.6
Accumulated depreciation	(0.4)	(0.1)	(0.7)	–	(1.2)
<b>Net book amount</b>	<b>0.2</b>	<b>0.2</b>	<b>1.0</b>	<b>–</b>	<b>1.4</b>

### 14. Goodwill

	2016 £m	2015 £m
<b>At 1 January</b>		
Cost	81.2	1.8
Accumulated impairment	–	–
<b>Net book amount</b>	<b>81.2</b>	<b>1.8</b>
<b>Year ended 31 December</b>		
Opening net book amount	81.2	1.8
Acquisition of businesses	–	77.2
Impairment	(74.5)	–
Exchange differences	3.0	2.2
<b>Closing net book amount</b>	<b>9.7</b>	<b>81.2</b>
<b>At 31 December</b>		
Cost	84.2	81.2
Accumulated impairment	(74.5)	–
<b>Net book amount</b>	<b>9.7</b>	<b>81.2</b>

During 2015, Circassia completed the acquisition of two businesses, resulting in the recognition of £77.2 million of goodwill. The majority of this goodwill related to the acquisition of Aerocrine AB (NIOX® business). This goodwill was allocated to the NIOX® and Allergy (existing Circassia business) cash generating units (CGUs) for impairment testing purposes as the benefits of the Aerocrine acquisition were split between these CGUs. The goodwill recognised on the acquisition of Prosonix Limited (Respiratory business) has been allocated to the Respiratory CGU, being the CGU for impairment testing purposes.



## Notes to the financial statements continued

The goodwill arising on the Aerocrine acquisition was attributable to the benefit of having an established sales force with future customer relationships. A large element of the advantages of having an established sales force was expected to accrue to the Allergy business as its products could have been cross sold to the same customers by this sales force. The acquisition of Aerocrine was based on a strategic benefit to the Allergy CGU in leveraging the existing sales force within the business to generate future sales within Circassia. Goodwill was allocated based on the proportion of discounted cash flows attributable to each CGU. For this reason, 94% of the goodwill acquired on acquisition of Aerocrine was allocated to the Allergy CGU.

Following the cat allergy immunotherapy phase III study results, the Allergy portfolio value has been fully discounted resulting in the impairment charge during 2016 for the Allergy CGU of £74.5 million.

The carrying value of goodwill, translated at year end exchange rates, is allocated to the following CGUs:

Cash generating unit	2016 £m	2015 £m
Allergy	–	72.1
NIOX®	5.3	4.7
Respiratory	4.4	4.4
	9.7	81.2

The recoverable amount of the Respiratory CGU is assessed using a value in use model. Value in use is calculated as the net present value of the projected risk-adjusted pre-tax cash flows plus a terminal value of the CGU to which the goodwill is allocated.

The value in use for the Respiratory CGU was calculated over a ten year period using a discount factor of 13% (being a weighted average cost of capital rate for the CGU used by some analysts covering the Group). The calculations use pre-tax cash flow projections. In light of the stage of development of the product candidates these cover a ten year period. Cash flows beyond the ten year period were extrapolated using the estimated terminal growth rate stated below. The growth rate does not exceed the long-term average growth rate for the business. The discount rate used is pre-tax and reflects specific risks relating to the Group and uncertainties surrounding the cash flow projections, particularly in relation to the assumed successful launch of the Group's products in the expected timeframe and the resulting sales.

As a result of recent strategic developments, management deemed it appropriate to change the valuation basis for the NIOX® CGU. The recoverable amount of the NIOX® CGU is assessed using a fair value less costs of disposal model (2015: value in use model). Fair value less costs of disposal is calculated using a discounted cash flow approach, with a pre-tax discount rate applied to the projected risk-adjusted pre-tax cash flows and terminal value of the CGU to which the goodwill is allocated. The valuation methodology uses significant inputs which are not based on observable market data, therefore this valuation technique is classified as level 3 in the fair value hierarchy.

The fair value less costs of disposal for the NIOX® CGU was calculated over a ten year period using a discount factor of 10% (being a weighted average cost of capital rate for the CGU used by some analysts covering the Group). The calculations use pre-tax cash flow projections. Cash flows beyond the ten year period were extrapolated using the estimated terminal growth rate stated below. The growth rate does not exceed the long-term average growth rate for the business. The discount rate used is pre-tax and reflects specific risks relating to the Group and uncertainties surrounding the cash flow projections.

The key assumptions used for the valuations of the Respiratory and NIOX® CGUs are as follows:

	Respiratory CGU	NIOX® CGU
Valuation basis	Value in use	Fair value less cost of disposal
Anticipated launch dates	Group product candidate portfolio 2017 – 2026	n/a – commercialised product
Research and development costs	Based on management forecasts of clinical study costs for its product candidates, as well as related expenses associated with the regulatory approval process and commercialisation	
Sales value, volume and growth rates	Estimates of sales value, volume and growth rates are internal forecasts based on both internal and external market information and market research commissioned by the Company	
Advertising and promotion investment	Based on management forecasts of advertising and promotion required in the key territories	
Profit margins	Margins reflect management's forecasts of sales values and costs of manufacture adjusted for its expectations of market developments	Margins reflect past experience adjusted for management's expectations of market developments
Period of specified projected cash flows	10 years	10 years
Terminal growth rate	Terminal growth rates based on management's estimate of future long-term average growth rate 2016 – 1% 2015 – 1%	
Discount rate	Discount rates based on weighted average cost of capital for the CGU, adjusted where appropriate. The discount factor has been adjusted to reflect the change in the risk profile of the CGU 2016 – 13% 2015 – 10%	Discount rates based on weighted average cost of capital for the CGU, adjusted where appropriate. The discount factor has been adjusted to reflect the change in the risk profile of the CGU 2016 – 10% 2015 – 10%

In each case the valuations of Respiratory and NIOX® indicate sufficient headroom such that a change to key assumptions that are reasonably possible is unlikely to result in an impairment of the related goodwill.

### Impact of possible changes in key assumptions

#### Delayed launch of key product candidate in the Respiratory CGU

Management have in their sensitivity analysis assessed the impact of the possibility that the launch of one of the key product candidates in the Respiratory CGU is delayed by two years.

#### Reduction in revenue growth in the NIOX® CGU

Management have in their sensitivity analysis assessed the impact of the possibility that the sales in the NIOX® CGU growth is less than that of internal forecasts.

Neither change in the key assumption mentioned above would have resulted in an impairment charge.

## 15. Intangible assets

Group	IPR&D £m	Customer relationships £m	Technology £m	Other £m	Total intangible assets £m
<b>At 1 January 2015</b>					
Cost	–	–	–	0.5	0.5
Accumulated amortisation and impairment	–	–	–	(0.3)	(0.3)
<b>Net book amount</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>0.2</b>	<b>0.2</b>
<b>Year ended 31 December 2015:</b>					
Opening net book amount	–	–	–	0.2	0.2
Acquisition of businesses	88.9	29.9	46.0	1.2	166.0
Additions	–	–	–	0.1	0.1
Amortisation charge	–	(0.9)	(0.9)	(0.6)	(2.4)
Exchange differences	–	0.9	0.8	–	1.7
<b>Closing net book amount</b>	<b>88.9</b>	<b>29.9</b>	<b>45.9</b>	<b>0.9</b>	<b>165.6</b>
<b>At 31 December 2015</b>					
Cost	88.9	30.8	46.8	1.8	168.3
Accumulated amortisation and impairment	–	(0.9)	(0.9)	(0.9)	(2.7)
<b>Net book amount</b>	<b>88.9</b>	<b>29.9</b>	<b>45.9</b>	<b>0.9</b>	<b>165.6</b>
<b>Year ended 31 December 2016:</b>					
Opening net book amount	88.9	29.9	45.9	0.9	165.6
Amortisation charge	(0.1)	(1.8)	(2.0)	(0.7)	(4.6)
Impairment charge	–	–	–	(0.3)	(0.3)
Exchange differences	–	3.3	3.0	0.1	6.4
<b>Closing net book amount</b>	<b>88.8</b>	<b>31.4</b>	<b>46.9</b>	<b>–</b>	<b>167.1</b>
<b>At 31 December 2016</b>					
Cost	88.9	34.3	50.0	1.6	174.8
Accumulated amortisation and impairment	(0.1)	(2.9)	(3.1)	(1.6)	(7.7)
<b>Net book amount</b>	<b>88.8</b>	<b>31.4</b>	<b>46.9</b>	<b>–</b>	<b>167.1</b>

An impairment test is performed annually based on the value in use of the intangible assets.

The Group tests annually whether goodwill and intangible assets have suffered any impairment and tests more frequently when events or circumstances indicate that the current carrying value may not be recoverable. Due to the negative result of the investigational cat allergy immunotherapy phase III study and the subsequent impact on a wider Allergy product portfolio, related licences and patents have been fully impaired in 2016. Key assumptions and sensitivities used in the impairment review are disclosed in note 14.

### In-Process Research & Development (IPR&D)

IPR&D comprise a portfolio of asthma and chronic obstructive pulmonary disease product candidates still in development.

The IPR&D has been initially valued using the Excess Earnings Method. This valuation method is based on discounting the cash flows that are attributable to the intangible asset, after taking into account the contribution of other assets. IPR&D assets are tested for impairment on the same basis.

### Customer relationships

Customer relationships represent the existing customers, as at the date of acquisition that are expected to continue to support the business. A remaining useful life of 18 years was determined at acquisition. Amortisation has been calculated on a straight line basis over this period from the date of acquisition.

# Notes to the financial statements continued

## Technology

Prosonix achieves a sophisticated level of control over the physicochemical properties of drug particles via an integrated platform of unique and proprietary particle engineering technologies and formulation processes. The Relief from Royalty Method was used to determine the fair value of the acquired Technology. In the Relief from Royalty Method, estimates of the value of these types of intangible assets are made by capitalising the royalties saved because the company owns the intangible asset. A remaining useful life of 20 years was determined at acquisition and amortisation will commence when the products underpinned by this technology become available for commercial use. A value in use model is used in testing for impairment.

Aerocrine has been developing its technology to measure fractional exhaled nitric oxide ("FeNO") since the mid-1990s. The Company was the first to develop an instrument for the measurement of FeNO and is continuously developing the measurement FeNO as a valuable tool in the management of airway inflammation. The valuation of the Technology was based on pre-determined hypothetical royalty rate attributable to the use of the Technology. The estimated remaining useful life of the Technology is 15 years. Amortisation has been calculated on a straight line basis over this period from the date of acquisition.

## Other

Other intangible assets relate to licences and software.

## 16. Investments in subsidiaries

	2016 £m	2015 £m
Investments in subsidiaries at 1 January	242.6	3.0
Investment in Prosonix Limited	–	100.3
Investment in Aerocrine AB	3.2	136.9
Investment in Circassia Pharmaceuticals Inc (formerly Aerocrine Inc)	15.5	–
Equity settled instruments granted to employees of subsidiaries	2.4	2.4
Impairment of Circassia Limited investment	(1.7)	–
<b>Investments in subsidiaries at 31 December</b>	<b>262.0</b>	<b>242.6</b>

The capital contribution relating to share based payment is for 7,660,654 (2015: 5,532,518) 0.08p share options granted by the Company to employees of subsidiary undertakings in the Group. Further details on the Group's share option schemes can be found in note 25.

Following the cat allergy immunotherapy phase III study results, the investment relating to the Allergy technology purchase has been fully impaired.

Details of the Company's related entities are provided below. All subsidiaries are included in the consolidation and the Directors believe that the fair value of the investment in all subsidiaries exceeds their carrying values.

Name	Registered address	Nature of business	Proportion of ordinary shares held
Adiga Life Sciences	McMaster Innovation Park, Suite 305, 175 Longwood Road South Hamilton, Ontario, Canada	Pharmaceutical research	50%
Circassia Limited	The Magdalen Centre, Robert Robinson Avenue, Science Park, Oxford, OX4 4GA, UK	Pharmaceutical research and sale of devices for management of asthma	100%
Circassia Pharma Limited	The Magdalen Centre, Robert Robinson Avenue, Science Park, Oxford, OX4 4GA, UK	Pharmaceutical research	100%
Circassia Pharmaceuticals Inc	5151 McCrimmon Parkway, Suite 260, Morrisville, North Carolina 27560, USA	Pharmaceutical research and sale of devices for management of asthma	100%
Circassia AB	Fyrilundsgatan 80, 754 50, Uppsala, Sweden	Development and sale of devices for management of asthma	100%
Circassia AG	Louisenstraße 21, 61348, Bad Homburg, Germany	Sale of devices for management of asthma	100%
Prosonix Limited	The Magdalen Centre, 1 Robert Robinson Avenue, Oxford Science Park, Oxford, OX4 4GA, UK	Pharmaceutical research	100%

## 17. Investment in joint venture

	2016 £m	2015 £m
<b>At 1 January</b>	<b>0.2</b>	0.1
Share of profit	0.6	0.1
Share of other comprehensive income	0.1	–
<b>At 31 December</b>	<b>0.9</b>	0.2

### Nature of investment in joint venture 2016 and 2015

Name of entity	Registered address	% of ownership interest	Nature of the relationship	Measurement method
Adiga Life Sciences	McMaster Innovation Park, Suite 305, 175 Longwood Road South Hamilton, Ontario, Canada	50	Note 1	Equity

#### Note 1.

Adiga Life Sciences (“Adiga”) is a joint venture with McMaster University in Canada for early epitope and mechanistic clinical studies. Adiga is a private company and there is no quoted market price available for its shares.

There are no contingent liabilities or commitments relating to the Group’s interest in the joint venture.

### Summarised financial information for joint venture

Set out below is the summarised financial information for Adiga which is accounted for using the equity method.

#### Summarised statement of financial position at 31 December

	2016 £m	2015 £m
<b>Current assets</b>		
Trade and other receivables	1.0	1.2
Cash	0.8	0.2
	<b>1.8</b>	1.4
<b>Current liabilities</b>		
Trade payables	–	(0.9)
Other payables	–	(0.1)
	–	(1.0)
<b>Net assets</b>	<b>1.8</b>	0.4

#### Summarised statement of comprehensive income for the year ended 31 December

	2016 £m	2015 £m
Revenue	1.8	2.3
Research & development costs	(1.8)	(2.6)
Administration expense	0.2	(0.2)
Profit/(loss) from continuing operations	0.2	(0.5)
Income tax	1.0	0.7
Post tax profit from continuing operations	1.2	0.2
Other comprehensive income:		
Currency translation differences	0.2	–
<b>Total comprehensive income</b>	<b>1.4</b>	0.2

The information above reflects the amounts presented in the financial statements of the joint venture adjusted for differences in accounting policies between the Group and the joint venture (and not Circassia Pharmaceuticals plc’s share of those amounts).

# Notes to the financial statements continued

## Reconciliation of summarised financial information

Reconciliation of the summarised financial information presented to the carrying amount of the Company's interest in the joint venture.

Summarised financial information	2016 £m	2015 £m
<b>Opening net assets 1 January</b>	<b>0.4</b>	0.2
Profit for the year	1.2	0.2
Other comprehensive income	0.2	-
<b>Closing net assets</b>	<b>1.8</b>	0.4
Interest in joint venture @ 50%	0.9	0.2
<b>Carrying value</b>	<b>0.9</b>	0.2

## 18. Inventories

	2016 £m	2015 £m
Finished goods	4.6	3.0

Inventories recognised as an expense during the year ended 31 December 2016 amounted to £7.1 million (2015: £3.6 million). These were included in 'Cost of sales'.

Write-down of inventories to net realisable value amounted to £0.5 million (2015: £0.5 million). These were recognised as an expense during the year and included in 'Cost of sales'.

## 19. Trade and other receivables

	Group		Company	
	2016 £m	2015 £m	2016 £m	2015 £m
Trade receivables	3.4	3.0	-	-
Other receivables	2.1	1.4	1.9	0.3
Prepayments and accrued interest	2.2	0.7	0.4	0.2
Receivables from subsidiary undertakings	-	-	218.6	184.5
<b>Total trade and other receivables</b>	<b>7.7</b>	5.1	<b>220.9</b>	185.0

The fair value of other receivables are their current book values. Included within receivables is £1.2 million (2015: £0.3 million) of trade receivables that were past due at the end of the reporting period but have not been impaired.

Receivables from subsidiary undertakings are amounts provided by the Company to its subsidiaries in order to undertake commercial operations and research studies. The receivable is unsecured, interest free and has no fixed date of repayment. Recoverability of the amounts are dependent on the success of those studies and future profitability of subsidiary undertakings.

The carrying amounts of the Group and Company receivables, excluding prepayments and recoverable taxes, are denominated in the following currencies:

	Group		Company	
	2016 £m	2015 £m	2016 £m	2015 £m
UK pound	0.6	0.4	192.1	176.2
United States dollar	2.0	1.4	27.7	4.8
Swedish krona	1.2	0.9	1.1	2.0
Euro	1.5	1.1	-	2.0
<b>Total</b>	<b>5.3</b>	3.8	<b>220.9</b>	185.0

## 20. Cash and cash equivalents and short-term bank deposits

	Group		Company	
	2016 £m	2015 £m	2016 £m	2015 £m
Short-term bank deposit, with original maturity: More than 3 months	20.0	37.8	20.0	37.8
<b>Total short-term bank deposits</b>	<b>20.0</b>	<b>37.8</b>	<b>20.0</b>	<b>37.8</b>
Cash and cash equivalents: Cash at bank and in hand	97.4	166.0	73.0	130.7
<b>Total cash and cash equivalents</b>	<b>97.4</b>	<b>166.0</b>	<b>73.0</b>	<b>130.7</b>

The Group and Company cash and cash equivalents and short-term deposits are held with institutions with the following Fitch IBCA long-term rating:

	Group		Company	
	2016 £m	2015 £m	2016 £m	2015 £m
AA	0.8	–	–	–
AA–	32.7	33.1	11.9	0.5
A+	35.0	72.7	35.0	70.0
A	48.9	90.7	46.1	90.7
A–	–	7.3	–	7.3
	<b>117.4</b>	<b>203.8</b>	<b>93.0</b>	<b>168.5</b>

The Group and Company cash and cash equivalents and short-term deposits are held in the following currencies at 31 December:

	Group		Company	
	2016 £m	2015 £m	2016 £m	2015 £m
UK pound	96.0	138.3	90.9	135.5
United States dollar	3.2	22.2	–	20.5
Canadian dollar	0.6	8.5	–	7.3
Euro	10.5	7.5	2.1	5.2
Swiss franc	2.0	7.1	–	–
Swedish krona	5.0	20.2	–	–
Chinese yuan renminbi	0.1	–	–	–
	<b>117.4</b>	<b>203.8</b>	<b>93.0</b>	<b>168.5</b>

## 21. Trade and other payables

	Group		Company	
	2016 £m	2015 £m	2016 £m	2015 £m
Trade payables	9.2	5.1	0.1	0.1
Social security and other taxes	0.5	0.3	–	–
Accruals	8.1	12.0	0.2	0.1
Other payables	3.7	0.9	–	–
Contingent consideration <sup>1</sup>	–	30.0	–	30.0
Payables to subsidiary undertakings	–	–	5.1	–
<b>Total trade and other payables</b>	<b>21.5</b>	<b>48.3</b>	<b>5.4</b>	<b>30.2</b>

<sup>1</sup> The contingent consideration arrangement required the Group to pay the former owners of Prosonix Limited £30.0 million upon the Company receiving a product marketing authorisation in respect of Prosonix Limited's lead product in the United Kingdom on or before 31 December 2016. UK marketing approval was received during 2015 and the contingent consideration of £30.0 million was paid on 6 January 2016. The fair value of the contingent consideration as at 31 December 2015 was equal to its book value and was no longer contingent.



# Notes to the financial statements continued

## 22. Financial instruments

The Group's financial instruments comprise cash and cash equivalents, short-term bank deposits, trade and other receivables, trade and other payables and contingent consideration. Additional disclosures are set out in the accounting policies relating to financial and capital risk management (note 2).

The Group had the following financial instruments at 31 December each year:

	2016 £m	2015 £m
<b>Assets</b>		
Cash and cash equivalents	97.4	166.0
Short-term bank deposits	20.0	37.8
Trade and other receivables	5.3	3.8
<b>Loans and receivables</b>	<b>122.7</b>	<b>207.6</b>
<b>Liabilities</b>		
Trade and other payables – current	18.4	47.5
<b>Financial liabilities at amortised cost</b>	<b>18.4</b>	<b>47.5</b>

The Company had the following financial instruments at 31 December each year:

	2016 £m	2015 £m
<b>Assets</b>		
Cash and cash equivalents	73.0	130.7
Short-term bank deposits	20.0	37.8
Other receivables	2.3	0.5
Receivable from subsidiary undertaking	218.6	184.5
<b>Loans and receivables</b>	<b>313.9</b>	<b>353.5</b>
<b>Liabilities</b>		
Trade and other payables – current	0.3	30.2
Payables to subsidiary undertakings	5.1	–
<b>Financial liabilities at amortised cost</b>	<b>5.4</b>	<b>30.2</b>

Cash balances comprise floating rate instant access deposits earning interest at prevailing bank rates.

Short-term deposits earn interest at fixed rates.

In accordance with IAS 39 'Financial Instruments Recognition and Measurement' the Group has reviewed all contracts for embedded derivatives that are required to be separately accounted for if they do not meet certain requirements set out in the standard.

There were no such derivatives identified at 31 December 2016 or 31 December 2015.

### Fair value

The Directors consider that the fair values of the Group's financial instruments do not differ significantly from their book values.

### 23. Deferred taxation

	Intangibles £m	Tax losses £m	Net deferred tax liability £m
<b>As at 1 January 2015</b>	–	–	–
Acquisitions	34.0	(17.8)	16.2
Change in rate	(2.2)	0.5	(1.7)
(Credit)/charge to the income statement	(0.6)	0.1	(0.5)
<b>As at 31 December 2015</b>	<b>31.2</b>	<b>(17.2)</b>	<b>14.0</b>
<b>As at 1 January 2016</b>	31.2	(17.2)	14.0
Charge to the income statement	0.7	0.6	1.3
<b>As at 31 December 2016</b>	<b>31.9</b>	<b>(16.6)</b>	<b>15.3</b>

In 2015 on acquisition of Aerocrine and Prosonix, the Group recognised a net deferred tax liability of £16.2 million, comprising a deferred tax liability of £34.0 million, offset by a deferred tax asset arising in the same jurisdictions of £17.8 million.

	2016 £m	2015 £m
Deferred tax liabilities	31.9	31.2
Deferred tax assets	(16.6)	(17.2)
<b>Total deferred tax position</b>	<b>15.3</b>	<b>14.0</b>

The Group has the following unrecognised potential deferred tax assets as at 31 December:

	2016 £m	2015 £m
Losses	51.8	40.2
Accelerated capital allowances	–	0.5
Share based payments and provisions	1.3	1.7
<b>Total unrecognised deferred tax asset</b>	<b>53.1</b>	<b>42.4</b>

### 24. Share capital

Authorised, called up and fully paid	2016 £m	2015 £m
284,889,171 (2015: 284,889,171) Ordinary shares of 0.08p each	0.2	0.2

On 11 June 2015, the Company issued 95,469,537 Ordinary shares which funded the acquisitions of Aerocrine and Prosonix. The shares were offered at 288.05p each, raising gross proceeds of £275.0 million. Deal costs relating to the acquisitions and the share issue were £12.8 million, of which £8.8 million was offset against the Share Premium Account and £4.0 million of indirect Admission costs were included in the income statement in 2015.

### 25 Share based payments

#### Share options

Options have been awarded under the Circassia PSP Share Option Scheme ("the PSP Scheme"), the Circassia EMI Share Option Scheme ("the EMI Scheme") and the Circassia Unapproved Share Option Scheme ("the Unapproved Scheme").

The share options outstanding can be summarised as follows:

	2016 Number of Ordinary shares (‘000)	2015 Number of Ordinary shares (‘000)
PSP Scheme <sup>(i)</sup>	6,610	4,336
EMI Scheme <sup>(ii)</sup>	535	535
Unapproved Scheme <sup>(iii)</sup>	516	661
	<b>7,661</b>	<b>5,532</b>

The contractual life of all options is 10 years and the options cannot normally be exercised before the third anniversary of the date of grant.

- (i) Options granted under the PSP Scheme do not have a fixed exercise price and are subject to additional vesting performance conditions. The performance conditions state that a proportion of an award shall vest subject to the Company Total Shareholder Return (TSR) ranking against the Comparator Index TSR and the remaining shall vest subject to the meeting of certain strategic Company objectives.
- (ii) Options granted under the EMI Scheme have a fixed exercise price based on the market price at the date of grant.
- (iii) Options granted under the Unapproved Scheme also have a fixed exercise price based on the market price at the date of grant.

# Notes to the financial statements continued

The movement in share options outstanding is summarised in the following table:

	2016 Number ('000)	2016 Weighted average exercise price (£)	2015 Number ('000)	2015 Weighted average exercise price (£)
Outstanding at 1 January	5,532	0.15	3,165	0.25
Granted	3,346	0.0008	2,853	0.0008
Expired	–	n/a	–	n/a
Forfeited	(1,217)	0.29	(486)	0.0003
Exercised	–	n/a	–	n/a
Outstanding at 31 December	7,661	0.06	5,532	0.15
Exercisable at 31 December	1,014	0.36	708	0.0008

The exercise prices of the share options outstanding at the end of the year were £nil, £0.0008 and £2.42 (2015: £nil, £0.0008 and £2.42). The weighted average remaining contractual life of share options outstanding at the end of the period was 7.9 years (2015: 8.2 years).

There were no options exercised during the year ended 31 December 2016 or 2015.

## Valuation models

The fair value of PSP share options granted during the period was determined using the Monte Carlo Simulation model and Black Scholes model dependent on the performance vesting conditions.

There have been no EMI Scheme or Unapproved Scheme options granted during the year (2015: nil), all options granted in previous years were valued using the Black Scholes model.

## Black Scholes

There were no options granted during the year (2015: nil) that were valued solely using the Black Scholes model.

## Monte Carlo Simulation

The following weighted average assumptions were used in the Monte Carlo Simulation model in calculating the fair values of the options granted during the year:

	2016	2015
Exercise price	£0.0008	£0.0008
Expected volatility	35%	32%
Expected life	3 years	3 years
Expected dividends	0%	0%
Risk free interest rate	0.4%	1%

The Monte Carlo Simulation model has been used to value the portion of the awards which have a market performance vesting condition (Total Shareholder Return (TSR)). The model incorporates a discount factor reflecting this performance condition into the fair value of this portion of the award.

The weighted average fair value of options granted during the period determined using the Monte Carlo Simulation model at the grant date was £1.75 per option (2015: £2.04).

For the options valued using the Monte Carlo Simulation, expected volatility is measured by calculating the standard deviation of the natural logarithm of share price movements of comparable companies. This is a standard approach to calculating volatility. The risk free rate of return is the rate of interest obtainable from government securities as at the date of grant (i.e. Gilts in the UK) over the expected term (i.e. three years).

## Restricted shares

The Company previously made awards of Ordinary shares to employees and Non-Executive Directors by entering into a form of restricted share agreement with each participant, under which the participant subscribed for or purchased Ordinary shares in the Company at 10p per ordinary share (converted into 0.08p shares post capital reorganisation). These shares are subject to certain restrictions on transfer and forfeiture, as set out in the restricted share agreement. The restrictions lift on the earlier of a sale of the Company and the expiry of a vesting period of between two and three years (depending on the date of award of the restricted shares).

There were 0.1 million Ordinary shares of 0.08p (2015: 0.6 million Ordinary shares of 0.08p) in issue at 31 December 2016.

## Deferred shares

During the year the Group awarded 156,035 (2015: 110,845) deferred shares to Executive Directors as part of a deferred bonus for 2015. The shares are held by the Group's Employee Benefit Trust until the third anniversary of the grant date when they will transfer to the Executive Directors so long as they are still an officer or employee of the Group.

## Income statement

See note 5 for the total expense recognised in the income statement in respect of the above equity settled instruments granted to Directors and employees.

## 26. Share premium

Group and Company	2016 £m	2015 £m
At 1 January	564.0	297.9
Issue of new shares	–	274.9
Expenses relating to share issue	(0.2)	(8.8)
<b>At 31 December</b>	<b>563.8</b>	<b>564.0</b>

## 27. (Accumulated losses)/retained earnings

	Group		Company	
	2016 £m	2015 £m	2016 £m	2015 £m
At 1 January	(158.5)	(108.6)	(2.0)	1.2
(Loss)/profit for the year	(137.3)	(49.9)	2.4	(3.2)
<b>At 31 December</b>	<b>(295.8)</b>	<b>(158.5)</b>	<b>0.4</b>	<b>(2.0)</b>

## 28. Other reserves

Group	Share option reserve £m	Translation reserve £m	Treasury shares reserve £m	Transactions with non-controlling interests <sup>(a, b)</sup> £m	Total other reserves £m
<b>At 1 January 2015</b>	1.3	–	–	–	1.3
Employee share option scheme	2.7	–	–	–	2.7
Currency translation differences	–	3.1	–	–	3.1
Purchase of own shares (note 33)	–	–	(0.3)	–	(0.3)
Transactions with non-controlling interests	–	–	–	(4.0)	(4.0)
<b>At 31 December 2015</b>	4.0	3.1	(0.3)	(4.0)	2.8
Employee share option scheme	2.4	–	–	–	2.4
Currency translation joint venture	–	0.1	–	–	0.1
Other currency translation differences	–	9.7	–	–	9.7
Purchase of own shares (note 33)	–	–	(0.4)	–	(0.4)
Transactions with non-controlling interests	–	–	–	(2.1)	(2.1)
<b>At 31 December 2016</b>	<b>6.4</b>	<b>12.9</b>	<b>(0.7)</b>	<b>(6.1)</b>	<b>12.5</b>

(a) On 1 July and 4 July 2015, the Group acquired an additional 4.6% and 0.7% respectively of the issued shares of Aerocrine AB for SEK94.3 million (£7.2 million). Immediately prior to the purchase, the carrying amount of the existing 7.4% non-controlling interests in Aerocrine AB was £4.5 million. The Group recognised a decrease in non-controlling interests of £3.2 million and a decrease in equity attributable to owners of the parent of £4.0 million.

(b) On 13 May 2016, the Group acquired the remaining 2.1% of the issued shares of Aerocrine AB for SEK37.6 million (£3.2 million) to become the owner of 100% of the shares in Aerocrine AB. Immediately prior to the purchase, the carrying amount of the existing 2.1% non-controlling interests in Aerocrine AB was £1.1 million. The Group recognised a decrease in non-controlling interests of £1.1 million and a decrease in equity attributable to owners of the parent of £2.1 million.

The effect on the equity attributable to the owners of Circassia Pharmaceuticals plc is summarised as follows:

	2016 £m	2015 £m
Carrying amount of non-controlling interests acquired	1.1	3.2
Consideration paid to non-controlling interests	(3.2)	(7.2)
<b>Excess of consideration paid recognised in the transactions with non-controlling interests reserve within equity</b>	<b>(2.1)</b>	<b>(4.0)</b>

# Notes to the financial statements continued

Company	Share option reserve £m	Total other reserves £m
<b>At 1 January 2015</b>	1.3	1.3
Employee share option scheme	2.4	2.4
<b>At 31 December 2015</b>	3.7	3.7
Employee share option scheme	2.4	2.4
<b>At 31 December 2016</b>	<b>6.1</b>	<b>6.1</b>

## 29. Cash used in operations

### Reconciliation of (loss)/profit before tax to net cash used in operations

	Group		Company	
	2016 £m	2015 £m	2016 £m	2015 £m
<b>Continuing operations</b>				
(Loss)/profit before tax	(144.9)	(62.8)	2.4	(3.2)
Adjustment for:				
Interest income	(0.9)	(1.7)	(0.9)	(1.6)
Interest expense	0.1	–	0.1	–
Depreciation	0.7	0.5	–	–
Amortisation	4.6	2.4	–	–
Impairment	74.8	–	1.7	–
Share of joint venture profit	(0.6)	(0.1)	–	–
Fair value gain on forward contract	–	(1.1)	–	–
Share based payment charge	2.4	2.7	–	–
Foreign exchange on non-operating cash flows	(7.8)	(1.1)	–	0.1
Changes in working capital:				
(Increase)/decrease in trade and other receivables	(1.4)	1.5	(1.6)	(0.3)
Increase in inventories	(1.2)	(0.4)	–	–
Increase/(decrease) in trade and other payables	5.8	(4.8)	0.2	(0.8)
<b>Net cash (used in)/generated from operations</b>	<b>(68.4)</b>	<b>(64.9)</b>	<b>1.9</b>	<b>(5.8)</b>

## 30. Contingent liabilities

There were no contingent liabilities at 31 December 2016 or at 31 December 2015.

## 31. Operating lease commitments

The total of future minimum lease payments payable under the Group's non-cancellable operating lease for each of the following periods is as follows:

	2016 £m	2015 £m
Due within one year	1.0	1.0
Due between one and five years	1.7	0.8
Over five years	0.7	–

The Group leases various offices and warehouses under non-cancellable operating leases expiring within one to over five years.

### 32. Capital commitments

The Group had no capital commitments at 31 December 2016 or at 31 December 2015.

### 33. Related party transactions

#### Group

There is no ultimate controlling party of the Group as ownership is split between the Company's shareholders. The most significant shareholders as at 31 December 2016 are as follows: Invesco Asset Management (35.13% of total voting rights); Woodford Investment Management (22.17% of total voting rights); OppenheimerFunds Inc (10.58% of total voting rights); Touchstone Innovations (9.30% of total voting rights); Aviva Investors (5.57% of total voting rights).

Transactions with related parties during the year and balances with related parties at 31 December are as follows:

Related party	2016 Purchases £'000	2015 Purchases £'000	2016 Payables £'000	2015 Payables £'000
Adiga Life Sciences (Joint venture)	1,929	1,370	–	7
Touchstone Innovations <sup>1</sup>	42	42	–	–
Iterum Pharmaceuticals LLC <sup>2</sup>	–	89	–	–

1 'Purchases' includes compensation paid or payable in respect of services provided by Russ Cummings as Non-Executive Director of the Company.

2 Iterum Pharmaceuticals LLC was considered a related party by virtue of Paul Edick, a Non-Executive Director of the Company, being the Chairman of the Board until 19 May 2016.

Disclosure of compensation provided to Directors is given in the Annual Report on Remuneration and in note 5 for key management. Included within key management personnel is Chief Commercial Officer Linda Szyper. Linda is the spouse of Paul Edick, a Non-Executive Director of the Company who stepped down on 19 May 2016. The compensation paid or payable to Linda up to 19 May 2016 is shown below:

	2016 £m	2015 £m
<b>Linda Szyper:</b>		
Short-term employee benefits (including bonus)	0.3	0.5
Share based payment	0.1	0.1
<b>Total</b>	<b>0.4</b>	<b>0.6</b>

#### Company

The following transactions with subsidiaries occurred in the year:

Related party	2016 £m	2015 £m
Rendering of services to Circassia Limited <sup>1</sup>	0.8	1.3
Settlement of liabilities on behalf of the subsidiaries	(5.5)	(139.2)
Net transfer of funds to subsidiaries	33.6	201.4
	<b>28.9</b>	<b>63.5</b>

1 Remuneration costs (excluding share options charges) relating to Steven Harris and Julien Cotta in respect of services rendered to Circassia Limited.

	2016 £m	2015 £m
Balances due from subsidiary companies	218.6	184.5
Balances due to subsidiary companies	(5.1)	–

The amount due is unsecured, interest free and has no fixed date of repayment.

#### Employee benefit trust

In 2014 the Company set up an Employee benefit trust for the purposes of buying and selling shares on the employees' behalf. A total of £414,729 of funding was paid into the Trust by the Company during the year ended 31 December 2016 (2015: £291,081).

A total of 156,035 shares (0.08p nominal value each) were purchased by the Trust during the year ended 31 December 2016 (2015: 110,845). As at 31 December 2016 a cash balance of £5,068 (2015: £5,080) was held by the Trust.



# Notes to the financial statements continued

## 34. Events occurring after the reporting date

### Collaboration and profit share arrangement with AstraZeneca

On 17 March 2017 Circassia Pharmaceuticals Plc announced a collaboration and profit share arrangement with AstraZeneca and secured certain US commercial rights to Tudorza® and Duaklir® for a maximum total consideration of \$230 million (including \$50 million in ordinary shares) plus future sales based royalties upon the commercialisation of Duaklir® in the United States.

The consideration is structured as follows:

- Circassia issued 47,355,417 ordinary shares with a value of \$50 million to AstraZeneca;
- Circassia will pay AstraZeneca deferred non-contingent consideration of \$100 million on the earlier of: (i) 30 June 2019; and (ii) the approval of Duaklir® by the FDA;
- Circassia will initially enter a commercial collaboration and profit share arrangement with AstraZeneca for Tudorza® in the United States. Based on the sales performance of Tudorza® in a 12 month period ending no earlier than 30 September 2018, or if Duaklir® gains FDA approval before 31 December 2019, Circassia will have the option to secure the remaining commercial rights and economic benefits of Tudorza®. If this option is taken, Circassia will make further payments to AstraZeneca of up to \$80 million dependent on the level of Tudorza®'s sales in the United States;
- Circassia will pay royalties to AstraZeneca on sales of Duaklir® in the United States; and
- Circassia will make R&D contributions of up to \$62.5 million payable to AstraZeneca as deferred payments.

### Transfer of trade and certain assets from Prosonix Limited to Circassia Limited

On 2 March 2017, Prosonix Limited allotted one new Ordinary share to Circassia Pharmaceuticals plc for £9.0 million. This consisted of share capital of £0.001 and share premium of £8,999,999.999. Immediately following the share issue, Prosonix Limited reduced its issued share capital from £35,394,779.66 to £1,189.72 by cancelling and extinguishing 2,284,294 ordinary shares of £0.001 each, 1,891,840 A shares of £0.001 each and 9,941,261 B shares of £0.001 each, and by cancelling and extinguishing the entire share premium account, leaving behind 1,189,724 C shares of £0.001 each. The reduction in share capital was credited to a Capital reduction reserve account.

On 3 March 2017, Prosonix Limited fully repaid the intercompany loan due to Circassia Pharmaceuticals plc of £10,906,586.98. In addition, Prosonix Limited sold its business and certain assets for the price of £1,284,321.55 to Circassia Limited, representing the net book value of its business and certain assets, as part of a bona fide solvent reorganisation of the Circassia Group, subject to and on the terms and conditions of an asset purchase agreement between Prosonix Limited and Circassia Limited.

# Glossary

## **Active pharmaceutical ingredient (API)**

An active ingredient to the product

## **Allergen**

A substance causing an allergic reaction or allergy

## **Allergic rhinitis**

An allergic inflammation of the eyes, nasopharynx and nasal airways

## **Allergist**

A physician specialising in the diagnosis and treatment of allergies

## **Allergy**

An inappropriate immune response by the body to an allergen i.e. a substance (for example a particular food, pollen, animal or plant protein) to which the body has become hypersensitive

## **Asthma**

A common chronic inflammatory disease of the airways characterised by variable and recurring symptoms, reversible airflow obstruction and bronchospasm (which is a sudden constriction of the muscles in the walls of the bronchioles – part of the lungs)

## **Beta agonist**

A medication which relaxes the muscles around the airways

## **Birch**

A broadleaved deciduous hardwood tree of the genus *Betula*

## **Bronchodilation**

Widening of the major air passages of the lungs

## **Bronchodilator**

A drug that causes widening of the bronchi in the lungs

## **cGMP**

Refers to the Current Good Manufacturing Practice regulations enforced by the FDA

## **COPD**

Chronic obstructive pulmonary disease

## **Corticosteroid**

An anti-inflammatory medicine

## **Double-blind**

Neither the participants nor the researchers know which participants receive the placebo or the study drug

## **Efficacy**

The ability of an intervention or drug to produce a desired effect

## **FeNO**

Fractional exhaled nitric oxide

## **FEV<sub>1</sub>**

Forced expiratory volume in one second

## **Fill finish**

Filling and closure of the primary drug container and conduct of post-filling processes, e.g. sealing and inspection, resulting in a product that is suitable for commercial or investigational use following appropriate labelling and packaging

## **House dust mite (HDM)**

A small translucent organism belonging to the arachnid class commonly found in mattresses, pillows, sofas and carpets

## **ICS**

Inhaled corticosteroid

## **LABA**

Long-acting beta-agonist

## **LAMA**

Long-acting muscarinic antagonist

## **NO/nitric oxide**

A molecule with chemical formula NO, which is present in air exhaled by humans

## **Phase II**

In phase II trials a new product candidate is studied in a relatively homogenous population of subjects who have the relevant disease/disorder. These studies are undertaken to further characterise possible adverse effects and safety risks, and to explore the preliminary or potential efficacy of the product candidate, as well as dosage tolerance and the optimal effective dose

## **Phase IIb**

Phase II studies are sometimes further divided into two phases: phase IIa trials are designed to assess dosage (how much product candidate subjects should be given); and phase IIb trials are specifically designed to study efficacy (how well the product candidate works at a prescribed dose). Often phase II trials are designed as randomised clinical studies, where some subjects receive the product candidate and others receive a placebo/standard treatment. Randomised phase II trials typically have fewer subjects than randomised phase III trials

## **Phase III**

When phase II trials demonstrate that a specific dosage range of the product candidate is likely to be effective and has an acceptable safety profile, confirmatory phase III trials are undertaken. These studies are intended to provide an adequate basis for establishing the benefit/risk ratio for a subsequent application for marketing approval. Therefore, a sufficiently high number of subjects must be enrolled and exposed to the product candidate for a duration which will provide adequate efficacy and safety data for the envisaged clinical use. The studies must be controlled, i.e. compare the product candidate to placebo and/or to active treatment depending on the medical condition and the product candidate under investigation. Confirmatory phase III trials on specific immunotherapy for the treatment of allergic diseases should be performed using a randomised placebo-controlled double-blind design

## **Placebo**

A sham or simulated medical treatment or procedure

## **Placebo controlled**

A way of testing a medical therapy in which, in addition to a group of subjects that receives the treatment to be evaluated, a separate control group receives a placebo treatment

## **Randomised**

The process of allocating subjects to active drug or placebo in a clinical study

## **Regimen**

A plan or a regulated course designed to give a positive result

## **Rescue medication**

Short-term medication that provides immediate relief

## **Rhinoconjunctivitis**

Irritation and inflammation of the mucous membrane inside the nose and eyes

## **SABA**

Short-acting beta2-agonist

## **Safety profile**

The known information about a medicine's safety

## **Short acting beta agonist**

Medication typically used to provide quick relief of asthma symptoms

## **Total Rhinoconjunctivitis Symptom Score (TRSS)**

Scoring system used to track the severity of symptoms of rhinoconjunctivitis

# Advisors and contact details

## Financial calendar

- Annual General Meeting:  
26 May 2017
- Interim results for the  
six months ending  
30 June 2017: Q3 2017

## Registrars

All administrative enquiries relating to shareholdings and requests to receive corporate documents by email should, in the first instance, be directed to Equiniti. Shareview is Equiniti's shareholder portal offering access to services and information to help manage your shareholdings and inform your important investment decisions.

## Shareview Portfolio

Shareview Portfolio is an online portfolio management tool which enables you to view and manage all the shareholdings you have, where Equiniti is the Registrar, in one place. It is free to use and provides access to a wide range of market information and investment services. Please visit [www.shareview.co.uk](http://www.shareview.co.uk)

This is not a recommendation to buy or sell shares. The price of shares can go down as well as up, and you are not guaranteed to get back the amount that you originally invested.

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Lines are open 8:30am to 5:30pm Monday to Friday.

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## Forward-looking statements

This Annual report and accounts contains certain projections and other forward-looking statements with respect to the financial condition, results of operations, businesses and prospects of Circassia. The use of terms such as “may”, “will”, “should”, “expect”, “anticipate”, “project”, “estimate”, “intend”, “continue”, “target” or “believe” and similar expressions (or the negatives thereof) are generally intended to identify forward-looking statements. These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors that could cause actual results or developments to differ materially from those expressed or implied by these forward-looking statements. Any of the assumptions underlying these forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in the forward-looking statements may not actually be achieved. Nothing contained in this press release should be construed as a profit forecast or profit estimate. Investors or other recipients are cautioned not to place undue reliance on any forward-looking statements contained herein. Circassia undertakes no obligation to update or revise (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or other circumstances.

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