

# Pillars of growth

## **Circassia Pharmaceuticals plc**

Annual report and accounts 2017



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## About Circassia

Circassia is a world-class specialty pharmaceutical business focused on respiratory disease. Circassia sells its novel, market-leading NIOX® 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. In 2017, the Company established a commercial collaboration with AstraZeneca in the United States in which it promotes the chronic obstructive pulmonary disease (COPD) treatment Tudorza®, and has the commercial rights to pre-NDA COPD product Duaklir®.

For more information on Circassia please visit [www.circassia.com](http://www.circassia.com).

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## Investment proposition

### **Our growth strategy is built on multiple pillars**

Circassia's strategic objective is to build a world-class, self-sustaining, specialty pharmaceutical company focused on respiratory disease.

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## Adding to our marketed products

As part of a new commercial collaboration with AstraZeneca we have added chronic obstructive pulmonary disease (COPD) treatment Tudorza® to our portfolio in the United States, alongside our NIOX® asthma management products. We also added late-stage COPD product Duaklir®, and with its US clinical development now complete we look forward to its filing in the near future.

### **NIOX® and asthma**

Our market-leading NIOX® system is used by physicians around the world to help improve asthma diagnosis and management. Our current generation NIOX VERO® device is available across major markets, including the US, Europe, Japan and China.

### **Tudorza®, Duaklir® and COPD**

As part of a transformational partnership with AstraZeneca we commercialise the COPD treatment Tudorza® in the United States. We also have the US commercial rights to COPD combination therapy Duaklir®, which AstraZeneca plans to file for approval in the first half of 2018.

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## Major opportunities in a major market

Asthma and COPD are major causes of mortality and morbidity, and consequently are a significant healthcare burden. The treatment market represents a major opportunity, with inhaled therapies accounting for estimated revenues of approximately \$20 billion in 2017.

### \$2.6bn

US sales of respiratory treatments containing long-acting muscarinic antagonists (LAMAs) reached an estimated \$2.6 billion in 2017.

### 2.4%

At the end of the year, Tudorza® prescriptions accounted for approximately 2.4% of this market. Just a modest increase in market penetration would represent a major increase in revenues for Circassia.

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## Global sales infrastructure

Our direct sales teams sell our products in the United States, United Kingdom and Germany, while our Beijing-based commercial group manages local distributors in China. Our wider network of international partners targets customers in more than 35 additional countries.

### USA

The United States is responsible for the majority of our revenues, and our US field force promotes both NIOX® and Tudorza® across the key regions of the country. Research Triangle, North Carolina is home to our commercial headquarters, as well as our US distribution centre for NIOX®.

### Europe

Our global headquarters are located in Oxford, UK where our corporate, research and development and international distributor management is based. Our UK sales team is supported from our Oxford base, while our German field force works from our Bad Homburg office and our NIOX® distribution centre is located in Uppsala, Sweden.

### Oxford, UK

Global headquarters, global R&D and UK commercial operations

### Research Triangle, North Carolina, USA

US commercial operations and NIOX® distribution

### Bad Homburg, Germany

Sales and marketing

### Uppsala, Sweden

Europe and RoW NIOX® distribution

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## Global network

### Specialty sales teams

Our direct sales teams target specialist and key primary care physicians in a number of key countries. During 2017, we doubled our US sales force and our UK team became well established following its launch at the end of 2016. In Germany, our local team continued NIOX® promotion, while our China organisation supported local distributors in this major market.

### Distribution partners

Our network of international partners distribute our NIOX® products in territories beyond those covered by our direct sales teams. Our network currently covers over 35 countries and we are exploring additional opportunities to extend this further.

### Asia

China and Japan are major markets for our NIOX® products. Our Beijing-based commercial team currently manages a number of distributors in China, while we work with a well-established distributor to sell our products in Japan. A number of other Asian countries, such as South Korea, offer significant potential and we are working with our distributors to increase our revenues in these markets.

### Beijing, China

Commercial operations

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## Rapidly growing revenues

During 2017, we established a transformational commercial collaboration with AstraZeneca in the United States. Under the initial profit share we promote the COPD treatment Tudorza® alongside our NIOX® products. During 2017 Tudorza® contributed to our business for over half of the year, while our global NIOX® sales continued to grow strongly throughout the period. As a result, we increased our revenues 100% compared with 2016.

**100%**

In 2017 we doubled our revenues compared with the prior year. NIOX® sales increased 18% to £27.3 million and our Tudorza® collaboration contributed £19.0 million to our top line.



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## Robust cost controls

As well as continuing our focus on revenue growth, we maintained robust control of our costs. Following the difficult decision to cease investment in the allergy field, we scaled back our in-house R&D\*, reducing expenditure by over 50% in 2017 compared with the year before, and reducing our R&D headcount by approximately 40%. We also cut our G&A costs, reducing expenditure by over 25%.

### £29.0 million

During 2017, we reduced our in-house R&D expenditure by £25.0 million compared with 2016 and decreased our G&A expenditure by £4.0 million. This combined saving of £29.0 million represents an overall reduction of nearly 50% in these two major cost centres.

\*In-house R&D: includes expenditure on underlying and discontinued operations excluding impairments to better reflect management expenditure at the time of operation

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## Moving our pipeline forward

Our most advanced pipeline product, Duaklir®, recently completed its US development programme and is awaiting regulatory filing. Our pipeline also includes direct substitutes of leading asthma and COPD products, as well as a number of treatments based on novel formulations of currently approved drugs, which we plan to out-license / partner as part of our refocused investment strategy.

### Direct substitute products

Our products target the direct substitution of a number of leading respiratory medicines, including Seretide® pMDI and Spiriva® DPI. These development programmes leverage regulatory procedures that permit approval based on the demonstration of product equivalence.

### Novel formulations

We have two specialist COPD development-stage treatments based on novel formulations of approved molecules. The most advanced of these is a combination long-acting muscarinic antagonist / long-acting beta agonist (LAMA / LABA) product that features an innovative smart nebuliser in-licensed from medical innovation company Philips.

## Our portfolio

Our portfolio includes a broad range of asthma and chronic obstructive pulmonary disease products. As part of our refocused investment strategy we plan to out-license / partner a number of programmes, leveraging third-party financing for their development.

Product	Research	Preclinical	Phase I	Phase II	Phase III/ Substitute	Approved	Marketed
NIOX VERO® / NIOX MINO®							
Tudorza® US*							
Duaklir® US**							
Flixotide® pMDI substitute***							
Flovent® pMDI substitute***							
Seretide® pMDI substitute							
Spiriva® DPI substitute							
Novel LABA/LAMA formulation							
Novel COPD therapy formulation							

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## Chairman's statement

Circassia has focused resolutely on building its respiratory franchise, and consequently has transitioned into a very different business in a relatively short period.

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I am pleased to report that Circassia made good progress in 2017, achieving significant growth following the major changes to its business the prior year. With its investment in the allergy field halted, Circassia has focused resolutely on building its respiratory franchise, and consequently has transitioned into a very different business in a relatively short period. Circassia is now highly commercially focused, with a broad sales infrastructure, which it plans to expand further through a refocused investment strategy, and a portfolio of marketed products.

### **Building strategic momentum**

In 2016, the Board reviewed and reconfirmed Circassia's strategy of building a self-sustaining specialty pharmaceutical company focused on respiratory disease. At the end of 2016, the Company significantly expanded its US commercial platform, both to increase revenues from its in-house NIOX® products and to attract in-licensing, partnering and acquisition opportunities. This growth strategy proved successful, and in 2017 Circassia established a flagship US partnership with AstraZeneca for the chronic obstructive pulmonary disease (COPD) products Tudorza® and Duaklir®. With the collaboration making good progress, Circassia plans to build on this momentum by deploying a refocused investment strategy pursuing a similar approach in China. By leveraging its existing presence in the country to establish an initial sales force, Circassia plans to boost its NIOX® revenues and provide a commercialisation option for third-party products in this major market.

### **Refocused investment strategy**

Under its refocused strategy, Circassia intends to reallocate its resources and complete its transformation into a commercial business. The Company plans to fund commercial investment through a combination of growing revenues, corporate cost containment and reductions in research and development (R&D) expenditure by seeking to out-license / partner its respiratory pipeline of directly substitutable generic products and novel formulations of currently approved drugs. These development candidates are based on approved molecules, thereby reducing their risk profile, and the Company plans to initiate discussions with a number of potential partners. This strategy will allow Circassia to retain a stake in the products' future potential success whilst utilising third-party financing to progress the programmes through development. The Company will continue to invest in its R&D, medical affairs, pharmacovigilance, quality and regulatory activities supporting its US COPD products and global NIOX® franchise.

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**Dr Francesco Granata**  
Chairman

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During the past year Circassia has made significant strategic progress, and with its refocused investment strategy the Company plans to complete its transition into a commercial business in the coming months. As a result, in a period of just two years Circassia will have transformed from an R&D-focused organisation into a growing commercial business with increasing revenues and global commercial infrastructure.

#### **Significant operational progress**

Throughout 2017, the Company's operational execution has underpinned this strategic progress. Following the establishment of its collaboration with AstraZeneca, Circassia rapidly doubled the size of its US field force, recruiting, training and launching the enlarged team in under two months. This new sales team has performed well, and at the end of the year Tudorza® prescriptions were significantly ahead of the declining trend established prior to Circassia's full promotion and are set for future growth. In parallel, Circassia's global commercial team continued to grow NIOX® revenues, while the R&D team filed for additional NIOX® approvals. The Company also advanced its broader pipeline, in-licensing novel nebuliser technology from Philips and preparing several programmes for clinical studies, positioning the products for potential out-licensing / partnering under Circassia's refocused investment strategy.

#### **Evolving team**

The rapid changes to Circassia's business are reflected in the make-up of its team. During 2017, the commercial group grew substantially, accounting for over 75% of the Company's headcount at the end of the year, while the R&D team was reduced by approximately 40%. This changing profile also extends to the Board. Circassia recently welcomed new Non-Executive Directors Jo Le Couiliard, Sharon Curran and Dr Heribert Staudinger, who bring significant commercial, specialty pharmaceutical and respiratory development experience to the Company. At the same time, the Board thanks Dr Jean-Jacques Garaud and Marvin S Samson for their invaluable advice and strategic counsel, and wishes them well on their retirement at the forthcoming Annual General Meeting.

#### **Positioned for growth**

With a period of extensive change nearing completion, Circassia is emerging as a strong, commercially-focused specialty pharmaceutical business. The Company's revenues doubled in 2017 and are positioned for further growth. During the coming year, Circassia plans to drive sales in its NIOX® franchise, building on positive new recommendations issued by the UK's National Institute for Health and Care Excellence (NICE). The Company will also benefit from a full year's revenues from its Tudorza® collaboration. In the coming year, Circassia anticipates exercising its option to acquire the full US commercial rights to Tudorza® from AstraZeneca and looks forward to its partner filing for Duaklir® approval.

During 2018, Circassia intends to leverage the ongoing momentum in its business, continuing its transition towards self-sufficiency. It plans to extend its commercial platform in China and seek additional third-party products to commercialise through its specialty infrastructure. Having undergone a period of difficult decisions and great change, Circassia's ambition to build a world-class global specialty pharmaceutical company, creating significant shareholder value, remains stronger than ever.

**Dr Francesco Granata**  
Chairman

# Operational and financial highlights

## Strong NIOX® progress

- Sales increased 18% (12% at CER<sup>1</sup>) to £27.3 million (2016 CER: £24.4 million)
- Direct clinical sales (non-research sales<sup>2</sup>) increased 26% (20% at CER) compared with 2016
- US clinical revenues grew 34% (27% at CER) vs 2016
- China clinical sales increased 44% (36% at CER) vs 2016
- New NICE guidelines issued in November highly supportive for FeNO testing in asthma diagnosis
- NIOX VERO® product evolution and digital app in development; targeting 2019 launch in Europe

## AstraZeneca (AZ) US commercial partnership progressing well

- Transformational transaction for COPD products Tudorza® and Duaklir®<sup>3</sup> completed April 2017
- Tudorza® profit share revenues £19.0 million from transaction completion to year end
- Tudorza® prescriptions stabilised; year ended 52% ahead of 2017 declining trend established prior to Circassia's full promotion
- Tudorza® ASCENT study met primary endpoints; compelling data to be filed for inclusion in label
- Duaklir® AMPLIFY phase III study met primary endpoints; AZ to submit NDA H1 2018
- AstraZeneca to increase equity stake in Circassia from 14.2% up to a maximum of 19.9%

## Expanding commercial growth platform

- US sales force expanded to 200 with approximately 50-strong support team
- China commercial expansion; targeting NIOX® sales growth and platform for third-party products

## 2018 investment strategy refocused

- Investment strategy increases focus on commercial expansion to drive revenue growth
- Strategic plan to out-license / partner respiratory direct substitute and novel formulation candidates
- R&D annualised expenditure to decrease by approximately £5 million
- G&A cost containment to deliver annualised savings of approximately £2 million
- S&M investment to increase approximately £7 million in 2018

+100%

Revenues increased 100% to £46.3 million  
(2016: £23.1 million)

## Financial highlights

The following table includes key performance indicators (KPIs) representing the Group's underlying operations at the time of operation; these include allergy R&D costs and exclude a one-off R&D contribution to AZ and R&D impairments

	2017 KPI*	2016 KPI*	2017 total	2016 total
Revenue	£46.3m	£23.1m	£46.3m	£23.1m
R&D expenditure	£20.9m <sup>4</sup>	£45.9m <sup>4</sup>	£97.4m	£17.8m
G&A expenditure	£11.0m <sup>5</sup>	£14.6m <sup>6</sup>	£10.9m	£14.9m
S&M expenditure	£49.6m <sup>5</sup>	£27.0m <sup>6</sup>	£49.6m	£27.2m
Group loss	£36.9m <sup>5</sup>	£35.9m <sup>6</sup>	£99.1m	£137.4m
Cash <sup>7</sup> at period end	£59.5m at 31/12/17	£82.9m at 30/06/17	£59.5m	£117.4m

£20.9m

In-house R&D expenditure<sup>4</sup>  
reduced 54% to £20.9 million  
(2016: £45.9 million)

£11.0m

Underlying G&A expenditure<sup>5</sup>  
reduced 25% to £11.0 million  
(2016: £14.6 million)

£59.5m

£59.5 million of cash<sup>7</sup>  
at 31 December 2017  
(30 June 2017: £82.9 million)

\*The Financial highlights section contains key performance indicators (KPIs) that management believes better represent the underlying performance of the Group, reflecting the functioning of the departments at the time of operation; where relevant these exclude irregular or infrequent items

<sup>1</sup> Constant exchange rates (CER) for 2016 represent reported 2016 numbers re-stated using 2017 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>2</sup> Direct clinical sales to clinicians, hospitals and distributors; research sales to pharmaceutical companies for use in clinical studies

<sup>3</sup> Duakir® is a registered trademark in Europe and other markets; use of the trademark in the US is subject to review and approval by the FDA

<sup>4</sup> In-house R&D: includes expenditure on underlying and discontinued operations excluding impairments to better reflect management expenditure at the time of operation

<sup>5</sup> Underlying operations, see consolidated statement of comprehensive income

<sup>6</sup> Underlying operations restated to show the results of the allergy business in discontinued operations; see note 10 of the consolidated financial statements for further details

<sup>7</sup> Cash, cash equivalents and short-term deposits

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## Chief Executive's review

2017 was a period of major transformation for Circassia, with the Company making good progress to becoming a commercially-focused specialty respiratory business.

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2017 was a period of major transformation for Circassia, with the Company making good progress to becoming a commercially-focused specialty respiratory business. During the year our market-leading NIOX<sup>®</sup> asthma management products continued their strong growth, and in November we welcomed new NICE recommendations that are highly supportive for our products. We also established a major US collaboration with AstraZeneca for COPD products Tudorza<sup>®</sup> and Duaklir<sup>®</sup>, and markedly expanded our specialty sales infrastructure in the United States. The partnership is making good progress, and with Tudorza<sup>®</sup> US prescriptions well ahead of the trend prior to our involvement, we aim to increase uptake in the coming year. We also received compelling clinical data from large trials of both COPD products, and we look forward to filings seeking Duaklir<sup>®</sup> approval and an extension to Tudorza<sup>®</sup>'s label.

With our revenues doubling in 2017 and our cost containment measures delivering tangible savings, we are driving our business towards self-sustainability. We intend to maintain this progress during 2018. We have refocused our investment strategy to support the ongoing expansion of our commercial platform, particularly in China, whilst reducing our R&D and corporate costs. During 2018, we will benefit from a full year's contribution from our enlarged US sales team and our collaboration with AstraZeneca, 'locking in' significant growth potential. With a strong commercial infrastructure, compelling portfolio and increasingly attractive platform for third-party products we look forward to the coming year with great optimism.

### Period of transformation

During the past year Circassia successfully underwent a number of major changes, as part of the Company's transition into a commercially-focused specialty pharmaceutical business. Following disappointing allergy clinical results in 2016, we took the difficult decision to switch investment to our respiratory assets and focus on expanding our business. This strategy has produced positive results, and with our portfolio of marketed products and commercial platform now significantly broader, our 2017 revenues were 100% ahead of the previous year.

### Commercial growth

In the last 12 months we have expanded our commercial presence dramatically. In the United States we established a transformational commercial collaboration with AstraZeneca, and subsequently doubled the size of our field force to promote the COPD treatment Tudorza<sup>®</sup> alongside our NIOX<sup>®</sup> asthma management products. We also increased our commercial support capabilities, and the team, which includes marketing, market access, training, analytics and commercial operations, is now more than 50 strong. With our US commercial platform acting as an important factor in attracting AstraZeneca as a strategic partner, we plan to mirror this strategy in China. By building an initial sales force alongside our existing distributor base we plan to rapidly grow our NIOX<sup>®</sup> revenues in this major market, and offer third-parties the opportunity to commercialise their products via our infrastructure.



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**Steven Harris**  
Chief Executive Officer

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#### **Broadening the portfolio**

As well as adding Tudorza® to our portfolio, our AstraZeneca collaboration brought the US commercial rights to late-stage COPD therapy Duaklir®. At the end of 2017, the product successfully completed its US clinical development programme. As a result, we look forward to its filing in the first half of 2018, potentially further broadening our portfolio of marketed respiratory treatments. During 2017 we also took steps to advance our in-house pipeline, licensing smart nebuliser technology to incorporate in our LAMA / LABA novel formulation development programme. We now plan to out-license / partner this and our other pipeline products based on currently approved drugs, to leverage third-party funding for their development. This refocused investment strategy will enable us to rapidly complete our transition into a fully commercially-focused business, whilst retaining a financial stake in the potential future success of our pipeline products.

#### **'Locking in' future growth**

The significant investments we made in 2017, expanding our commercial infrastructure and establishing our AstraZeneca partnership, are designed to 'lock in' growth in the coming years. During 2018 we will benefit from a full year's contribution from our Tudorza® collaboration, as well as broader promotion of our NIOX® products in the United States. We also anticipate having the first opportunity to acquire the full US commercial rights to Tudorza® during the year. In 2019, we anticipate a full year of Tudorza® revenues, increased NIOX® sales in China, and initial sales of Duaklir® following US approval. Alongside this growth, we plan to continue our business development activities, seeking to further expand our portfolio through in-licensing, acquisition or partnering.

#### **Positive outlook**

Having transformed our business during the past year, we look forward to the future with optimism. We anticipate ongoing significant revenue growth from our commercial portfolio, we plan to continue expanding our commercial platform and we expect to fund any payment to AstraZeneca for the full US commercial rights to Tudorza® through third-party financing or a vendor loan. With our cost containment measures delivering savings and our investment strategy focused on our commercial business we are building a strong and highly differentiated company. With continuing robust sales growth, a portfolio of exciting products and expanding commercial presence, we are highly positive about the coming year.

**Steven Harris**  
Chief Executive Officer

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# Business model

| Our business model is designed for efficient product development and commercialisation.

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Circassia development      Circassia      Circassia commercialisation

Development partners      Manufacturing partners      Commercial partners

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**Circassia's business model is focused on building value through the in-house retention of core expertise and efficient outsourcing of support functions. Circassia's expertise includes corporate development, product commercialisation, strategic development, intellectual property management, device development, clinical study design and regulatory affairs. The Company uses a range of external experts to deliver support activities, including manufacturing, contract research and commercialisation in territories beyond Circassia's direct sales presence.**

#### **Circassia's partners**

- PHC for NIOX® supply and ITG for sensor manufacture
- Commercialisation partners for NIOX® products outside the United States, United Kingdom and Germany
- AstraZeneca and third-parties for manufacture and supply of Tudorza® and Duaklir®
- AstraZeneca for distribution, pharmacovigilance and regulatory support for Tudorza®
- AstraZeneca for filing Duaklir®'s NDA and Tudorza®'s label extension sNDA
- Contract manufacturing organisations for production of pipeline products and fill-finish
- Parexel for clinical study
- Mylan for commercialisation of lead direct substitute product in specific territories\*

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

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# Strategy and progress against objectives

Circassia's goal is to build a self-sustaining, world-class specialty pharmaceutical business.

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Circassia has three strategic objectives as part of its overarching ambition to become a leader in its field. The Company aims to build significant shareholder value by:

- i) promoting its specialty products direct in key markets;
- ii) developing a broad portfolio of treatments; and
- iii) delivering its pipeline. By delivering against each of these three objectives, Circassia intends to build a highly attractive business.

## Strategic objectives

### Marketing specialty products direct to customers in key markets

We market our NIOX® asthma management products directly in the key United States market, as well as promoting COPD treatment Tudorza® under our commercial collaboration with AstraZeneca. We also sell NIOX® directly to customers in the United Kingdom and Germany, and have a commercial team based in Beijing managing our local distributors in the Chinese marketplace. Elsewhere we have a network of international partners that sell our NIOX® products in more than 35 additional countries.

### Building a broad and balanced portfolio

We have a number of respiratory products in our portfolio. Our COPD treatment Duaklir® is awaiting filing for approval in the United States and we are developing an evolutionary update to enhance our currently marketed NIOX VERO® product. In addition, we are increasingly well positioned to attract third-party products to our portfolio through in-licensing, acquisition or partnering, exploiting our expanding commercial capabilities.

### Delivering pipeline products

We aim to advance our pipeline of asthma and COPD treatments, while also maintaining our focus on cost control. In the first half of 2018 we look forward to the US filing of our lead COPD product candidate Duaklir®. We also aim to advance our products targeting direct substitution of leading respiratory medicines, as well as our specialty COPD products based on novel formulations of currently approved drugs, through out-licensing / partnering.

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

**Deliver the pipeline**

**Market novel  
products**

**Build broad and  
balanced portfolio**

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## Progress in 2017

During the past year we continued to make good progress towards each of our strategic objectives. We dramatically increased our commercialisation capabilities, particularly in the United States, and we established a collaboration with AstraZeneca expanding our portfolio with COPD products Tudorza® and Duaklir®. We also continued to advance our pipeline, in-licensing smart nebuliser technology from Philips to incorporate into one of our development programmes.

### Marketing products directly

In the past year we substantially increased our commercial presence in the key US market, doubling the size of our field force and boosting our support capabilities. Our enlarged US sales team now promotes COPD product Tudorza® as part of our commercial collaboration with AstraZeneca, alongside our NIOX® products. In the UK, our direct field force performed well during its first full year and as a result UK revenues were 134% ahead of 2016. Revenues in Germany declined somewhat due to local restructuring, which is now delivering results. In the coming year we intend to build on our momentum, launching a sales force in China to extend our NIOX® sales. This commercial expansion will also build a platform to attract third-party products in this important market.

### Building the portfolio

During 2017 we made good progress broadening our portfolio of marketed and late-stage products. In April, we established a transformational partnership with AstraZeneca for COPD products Tudorza® and Duaklir®. Under the terms of the agreement, we promote Tudorza® direct to physicians while AstraZeneca is responsible for manufacturing, supply, pharmacovigilance and regulatory activities. The partnership is progressing well. During the year Tudorza® achieved compelling positive results in a large-scale post marketing study and the product's prescription levels are well ahead of the trend established prior to Circassia's involvement. In addition, Duaklir® completed its US clinical development programme, achieving positive phase III results, and awaits filing in Q2 2018.

### Delivering the pipeline

Alongside our 2017 commercial progress we also advanced our pipeline. We received FDA clearance for our NIOX VERO® six second test mode and filed the product for approval in a number of additional territories. We completed EU certification for our NIOX VERO® primary ciliary dyskinesia screening application, which we launched at the European Respiratory Society meeting and subsequently received clearance for its use in Australia and South Korea. We also continued to progress our other respiratory pipeline programmes, in-licensing smart nebuliser technology from Philips for use in our LABA / LAMA novel formulation product, which targets specialist COPD treatment. We plan to out-license / partner these programmes as part of our refocused investment strategy, to leverage third-party financing for their development.

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## Operating review

Circassia made significant progress during the past year, continuing its transition into a commercial specialty pharmaceutical business focused on respiratory disease.

Circassia made significant progress during the past year, continuing its transition into a commercial specialty pharmaceutical business focused on respiratory disease. The Company established a transformational US commercial collaboration with AstraZeneca for the COPD products Tudorza® and Duaklir® and its NIOX® asthma management franchise continued to grow strongly. Circassia expanded its commercial growth platform, doubling its US sales force to promote both Tudorza® and NIOX®, and its UK direct sales team performed well during its first full year since launch. As a result, the Company's revenues grew by 100%, while in parallel, Circassia's cost control measures delivered savings.

### **NIOX® asthma management products**

Fractional exhaled nitric oxide (FeNO) is an important biomarker of underlying Th2 airway inflammation, and its measurement is increasingly recognised as a valuable component of asthma diagnosis and management. NIOX® is the leading point-of-care FeNO testing system available across major markets and the current VERO® generation is sold in a large number of countries, including in the US, Europe, Japan and China.

### **Strong sales performance**

NIOX® revenues continued to grow strongly during 2017, increasing 18% to £27.3 million (12% at CER). Sales for clinical use (ie excluding sales to pharmaceutical companies for use in clinical trials) increased at a faster rate, growing 26% worldwide (20% at CER), 34% in the United States (27% at CER) and 44% in China (36% at CER). In the UK, revenues more than doubled compared with 2016, increasing 134% during the first full year since the Company established its direct sales capability. Revenues in Germany declined by 5% (11% at CER) due to local restructuring to focus on market access and revised pricing to encourage greater test usage, which is now delivering results. Research sales to pharmaceutical companies also offset the growth in clinical sales to some extent, with these less controllable revenues decreasing 8% (13% at CER) in 2017 compared with the prior year.

### **Expanding access**

In 2017, Circassia continued to expand market access for its NIOX® products. In the United States, we established new agreements with over 50 major healthcare providers and recently signed an Innovative Technology contract with Vizient Inc., the largest member-owned healthcare company in the country. In parallel, our market access team extended NIOX® coverage to an additional nine million Americans and at the beginning of 2018 Medicare increased its FeNO testing reimbursement rate.

**1, Expanding NIOX® market access**  
In the United States, we established new agreements with over 50 major healthcare providers.

**2, NIOX® web portal**  
We plan to roll out a digital promotional strategy, which includes the use of targeted channels alongside a relaunch of our flagship NIOX.com web portal.

### Improving distributor performance

We sell NIOX® directly in the US, UK and Germany, and in a large number of additional countries through a network of international partners. During 2017, we extended our distributor base in the Middle East and we continue to review commercialisation opportunities in Canada and South East Asia. We are also undertaking initiatives to assist our distributors' performance, including the provision of dedicated NIOX® training to improve local promotion. We intend to continue this distributor support in 2018 with the provision of tailored marketing materials.

### Expanding NIOX® clearances

As part of our NIOX® growth strategy, we are seeking product clearances in additional territories and for new applications in existing markets. During 2017, we submitted regulatory filings for NIOX VERO® in Singapore and South Korea, and recently we received approval from the authorities. We also plan to complete submissions in Mexico, Taiwan and Saudi Arabia. In Europe, we launched a primary ciliary dyskinesia screening application for NIOX VERO® at the world's largest respiratory conference, the European Respiratory Society International Congress. This new application was subsequently cleared for use in Australia and South Korea. We also made regulatory progress in the United States, where the VERO®'s six second test mode received FDA clearance, providing physicians with an additional option that can be easier for children to use.

### NIOX® brand strategy development

As well as extending access to NIOX®, our commercial team has evolved the product's brand strategy to enhance its promotion. As part of a new 2018 marketing campaign, we have developed revised selling materials, customer economic modelling tools, pricing and payment options and enhanced visual aids. We plan to roll out a digital promotional strategy, which includes the use of targeted channels alongside a relaunch of our flagship NIOX.com web portal. The 2018 campaign will also include updated advertising, which is built around a new core theme: "If you could see it you would treat it differently". Creative work and market testing of potential adverts is nearing completion and roll out is planned for the coming months.

### New publications support FeNO testing

At the end of November, the UK's National Institute for Health and Care Excellence (NICE) published new clinical guidelines recommending the use of FeNO testing as a key component of asthma diagnosis. The guidelines call for the establishment of diagnostic hubs to achieve economies of scale when implementing the new recommendations. This provides Circassia with the opportunity to target Clinical Commissioning Groups throughout the UK to help implement the NICE guidance locally. As a result, we plan to assess opportunities to expand our current commercial organisation to leverage these recommendations.

The new NICE guidelines were subsequently complemented by publications in the US and Germany. In the United States, the government Agency for Healthcare Research and Quality published an evidence report that highlights the use of FeNO testing as a valuable part of asthma diagnosis and management. In Germany, new guidelines issued by leading German and Austrian respiratory societies confirmed the important role FeNO testing can play in assisting asthma assessment and treatment.

### NIOX® product evolution

During 2017 we completed market research with NIOX® users to identify potential improvements to the system. The results revealed strong satisfaction with the current VERO® device, as well as uncovering a number of areas where we could enhance the NIOX® user experience without requiring modifications to the core technology. As a result, we plan to introduce a rapid evolution to the current product, incorporating enhancements to the screen, user interface and power consumption. This update will also exploit NIOX®'s existing Bluetooth capability and cloud connectivity, providing additional iOS and Android functionality. Development work for this evolution is underway and we plan to launch the new upgrade in 2019 in Europe.

# Operating review continued

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## 3, Tudorza® prescription rate

By the end of the 2017, previous declines were stabilising and prescriptions were more than 50% above the 2017 trend established prior to Circassia's full promotion of the product.

## 4, Significant growth opportunity

Tudorza® offers Circassia a significant growth opportunity. With over 15 million Americans diagnosed with COPD, the disease is the third leading cause of death in the United States.

## AstraZeneca US commercial collaboration

In the first half of 2017, we established a transformational commercial collaboration with AstraZeneca in the United States. Under the terms of the agreement we have an initial profit share arrangement for the COPD mono-therapy Tudorza®, with an option to acquire the full commercial rights exercisable from H2 2018. In addition, we acquired the commercial rights to the late-stage COPD combination product candidate Duaklir®.

The transaction structure is attractive, with AstraZeneca taking a 14% equity stake in the Company as upfront consideration of \$50 million. Further payments are deferred with the exact level payable dependent on the success of the two products, and will be based on Tudorza®'s in-market sales and Duaklir®'s approval. Acquisition of Tudorza®'s full US commercial rights will trigger a payment of between \$5 million and \$80 million, and a further \$100 million will be payable on Duaklir® approval, or at the end of H1 2019 if earlier. We anticipate satisfying these payments through third-party financing, and have agreed a vendor loan with AstraZeneca as a back stop.

AstraZeneca has agreed to increase its equity stake in Circassia. As a result, Circassia intends to issue AstraZeneca additional ordinary shares in the Company's share capital, subject to shareholder approval, such that AstraZeneca will increase its holding from 14.2% up to a maximum of 19.9%. Circassia will use the proceeds to fund a deferred R&D contribution of \$20 million, which is payable by the end of 2018 under the agreement with AstraZeneca, and part fund a final R&D contribution of \$25 million payable by the end of 2019. Additionally, AstraZeneca has agreed to include any remaining R&D contribution not paid by the end of 2019 in the loan arrangements in the existing development and commercialisation agreement. Circassia anticipates receiving approximately \$9 million of tax credits relating to these R&D contribution payments.

## Tudorza® commercial progress

Tudorza® contains the long-acting muscarinic antagonist (LAMA) aclidinium bromide. It is indicated for the long-term maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema. This twice-daily inhaled therapy is approved in the United States, and is available under a number of brand names in many countries around the world. Under our Tudorza® profit share arrangement we have responsibility for the product's promotion while AstraZeneca manages manufacturing, supply, regulatory and pharmacovigilance activities.

During the first year of our collaboration, Tudorza® has made good progress. By early June 2017 we had doubled the size of our sales force, completing the recruitment and training in under two months. We subsequently reached and exceeded our call targets well ahead of schedule and continue to regularly complete over 6,000 sales calls per week. Our 200-strong sales force is now supported by a team of over 50, including marketing, analytics, market access, training and medical affairs experts. Our Tudorza® promotional plan is highly focused, targeting the majority of existing customers and the modest number of physicians who account for the highest number of COPD prescriptions. The plan includes a significantly increased intensity of sales calls, with Tudorza® featuring in the number one product detailing position.

Less than a year since we began promoting Tudorza®, prescription rates have begun to respond positively. By the end of the 2017, previous declines were stabilising and prescriptions were more than 50% above the 2017 trend established prior to Circassia's full promotion of the product. As a result, we received £19.0 million in revenues from the profit share arrangement for the period from the completion of the transaction in April to the end of the year. Prescription levels continue to respond to promotion, and during the first quarter of 2018 we halted the previous decline and prescriptions are now stable at approximately 4,700 per week. During 2018 we plan to build on this progress and aim to increase product uptake. We recently began to roll out a new Tudorza® "TUNIGHT + TUMORROW" marketing campaign, which includes a range of new sales materials highlighting the benefit of twice-daily dosing, significantly improving lung function with an evening and morning dose.

Tudorza® offers Circassia a significant growth opportunity. With over 15 million Americans diagnosed with COPD, the disease is the third leading cause of death in the United States. As a result, the US pharmaceutical treatment market was estimated to exceed \$5 billion in 2017. At the end of the year, Tudorza® accounted for approximately 2.4% of US LAMA-containing prescriptions. A modest increase in market share would substantially increase Circassia's revenues and third-party estimates suggest the product has annual peak sales potential of over \$90 million.



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Our newly-expanded US commercial platform was an important factor in attracting AstraZeneca as a partner.

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#### **Tudorza® clinical progress**

In December 2017, Tudorza® successfully completed a phase IV post-marketing study requested by the FDA. This large study, which was conducted in approximately 3,600 patients with moderate-to-very severe COPD and cardiovascular risk factors, met its primary efficacy and safety endpoints. Secondary endpoints included the rate of hospitalisations due to COPD exacerbations. The results demonstrate that alongside background therapy Tudorza® is effective at reducing exacerbation rates in patients with cardiovascular disease or risk factors. AstraZeneca plans to present these compelling data at a forthcoming medical meeting, and to submit them to the FDA seeking inclusion in the product's label. If successful this would present a competitive advantage for Tudorza® as other LAMAs do not have these cardiovascular safety data in this at-risk population included in their prescribing information.

#### **Duaklir® progress**

Duaklir® is a twice-daily inhaled fixed-dose combination COPD product. It contains the same LAMA as Tudorza®, aclidinium bromide, in combination with the long-acting beta agonist (LABA) formoterol fumarate. The product is approved in a number of countries under several brand names, and during the second half of 2017, the US development programme made significant clinical progress. The product successfully completed its phase III study, AMPLIFY, in which it met both co-primary efficacy endpoints achieving significant lung function improvements compared with the individual LAMA and LABA components. Additionally, a sub-study of 24-hour bronchodilation showed that twice-daily products Duaklir® and Tudorza® demonstrated significantly greater night-time bronchodilation than once-daily Spiriva®. These positive results were supported by data from the ACHIEVE dose-ranging study, which showed Duaklir® contains the optimal dose of formoterol. AstraZeneca plans to incorporate these clinical studies in a New Drug Application (NDA) for Duaklir®, which it intends to submit to the FDA in the first half of 2018. Duaklir® targets a significant market opportunity, with third-party estimates suggesting annual peak sales potential of over \$180 million.

#### **Commercial platform expansion**

In 2017, our newly-expanded US commercial platform was an important factor in attracting AstraZeneca as a partner. In the coming year, we intend to pursue this strategy beyond the United States, expanding our infrastructure to drive NIOX® growth and facilitate further in-licensing, partnering or product acquisition. To lead this expansion, we recently recruited the Head of Commercial Operations, Asia Pacific from Takeda, who has taken up the newly-created role of Senior Vice President, Commercial for Europe and Rest of World.

As part of our expansion strategy, we recently initiated a recruitment campaign in China and established a local subsidiary alongside our existing representative office. In the coming weeks, we plan to increase our Beijing-based team, which currently manages local distributors, and establish a commercial 'back office'. This will be complemented by a team of sales managers targeting new customers in key regional centres, enabling us to accelerate NIOX® sales in this important market. Later in the year we intend to recruit a modest sales force, which will complement our existing distributor base.

This new team will allow us to target top grade hospitals that are not currently NIOX® customers. We anticipate this strategy will substantially increase our China revenues beyond the £3.5 million achieved in 2017, which was itself an increase of 44% on the previous year. In addition, we anticipate our expanded capabilities will offer potential partners a commercialisation alternative in this major market.

#### **Respiratory pipeline portfolio**

Circassia's pipeline includes a number of respiratory products based on approved molecules, which are currently in clinical development or positioned to move into the clinic. Under our refocused investment strategy we now plan to out-license / partner these substitutable generic products and novel COPD treatment formulations to leverage third-party funding while retaining upside potential.

# Operating review continued

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## 5, US sales force doubled

Our 200-strong sales force is now supported by a team of over 50, including marketing, analytics, market access, training and medical affairs experts.

## 6, Targeting leading asthma and COPD products

The most advanced substitute product is a particle-engineered formulation targeting direct substitution of GlaxoSmithKline's Flixotide® pMDI.

## Substitutable generic products

Circassia's portfolio of substitute products target a number of marketed asthma and COPD treatments, exploiting regulatory processes that permit approval based on the demonstration of equivalence.

- The most advanced of these products is a particle-engineered formulation of the inhaled corticosteroid fluticasone propionate, which targets direct substitution of GlaxoSmithKline's Flixotide® / Flovent® pMDI. Prior to Circassia's ownership the product was out-licensed in key territories, including Europe and the US. With the United States remaining the main commercial opportunity, we sought to regain rights for the more modest European market. However, we did not reach agreement and the product rights remain with our partner.
- Our combination formulation containing fluticasone propionate and the LABA salmeterol xinafoate targets direct substitution of GSK's Seretide® pMDI. This targets a major market opportunity with GSK's product in pMDI and DPI formats achieving global sales of over \$4 billion in 2017. During 2017 we initiated an additional pharmacokinetic study having further adjusted the product following previous iterative studies, and we anticipate receiving the results in the near future.
- Our formulation of tiotropium bromide targets direct substitution of Boehringer Ingelheim's LAMA, Spiriva Handihaler®. This represents a significant commercial opportunity, with Spiriva®'s total global revenues estimated to total over \$3 billion in 2017. We recently completed manufacture of stability batches of our formulation in preparation to begin an initial pharmacokinetic clinical study.

## Novel COPD treatment formulations

Circassia's development candidates targeting the specialist treatment of COPD are based on novel formulations of approved drugs. The most advanced of these, a combination LAMA / LABA, incorporates mesh nebulisation technology in-licensed from medical innovation company, Philips Respiratory Drug Delivery. This next generation hand-held nebuliser is battery powered, easy-to-clean, Bluetooth enabled and features a breath actuation algorithm to improve usability. Our development programme advanced during 2017 and we recently completed manufacture of stability batches in preparation for a dose-ranging clinical study of the mono-components.

Our second development programme focuses on a novel formulation of an approved product that targets the treatment of severe COPD in patients with a history of exacerbations. Circassia's development programme aims to improve the efficacy and tolerability profile of the marketed product for use in this at-risk population.

## Cost containment

Following receipt of disappointing allergy clinical results in 2016 and 2017, we moved quickly to halt investment in the field and contain costs in our R&D activities and administrative functions. This included consolidating our facilities in the US, UK and Sweden and reducing the size of our R&D team. These measures have resulted in significant savings. Our G&A costs decreased over 25% during 2017 following the closure of our offices in Chicago and Solna, Sweden. In addition, we reduced our in-house R&D expenditure, with R&D headcount approximately 40% lower at the end of the year.

## Refocused investment strategy

During the coming year, we intend to build on these cost containment measures as part of a refocused investment strategy. This strategy is designed to complete our transition into a fully commercially-focused specialty pharmaceutical business, with rapidly growing revenues, strong commercial platform and expanding product portfolio. The strategy has a number of key elements:

### 1. Commercial expansion

We plan to continue investing in our commercial platform to drive revenues from our existing portfolio and attract additional third-party products through acquisition, in-licensing and partnering. In particular, we are building an initial sales force in China to rapidly increase our sales and build on the 44% growth achieved in 2017. We also intend to review opportunities to expand our UK sales organisation to leverage the opportunity created by the publication of new NICE guidelines in 2017.

### 7. China expansion

Our China expansion is progressing well, and we intend to significantly increase NIOX® sales and seek additional products to commercialise through our platform.

### 2. R&D refocusing

We intend to reduce our R&D investment and focus on supporting regulatory, medical affairs, pharmacovigilance, quality and supply chain activities for Tudorza® and Duaklir® and developing a near-term evolution of NIOX VERO® and subsequent next generation NIOX® product. In parallel, we plan to out-license / partner our respiratory pipeline portfolio based on currently approved products, which will allow us to retain potential financial upside whilst leveraging third-party funding for their development. A number of these candidates are positioned to enter the clinic, and clinical pharmacokinetic results are anticipated for the Seretide® pMDI substitute in the coming weeks.

### 3. Cost containment programme

Alongside the reductions in our R&D activities we plan to continue our broader programme of cost containment. In particular, we plan to decrease corporate overheads and reduce expenditure at our Oxford headquarters, including further consolidation of our facilities.

By implementing this investment strategy we plan to drive continued revenue growth from our portfolio of marketed products, while providing the financial flexibility to pursue additional product and geographical expansion opportunities. As a result of these measures, we expect annualised cost reductions of approximately £5 million in our R&D and approximately £2 million in our corporate expenditure, while increasing our 2018 sales and marketing investment by approximately £7 million.

### Summary and outlook

During the past year, Circassia made significant progress in its transition to a fully-fledged commercial specialty pharmaceutical business focused on the respiratory field. With sales of our NIOX® asthma management products growing strongly, our flagship COPD collaboration with AstraZeneca making good progress and our commercial platform expanding, we are building a highly attractive business.

In the coming year, we plan to capitalise on this momentum to complete our commercial transformation. Our China expansion is progressing well, and we intend to substantially increase NIOX® sales while seeking additional products to commercialise through our platform. In the United States, we look forward to regulatory submissions for Duaklir® approval and to extend Tudorza®'s label. We will continue our focus on growing Tudorza® revenues, leveraging our new marketing campaign and established field force, while also exploiting our commercial capabilities to promote NIOX® to a larger potential customer base. In parallel, we plan to progress development of our NIOX VERO® evolution, while seeking partners for our respiratory pipeline.

During 2018, we anticipate continued strong revenue growth building on the significant increase we achieved in 2017. With a full year's contribution from our Tudorza® collaboration and rapidly growing NIOX® sales we have significant growth potential 'locked in'. During the second half of the year, we anticipate the opportunity to acquire the full US commercial rights to Tudorza®, which we intend to fund through third-party financing, and we look forward to updating the market on this important milestone.

Overall, Circassia has a clear strategy. Since the Company's founding we have worked hard to build a strong specialty pharmaceutical business, commercialising novel products in key markets with a broad and balanced portfolio. Circassia has made good progress towards this objective during the past year, and with compelling products and robust commercial growth platform we are closer than ever to achieving our goal.

# Financial review

The financial results for the year reflect a period of transition for Circassia.

The financial results for the year reflect a period of transition for Circassia. The Company increased its revenues by 100% to £46.3 million (2016: £23.1 million) while reducing its in-house research and development (R&D) and underlying general and administrative (G&A) costs and increasing its sales and marketing investment to support its growing commercial platform. As a result, its underlying operating loss reduced to £39.6 million (2016 restated: £43.8 million) and the Group loss for the financial year from underlying activities was £36.9 million (2016 restated: £35.9 million). This is welcome progress, and a reduction in the net loss is expected in 2018 as a result of ongoing cost containment measures and increased revenues. The total loss for the period decreased to £99.1 million (2016: £137.4 million). Explanations of the difference can be found in this review.

The table on page 28 sets out results for the year ended 31 December 2017 for the Group separated into continuing and discontinued operations. Continuing operations are further divided into underlying and non-underlying operations. Underlying continuing operations include revenues and costs derived from the collaboration with AstraZeneca, as well as sales of NIOX® and costs for the existing underlying Circassia business. These are the measures primarily used by management to manage the business and measure performance. Significant irregular items are classified as non-underlying. In 2017 these include R&D contributions to AstraZeneca and impairments. Discontinued operations include direct costs and overheads associated with allergy programmes following the decision to stop all further development in the field in April 2017. The presentation of the results for the year ended 31 December 2016 has been restated in accordance with IFRS 5 to provide a clearer comparison.

## Revenue

Circassia's revenues for the year increased by 100% to £46.3 million (2016: £23.1 million). These include NIOX® sales, which increased by 18% (12% at constant exchange rates (CER)) to £27.3 million (2016: £23.1 million), and revenues of £19.0 million from the partnership with AstraZeneca for the sale of Tudorza®, which were recognised from 12 April 2017 when the companies' collaboration agreement became unconditional.

NIOX® revenues include sales for use in clinical practice, which grew by 26% (20% CER) to £22.8 million (2016: £18.0 million), sales for use in pharmaceutical company research, which decreased by 8% (13% CER) to £4.1 million (2016: £4.5 million), and other revenues of £0.4 million (2016: £0.6 million), which include freight. NIOX® clinical revenues increased by 34% (27% CER) in the United States, 44% (36% CER) in China and 134% in the UK. Revenues in Germany decreased by 5% (11% CER) following restructuring to focus on market access and revised pricing to encourage greater test usage.

Tudorza® revenues reflect 50% of the joint profit arrangement with AstraZeneca from sales of the product. AstraZeneca records in-market sales, cost of sales and other operational costs while Circassia records the costs of the field force and promotion.

Julien Cotta  
Chief Financial Officer

### Gross profit

Gross margin increased from 65% to 78%. This was mainly due to the contribution of revenues from the AstraZeneca collaboration. The gross margin was higher in H2 2017 than in H1 2017 based on these revenues for the full six month period. Gross profit on NIOX® sales was £17.3 million (2016: £15.1 million), with a gross margin of 63% (2016: 65%). This decrease mainly reflects the weakening of sterling.

### Sales and marketing

Sales and marketing costs increased to £49.6 million (2016 restated: £27.2 million). This was mainly due to an increase in the size of the US field force from 100 to 200 as part of the collaboration agreement with AstraZeneca. When including discontinued operations total sales and marketing costs decreased to £50.1 million (2016: £104.7 million), following a goodwill write-down of £74.5 million in 2016.

### R&D activities

R&D expenditure for underlying continuing operations decreased to £15.3 million (2016 restated: £17.3 million). This includes development work on NIOX® and the respiratory portfolio. In-house R&D, which better reflects expenditure at the time of operation by including underlying and discontinued operations and excluding impairments, decreased by 54% to £20.9 million from £45.9 million in 2016.

R&D expenditure for non-underlying continuing operations increased to £82.1 million (2016 restated: £0.5 million), which includes one-off costs of £45.1 million (\$62.5 million) for the R&D contributions to AstraZeneca, all of which have been expensed in the income statement in 2017. The remainder is due to impairments of product candidates in the respiratory portfolio. This includes the Seretide® pMDI substitute, for which the impairment reflects a decrease in the market potential following delays in product launch as a result of negative PK study results in the previous two years. It also includes the Flixotide® pMDI substitute (EU rights) and a partnered particle-engineered version of salmeterol xinafoate which are no longer being pursued.

Intangible	£m
Seretide® pMDI substitute	31.0
Flixotide® pMDI substitute (EU rights)	4.7
Particle-engineered version of salmeterol xinafoate	1.3
<b>Total</b>	<b>37.0</b>

Costs of £5.6 million (2016: £28.4 million) are included in discontinued operations, following the halting of expenditure on allergy programmes.

### Administrative expenditure

Administrative expenditure from continuing operations decreased by 27% to £10.9 million (2016 restated: £14.9 million). This reflects a number of cost saving measures, including the closure of the Company's sites in Solna, Sweden and Chicago, US and decreased expenditure on patent maintenance.

### Other gains and losses

Other gains for the Group increased to £10.4 million (2016 restated: £5.2 million). Included in this figure are £8.3 million (2016: £nil) of foreign exchange gains on payables to AstraZeneca due to weakening of the US dollar against sterling.

### Net finance income

Net finance costs were £2.4 million (2016 restated: £0.8 million income) for the year. Finance costs of £2.7 million (2016: £nil) reflect a charge to the income statement, which is based on the difference in the time value of money on the discounted \$100 million deferred consideration payable to AstraZeneca at the year end.

## Financial review continued

The outlook for 2018 is positive, reflecting the Company's increasing focus on commercial expansion and its intention to build on the cost containment measures achieved in 2017.

	Underlying operations		Non-underlying operations		Total continuing		Discontinued operations <sup>1</sup>		Total	
	2017	2016 Restated <sup>2</sup>	2017	2016 Restated <sup>2</sup>	2017	2016	2017	2016	2017	2016
	£m	£m	£m	£m	£m	£m	£m	£m	£m	£m
Revenue	46.3	23.1	–	–	46.3	23.1	–	–	46.3	23.1
Cost of sales	(10.0)	(8.0)	–	–	(10.0)	(8.0)	–	–	(10.0)	(8.0)
<b>Gross profit</b>	<b>36.3</b>	<b>15.1</b>	<b>–</b>	<b>–</b>	<b>36.3</b>	<b>15.1</b>	<b>–</b>	<b>–</b>	<b>36.3</b>	<b>15.1</b>
<b>Gross margin</b>	<b>78%</b>	<b>65%</b>	<b>–</b>	<b>–</b>	<b>78%</b>	<b>65%</b>	<b>–</b>	<b>–</b>	<b>78%</b>	<b>65%</b>
Sales and marketing	(49.6)	(27.0)	–	(0.2)	(49.6)	(27.2)	(0.5)	(77.5) <sup>4</sup>	(50.1)	(104.7)
Research and development	(15.3)	(17.3)	(82.1)	(0.5)	(97.4)	(17.8)	(5.6)	(28.4) <sup>4</sup>	(103.0)	(46.2)
Administrative expenditure	(11.0)	(14.6)	0.1	(0.3)	(10.9)	(14.9)	(0.2)	(0.8)	(11.1)	(15.7)
<b>EBITDA</b>	<b>(34.7)</b>	<b>(38.5)</b>	<b>(45.0)</b>	<b>(1.0)</b>	<b>(79.7)</b>	<b>(39.5)</b>	<b>(6.3)</b>	<b>(31.9)</b>	<b>(86.0)</b>	<b>(71.4)</b>
<b>Operating loss</b>	<b>(39.6)</b>	<b>(43.8)</b>	<b>(82.0)</b>	<b>(1.0)</b>	<b>(121.6)</b>	<b>(44.8)</b>	<b>(6.3)</b>	<b>(106.7)</b>	<b>(127.9)</b>	<b>(151.5)</b>
Other (losses)/gains	(1.1)	5.2	11.5	–	10.4	5.2	–	–	10.4	5.2
Share of (loss)/profit of joint venture	–	–	–	–	–	–	(0.2)	0.6	(0.2)	0.6
Finance income net	0.3	0.8	(2.7)	–	(2.4)	0.8	–	–	(2.4)	0.8
<b>Loss before tax</b>	<b>(40.4)</b>	<b>(37.8)</b>	<b>(73.2)</b>	<b>(1.0)</b>	<b>(113.6)</b>	<b>(38.8)</b>	<b>(6.5)</b>	<b>(106.1)</b>	<b>(120.1)</b>	<b>(144.9)</b>
Taxation	3.5	1.9	16.5	–	20.0	1.9	1.0	5.6	21.0	7.5
<b>Loss for the financial year</b>	<b>(36.9)</b>	<b>(35.9)</b>	<b>(56.7)</b>	<b>(1.0)</b>	<b>(93.6)</b>	<b>(36.9)</b>	<b>(5.5)</b>	<b>(100.5)</b>	<b>(99.1)</b>	<b>(137.4)</b>
<b>Cash<sup>3</sup></b>									<b>59.5</b>	<b>117.4</b>

<sup>1</sup> Disclosed as a single amount in the consolidated statement of comprehensive income.

<sup>2</sup> Restated to show the results of the allergy business in discontinued operations, see note 10 to the consolidated financial statements.

<sup>3</sup> Includes cash and cash equivalents and short-term deposits.

<sup>4</sup> Sales and marketing expenditure includes £74.5m goodwill impairment and research and development includes £0.3m intangible assets impairment.

### **Taxation**

Taxation for the year was a £21.0 million credit (2016: £7.5 million credit). The main component was the R&D tax credit on qualifying expenditure, which was £13.8 million (2016: £8.6 million). Of this £3.5 million (2016 restated: £1.9 million) is included in underlying continuing operations and has increased because of growth in expenditure on the respiratory programmes.

Included in non-underlying continuing operations is a tax credit of £16.5 million (2016: £nil). Of this, £10.2 million is an R&D tax credit (2016: £nil) for R&D contributions to AstraZeneca. The remaining £6.3 million credit relates to the reduction of a deferred tax liability as a result of impairment of intangible assets in the respiratory portfolio.

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

The loss per share for continuing operations was 29p (2016 restated: 13p), reflecting a loss for the financial period of £93.6 million (2016 restated: £36.9 million), with the increase mainly the result of non-underlying items of £82.1 million, which include the R&D contribution to AstraZeneca and impairment of intangible assets in the respiratory portfolio. Basic loss per share for the period was 31p (2016: 48p) reflecting a loss for the financial period of £99.1 million (2016: £137.4 million).

### **Statement of financial position**

The Group's net assets at 31 December 2017 were £224.8 million (2016: £280.7 million). An increase in non-current assets is offset by a similar increase in non-current liabilities and the remaining decrease mainly reflects the decrease in the Company's cash balance.

Non-current assets have increased to £312.5 million (2016: £195.7 million). This is mainly due to the recognition of assets giving rights to collaborate with AstraZeneca on the commercialisation of Tudorza® in the United States and an increase in intangible assets relating to the acquisition of Duaklir®.

Non-current liabilities have increased to £146.8 million (2016: £31.9 million). This is mainly due to the \$100 million consideration payable to AstraZeneca and recognition of the future royalties payable on Duaklir® sales.

### **Cash flow**

The Group's cash position (including short-term deposits) decreased from £117.4 million at 31 December 2016 to £59.5 million at 31 December 2017. The main cash outflow was £57.6 million cash used in operations (2016: £56.7 million). Cash used in operations decreased in H2 2017 to £23.3 million (H1 2017: £34.3 million). H2 2017 included receipt of an R&D tax credit of £8.9 million and payment of an R&D contribution to AstraZeneca of £13.1 million as well as payments for discontinued operations.

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## Financial review continued

### Outlook

The outlook for 2018 is positive, reflecting the Company's increasing focus on commercial expansion and its intention to build on the cost containment measures achieved in 2017. With anticipated savings in R&D and administration, together with the benefit of a full year of Tudorza® sales and growing NIOX® revenues, the overall net loss in 2018 is expected to decrease significantly.

With this revenue growth potential in effect 'locked in' in 2018, Circassia also anticipates the first opportunity to acquire the full US rights to Tudorza® in the second half of the year. If this option is exercised, Circassia will make further payments to AstraZeneca of between \$5 million and \$80 million dependent on Duakir®'s approval and Tudorza®'s US sales. Circassia anticipates utilising third-party financing to satisfy the consideration, and a vendor loan is in place in the event this cannot be secured.

During 2018, the Company also plans to implement its refocused investment strategy. As a result, sales and marketing costs are expected to increase by approximately £7 million in 2018, with the expanded US field force in the marketplace for the full year and the Company building a sales force in China. As part of this refocusing, annualised savings of approximately £5 million are expected in R&D expenditure compared with this year's underlying continuing operations. The reduction in R&D activities will also enable the Company to reduce its corporate and facilities overheads in Oxford, reducing anticipated G&A expenditure by approximately £2 million on an annualised basis. In addition, as a result of this change there may be an impairment in the carrying value of the respiratory cash generating unit in 2018.

Additionally, Circassia intends to issue further ordinary share capital to AstraZeneca, subject to shareholder approval, such that AstraZeneca's holding will increase from 14.2% to a maximum of 19.9%. Circassia will use the proceeds to fund a deferred R&D contribution of \$20 million, which is payable by the end of 2018 under the agreement with AstraZeneca, and part fund a final R&D contribution of \$25 million payable by the end of 2019. AstraZeneca has agreed to include any remaining R&D contribution not paid by the end of 2019 in the loan arrangements in the existing development and commercialisation agreement. Circassia anticipates receiving tax credits totalling approximately \$9 million on the R&D payments.

With sales growth potential in place, cost containment measures delivering results and a refocused investment strategy targeting commercial expansion, we look forward to 2018 with optimism.

### 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

- Our passion for delivering products to improve patients' lives energises us to attain our goals

## Recognition

- We recognise and acknowledge the contribution of teams and individuals in achieving our goals

## Integrity

- We act with honesty, and fairness at all times and always strive to do the right thing

## Drive

- We set ambitious goals and go for them, believing this drives extraordinary behaviour

## Effectiveness

- We understand key business drivers and manage our resources effectively

## 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 2017.

Member	Male	Female	Total	%Male	%Female
Plc Board including Non-Executive Directors	7	1	8	88	12
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	206	182	388	53	47
Total	216	184	400	54	46

## 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.

# Corporate social responsibility continued

## 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 and equivalent legislation in other countries such as France.

## Human rights

The Group support the UN Universal Declaration of Human Rights and recognises the obligation to promote universal respect for and observance of human rights and fundamental freedoms for all, without distinction. The Group complies 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. The Group works 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.

Emissions for 2017 are in line with those in 2016, reflecting the fact that they are largely a function of the heating and lighting of leased office premises.

	2017	2016
CO equivalent emissions – scope 1 (tonnes)	–	–
CO equivalent emissions – scope 2 (tonnes)	231	218
Intensity ratio (kg/m <sup>2</sup> of office space)	42	40

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 is committed to combatting slavery and human trafficking. As part of its initiative to identify and mitigate risks it performs due diligence on potential suppliers and distributors and protects whistleblowers, who can raise concerns anonymously through an externally provided reporting service. The Group's suppliers and distributors are provided with its Partner Code of Conduct which makes it clear that the Group expects them to comply with the requirements of the Modern Slavery Act.

# 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 during 2017 following the commencement of the collaboration with AstraZeneca relating to Tudorza®. Accordingly, the Compliance function has been expanded and a Director of US Compliance appointed to oversee the risks associated with the promotion and sale of both medical devices and pharmaceutical products.

## 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 commenced its collaboration with AstraZeneca to sell the long-acting muscarinic antagonist (LAMA), Tudorza® in the United States. There are currently three other LAMA products marketed in the United States, namely Spiriva® (sold by Boehringer Ingelheim), Incruse® (sold by GSK), and Seebri® from Sunovion. Tudorza® competes directly with all these products. Accordingly, there is no guarantee that the Group will be able to increase its share of the LAMA market. AstraZeneca's rights to Tudorza® and Duaklir® are the subject of a head licence between AstraZeneca and Almirall and Circassia has a sub-licence under this head licence. Both the licence and sub-licence contain customary diligence obligations. A continued failure to perform these diligence obligations could ultimately lead to termination of the head licence or sub-licence. The provision of Tudorza® samples to healthcare practitioners is currently managed by AstraZeneca. However, as and when the Group exercises its option to take full ownership of the product it will need to implement its own sample management programme.

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, Bosch Healthcare Solutions GmbH (based in Germany), and Spirosure Inc. (headquartered in the United States). In China, a competing product is supplied to the market by Sunvou Medical. None of these competing products are currently available in the US.

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.

# Risks and risk management continued

The successful commercialisation of the Group's fluticasone propionate product will, if 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, are generic products and so will compete with the innovator products as well as potentially generics from other third parties.

Other 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 and its partner AstraZeneca are implementing a jointly agreed Promotional Plan for Tudorza® and this is reviewed at regular meetings of the Joint Commercialisation Committee. Promotional efforts are focused on higher volume prescribers and the Group's sales representatives promote Tudorza® as the primary product in the majority of health care professional (HCP) calls. A dedicated team concentrates on selling the product to larger public and private institutions under fixed term contracts. To mitigate the risks of termination of the head licence or the sub-licence, Circassia and AstraZeneca have both agreed to use all reasonable efforts to ensure the relevant obligations under the head licence from Almirall are performed. Both the head licence and sub-licence contain customary provisions relating to cure periods and dispute resolution.

With regard to its NIOX® franchise, the Group continues to apply increasing resources to sales of the device. By the end of 2017 there were approximately 200 sales representatives selling NIOX® in the United States, double the number at the end of 2016. Distributor markets are managed by an experienced Director of Distributor Management and the resources available to this team have also increased in the course of the year.

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 development and marketing of its fluticasone propionate products. 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 and 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 has been extended and restructured in the course of the year. Two regional heads of Compliance, one focused solely on the United States, and the other on territories outside the US now report to the General Counsel and Chief Compliance Officer. The General Counsel and Chief Compliance Officer has a direct reporting line to the Chair of the Audit and Risk Committee. A Compliance Committee oversees activities in this area and meets on a quarterly basis. The Compliance function works with a network of external advisers in the relevant territories to ensure 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.

### 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 and medical device industries are highly regulated. Regulatory authorities across the world enforce a range of laws and regulations which govern the testing, approval, manufacturing, labelling and marketing of such 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, the UK 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, although clinical studies have been successfully completed and filing for a New Drug Application is currently anticipated in H1 2018.

During 2017, the Group also received the results of a Phase IV post-marketing study relating to Tudorza®. This met both its primary efficacy endpoint and its primary safety endpoint thereby eliminating a risk which had been highlighted in last year's report and accounts.

The Group is currently awaiting results from a clinical trial for one of its respiratory products. The respiratory programme seeks to develop a substitute for Seretide®. However, there can be no guarantee that this trial will meet its endpoint or that the product will ultimately be approved. Similarly, its nebulized LABA/LAMA formulation, which is being developed for use with smart nebulizer technology in-licensed from Philips and its generic tiotropium programme are still at an early stage. In order to extract value from its in-house respiratory programmes in the near term, the Group is seeking to out-license / partner these programmes to third parties. There is, however, a risk that the Group will not be able to negotiate such licence agreements.

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 took place with Tudorza® and Duaklir® during 2017 have been managed by AstraZeneca which is a global leader in the development of respiratory drugs. AstraZeneca will also take the lead on the regulatory activities which flow from the successful outcome of those studies.

# Risks and risk management continued

## 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 or device 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 pre-clinical and clinical trials which test for and identify adverse side effects of the pharmaceutical products which it is developing. Its medical devices 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® and NIOX VERO® products and sales of Tudorza®.

AstraZeneca administers the global safety database for Tudorza® and a Safety Data Exchange agreement is in place between the parties.

## 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® and NIOX VERO® devices and the sensors contained in those devices, and regulatory requirements may make substitution costly and time-consuming.

The supply chain for Tudorza® continues to be controlled by AstraZeneca. Even after exercise by the Group of the option to acquire full rights to the product, AstraZeneca will remain the sole source of supply for this product, and for Duaklir® 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 investigated where this is practicable. Manufacturing sites are well established FDA-approved facilities. AstraZeneca has an established global supply chain in place for Tudorza® and at the point when the Group is able to acquire the full rights to the product the existing arms'-length supply agreement negotiated by the parties will come into full effect.

## Research and development risks

The Group may not be successful in its efforts to out-license / partner its pipeline of respiratory products. This could have a material impact on the long-term success of the business. Failure of programmes could result from lack of 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® 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® and Duaklir® 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.

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® and Duaklir® 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.

### **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**

Remuneration packages for employees 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 exist 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.

# Risks and risk management continued

## Free float

The UK Listing Authority requires listing issuers to maintain at least 25% free float in their listed shares. At 29 March 2018 the Company had a free float of approximately 11.9%. The proposed issue of new shares to AstraZeneca will reduce the free float to approximately 11.2%. 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 and move its listing to another market in London. This might adversely affect the ability of new and existing shareholders to buy Ordinary shares and of holders to sell them.

## Mitigating activities

At the time of publication of its prospectus announcing its collaboration with and the issue of shares to AstraZeneca, on 17 March 2017, the Company obtained a derogation from the UKLA in respect of the Free Float requirement for a period of 12 months. During this period the Company has been in dialogue with the UKLA to discuss various ways in which the free float can be increased such as: (i) discussing 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) discussing with such Shareholders the prospect of reducing their holding below 5%. The Company's advisers are in continuing dialogue with the FCA regarding these matters.

## 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 a further period due to the high level of expenditure required to develop its NIOX® business, to promote Tudorza®, and launch Duaklir®.

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, currently receives in the United Kingdom.

## Mitigating activities

The Group's Viability Statement which appears on page 39 sets out the considerations relevant to solvency and liquidity. 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 partners for 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 established subsidiaries 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 2020, taking account of the Group's current position and the potential impact of the principal risks identified. 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 2020.

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 2020.

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.

The Group's annual budget was approved by the Board at its December 2017 meeting and the 10 year plan was reviewed at the same meeting.

In addition, after the year end, the Board reviewed a revised 10 year plan and approved the further cost containment measures as part of a focused investment strategy aimed at commercial expansion and refocusing of R&D expenditure as explained in the operating review. This also included the changes in the payment terms of the R&D AstraZeneca collaboration which have been recently negotiated.

This has been built from the bottom up and 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, there was sufficient headroom to ensure the solvency and liquidity of the Group to at least 31 December 2020. In addition, further mitigating actions could be taken to increase the size of the contingency.

This 10 year plan was reviewed by the Board and approved on 23 April 2018.

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 of the consolidated financial statements.

The Strategic report on pages 01 to 39 has been approved by the Board.

**Steven Harris**  
Chief Executive Officer

24 April 2018

# 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; Quanta 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 Kirln 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 Chairman of the Audit Committee and a member of the Management Engagement Committee 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 Jo Le Couilliard

### Independent Non-Executive Director

Jo Le Couilliard was appointed to the Board as an Independent Non-Executive Director on 8 February 2018. She was most recently Senior Vice President, Global Commercial Transformation at GSK and brings significant commercial and international pharmaceutical industry experience to Circassia. She previously held a number of senior roles at GSK, including Senior Vice President and Area Head, Asia Pacific and Senior Vice President, Corporate Development. Prior to this she was Chief Operating Officer at General Healthcare Group where she had operational responsibility for 49 private hospitals in the UK.

She was previously a Non-Executive Director of the Frimley Park Hospital NHS Foundation Trust and holds a Masters degree in Natural Sciences from the University of Cambridge. She is a Chartered Accountant and a member of the ICAEW.

## 7 Russell Cummings

### Non-Executive Director

Russell Cummings joined Circassia as a Non-Executive Director on 25 January 2007. Until November 2017 he was 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 Sharon Curran

### Independent Non-Executive Director

Sharon Curran was appointed to the Board as an Independent Non-Executive Director on 8th February 2018. She was most recently Vice President, Global Customer Excellence & Specialty at Abbvie Inc., and brings extensive commercial and specialty pharmaceutical experience to the Company. She has held a number of senior roles during her career, including Vice President, Specialty, Global Marketing & Commercial Operations at Abbvie, Global Brand Director, Anesthesia at Abbott and Division Head, Ireland at Eli Lilly.

She holds an Executive Master of Science, Business Administration from Trinity College Dublin and a Bachelor of Science in Biotechnology from Dublin City University.

#### **9 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 and a member of the Audit and Risk Committee and the Nomination 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.

#### **10 Dr Heribert Staudinger**

**Independent Non-Executive Director**  
Dr Heribert Staudinger was appointed as an Independent Non-Executive Director on 8th February 2018.

He is currently Immunology Clinical Lead at Sanofi Genzyme, and brings extensive respiratory medicine development expertise to Circassia. He previously held a number of senior development roles, including Head of Therapeutic Area, Respiratory Medicine at Boehringer Ingelheim, Head of Clinical Development at Chiesi Pharmaceuticals, Section Head Allergy and Respiratory at Merck and Vice President Clinical Development, Allergy, Respiratory and Immunology at Schering Plough.

He is a member of the American Thoracic Society, European Respiratory Society and the New York Academy of Sciences. He gained his medical degree at the University of Freiberg, Germany and subsequently practised medicine at the University of Hamburg teaching hospitals, where he also gained his PhD and Board Certification as a Pulmonary Physician.

#### **11 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 companies Hyperion Therapeutics, Inc. and Ikaria Inc.

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

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# Corporate governance

## Corporate governance report

### Dear Shareholders

On behalf of the Board, I am pleased to present Circassia's Corporate governance report for the year ended 31 December 2017. 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 and it has been looking to steadily increase the proportion of Independent Non-Executive Directors who sit on the Board. The changes to the Board which have occurred in 2017 and early 2018 have been consistent with this goal and with the evolution of the Company.

In the course of 2017, two of our long-serving Non-Executive Directors, Mr Charles Swingland and Dr Tim Corn, retired from the Board. We are very grateful to Charles and Tim for their significant contributions over the years. In addition, Dr Jean-Jacques Garaud and Mr Marvin Samson have announced their intention not to stand for re-election at the 2018 Annual General Meeting. We also extend our thanks to Jean-Jacques and Marvin for the excellent support and guidance they have provided.

We are delighted that we have been able to appoint three new independent Non-Executive Directors: Ms Jo Le Couilliard, Ms Sharon Curran, and Dr Heribert Staudinger. Their skills and experience will complement those of the existing Board members and ensure the Board is well equipped to help the Company realise its goals.

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 (April 2016) 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 although it has met the requirement applicable to Small Cap companies.

At the beginning of 2017, the Board consisted of ten members, the Chairman (who was independent on appointment), three Executive Directors, and six Non-Executive Directors. Of the six 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 33% at the beginning of the year, but, following the departures of Charles Swingland and Tim Corn after the Company's Annual General Meeting in May 2017, it had risen to 43%.

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. Dr Garaud exercised all of his options in June 2017.

As noted earlier in this report, the Company appointed three new independent Directors to the Board on 8 February 2018. Following these appointments, the Board has grown to eleven members of whom six are considered to be independent. From this date, the independence ratio of the Board (excluding the Chairman) has therefore been 60%.

Dr Jean-Jacques Garaud and Marvin Samson have indicated that they do not intend to stand for re-election at the Company's 2018 Annual General Meeting. Accordingly, following this meeting, the Board will consist of nine members. These will be the Chairman (who was independent on appointment), three Executive Directors, and five Non-Executive Directors. Of the five Non-Executive Directors, it is anticipated that four will be independent, namely Lota Zoth, Jo Le Couilliard, Sharon Curran, and Dr Heribert Staudinger. The independence ratio of the Board (excluding the Chairman) will therefore be 50% and the Board will meet the requirement that a FTSE Small Cap company should have at least two independent Non-Executive Directors (which it is expected will be the applicable requirement for the reporting year 2018).

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:

- From 1 January 2017 until 26 May 2017 the Committee was comprised of 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, a majority of the Committee was not therefore made up of Independent Non-Executive Directors, and the composition of the Nomination Committee therefore did not comply with the recommendations of the Code.
- Dr Tim Corn did not seek re-election at the 2017 Annual General Meeting, and his position on the Nomination Committee was taken by Marvin Samson who is an Independent Non-Executive Director. In addition, effective from 26 May 2017, Dr Jean-Jacques Garaud resigned from the Committee and his position was taken by Lota Zoth, who is also independent. Therefore from 26 May 2017 up to the date of this report, the composition of the Nomination Committee has complied with the recommendations of the Code.

#### **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 2017 until 26 May 2017, the Committee members were: Marvin Samson (Chair of the Committee); Dr Tim Corn and Lota Zoth. Marvin Samson and Lota Zoth are both considered to be independent. However Dr Tim Corn was not considered independent. Therefore, from 1 January 2017 until 26 May 2017, the composition of the Committee did not comply with the membership requirements of the Code insofar as they relate to independence.
- Dr Tim Corn did not seek re-election at the 2017 Annual General Meeting, and his position on the Remuneration Committee was taken effective from 26 May 2017 by Dr Jean-Jacques Garaud who is an Independent Non-Executive Director. Therefore from 26 May 2017 up to the date of this report, the composition of the Remuneration Committee complied with the recommendations of the Code, as they apply to FTSE 350 companies. The Remuneration Committee also complies with the smaller company requirement that it consist of at least two independent Non-Executive Directors which has applied to the Company since 1 January 2018.

#### **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 2017 up to 26 May 2017, 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 2017 until 26 May 2017, the membership of the Audit and Risk Committee did not comply with the membership requirements of the Code insofar as they relate to independence.
- Dr Tim Corn did not seek re-election at the 2017 Annual General Meeting, and his position on the Audit and Risk Committee was taken effective from 26 May by Marvin Samson who is an Independent Non-Executive Director. Therefore the Audit and Risk Committee has been fully compliant with the recommendations of the Code, as they apply to FTSE 350 companies, from 26 May 2017 up to the date of this report. The Audit and Risk Committee also complies with the smaller company requirement (relevant in 2018) 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 2017 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.

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# Corporate governance continued

## Corporate governance report continued

### 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 commercial performance, and reviews financial performance against the budget.

#### Roles and responsibilities

The Board is currently composed of the Chairman, three Executive Directors, and seven Non-Executive Directors. The biographies of the current members of the Board are set out on pages 40 to 41 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 2017.

#### 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 2017.

	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>	2 (3) <sup>1</sup>	2 (2) <sup>1</sup>
Julien Cotta	n/a	n/a	5 (5)	2 (2) <sup>2</sup>	3 (3) <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)	3 (3)	–	–
Jean-Jacques Garaud	A, R <sup>3</sup> , N <sup>4</sup>	Yes	3 (5)	1 (1)	2 (3)	–
Tim Corn <sup>5</sup>	A, R, N	No	2 (2)	1 (1)	1 (1)	2 (2)
Russell Cummings	–	No	5 (5)	–	–	–
Charles Swingland <sup>6</sup>	–	No	2 (2)	–	–	–
Lota Zoth	A (Chair), R, N <sup>7</sup>	Yes	5 (5)	2 (2)	3 (3)	2 (2)
Marvin Samson	A <sup>8</sup> , R (Chair), N <sup>9</sup>	Yes	3 (5)	1 (2)	1 (2)	2 (2)

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

Figures in brackets represent the total number of meetings (occurring in the period when the Director was in office).

<sup>1</sup> By invitation.

<sup>2</sup> In the capacity of Secretary to the Committee.

<sup>3</sup> From 26 May 2017 when he was appointed to the Remuneration Committee.

<sup>4</sup> Until 28 May 2017 when he resigned from the Committee.

<sup>5</sup> Until 26 May 2017 when he retired from the Board (not having put himself forward for re-election at the AGM).

<sup>6</sup> Until 26 May 2017 when he retired from the Board (not having put himself forward for re-election at the AGM).

<sup>7</sup> From 26 May 2017, when she was appointed to the Nomination Committee.

<sup>8</sup> From 26 May 2017 when he was appointed to the Audit and Risk Committee.

<sup>9</sup> From 26 May 2017 when he was appointed to the Nomination Committee.

## Board activity

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

- Detailed consideration and ultimately approval of the collaboration and licence agreement with AstraZeneca by virtue of which the Group acquired rights to commercialise Tudorza and Duaklir in the United States.
- Review and approval of the terms on which new shares were issued to AstraZeneca as consideration for entry into the collaboration and licence agreement referred to above. This was a Class I transaction for the Group and therefore required a full Prospectus.
- Reviews of the commercial progress made with the Group's NIOX device, and, following the completion of the transaction relating to Tudorza and Duaklir, reviews of the commercial performance of Tudorza in the US and of the planning for a Duaklir launch.
- Reviews of the progress of the clinical trials being conducted by AstraZeneca in relation to Tudorza and Duaklir.
- Reviews of NIOX life cycle management and improvements.
- Planning in relation to the future of the allergy business in advance of the release of the House Dust Mite results and subsequent approval for the implementation of those plans following receipt of the negative phase IIb results in April 2017.
- Reviews of the progress of business and corporate development activity and opportunities.
- Compliance updates.
- Review of the 10 year financial model for the business.
- Assessment of the financial performance against the budget for FY 2017.
- Approval of the budget for FY 2018.
- Completion of a Board evaluation exercise.

# Corporate governance continued

## Corporate governance report continued

### Effectiveness

#### Independence

The Board reviews the independence of its Non-Executive Directors each year. For the period 1 January 2017 to 26 May 2017, excluding the Chairman, three of the nine Board members were Non-Executive Directors who were considered by the Board to be independent.

For the period from 26 May 2017 to 31 December 2017, excluding the Chairman, three out of seven 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. Dr Garaud exercised these options in May 2017 and no longer holds any options over shares in the Company. 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 2017 to 31 December 2017.

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.

Russ Cummings was an employee of Touchstone Innovations plc which is a shareholder and was therefore not considered independent during 2017. In addition, he has served on the Board for more than nine years, and so is not considered independent due to length of service. Charles Swingland was not considered independent as he previously served as an Executive Director, General Counsel, and Company Secretary of the Company. Dr Tim Corn was not considered to be independent as he had 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 who then debate the responses and agree upon the actions required.

The Board subjects itself to an external review every third year. An external review was performed in 2016. Accordingly, the Board did not carry out an external review in 2017.

#### 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 twelve 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 5 December 2017. This was updated and reviewed by the Board and approved on 23 April 2018.

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 39 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, Senior Vice President US Commercial, Senior Vice President EU/RoW Commercial, Vice President Human Resources, and General Counsel and Chief Compliance Officer. 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 Quality Assurance 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 Compliance function maintains policies and delivers 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. Since the Group has commenced promotion of Tudorza in the United States a number of policies specifically related to this promotional activity have been implemented and appropriate training delivered to the sales representatives. The Compliance function also works with Human Resources to curate the Group's Code of Conduct. This is updated on an annual basis and training delivered. The Compliance Committee, which is chaired by the Chief Compliance Officer, meets on a quarterly basis.
- Promotional materials relating to the Group's products are reviewed by a Promotional Review Committee and non-promotional materials (for example material used by the Medical Affairs team) are reviewed by a Non Promotional Review Committee. Requests for research grants and support for investigator initiated studies are channeled through a Grants Committee.
- 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 reviewed by the Senior Management Team. Accompanying reports will explain any variances between these results and the budget.

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# Corporate governance continued

## Corporate governance report continued

- 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. This was revised 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 MAR.
- 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. Under the direction of this Committee an Insider List is maintained 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 2017 and up to the date of this report.

### Remuneration

The Board adopted a remuneration policy approved by shareholders at the 2015 AGM. As the remuneration policy should be approved by shareholders every 3 years, the policy has been updated and will be presented for approval at the 2018 AGM. The Board believes the revised policy 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.

# Corporate governance

## Audit and Risk Committee report

### 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 2017.

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

24 April 2018

### 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 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 Group markets approved medical devices to healthcare professionals in a number of markets around the world and following the commencement of the collaboration with AstraZeneca to market Tudorza®, the Group also promotes 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 Chief 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.

### 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 2017 and up to the date of this report, the Committee reviewed the Interim report and accounts for the period ended 30 June 2017 and the preliminary announcement and Annual report and accounts for the year ended 31 December 2017.

Member	Date of appointment	Meetings attended (held)
L S Zoth	27 February 2015	3 (3)
T Corn (resigned 26 May 2017)	21 February 2014	1 (1)
J-J Garaud	21 February 2014	2 (3)
M. Samson	26 May 2017	1 (2)

# Corporate governance continued

## Audit and Risk Committee report continued

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 was not independent, the recommendation of the Code has not been met for the period from 1 January 2017 to 26 May 2017. However, following the appointment of Marvin Samson on 26 May 2017, this requirement has been satisfied.

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:

- Accounting for the Collaboration with AstraZeneca
- Goodwill and intangibles impairment assessment

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 for the full year results. Review of significant accounting judgements and estimates (see overleaf). 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. Recommend re-appointment of Auditors.
Risk management and internal control	Review of risk, risk management systems, internal controls, and whistleblowing policy. Review of Compliance activities.
Governance	Review of the Committee's terms of reference.

## Accounting for the Collaboration with AstraZeneca

Following the collaboration and profit share arrangement with AstraZeneca, a Purchase Price Allocation exercise was performed focusing on the following key accounting areas:

### – Determination and allocation of the consideration

Under the terms of the agreement to secure certain US commercial rights to Tudorza® and Duaklir®, a maximum total consideration of \$230 million plus future sales-based royalties is payable to AstraZeneca. For the purposes of IFRS 3, the total consideration included in the valuation consists of \$50 million for shares issued to AstraZeneca, \$100 million deferred non-contingent consideration and the fair value of royalties payable to AstraZeneca. It does not include the amount (up to \$80 million) that would be paid to exercise the Tudorza® option, which will be accounted for once exercised. The allocation of consideration between both products was based on a relative fair value approach. This was determined using a bottom-up business valuation for both products and allocating the amount expected to be paid for both products proportionately between both products.

### – Initial valuation and subsequent measurement of Duaklir IPR&D

The Excess Earnings Method approach was determined to be the most appropriate methodology to use for the valuation of the In-Process Research & Development (IPR&D). The IPR&D asset was valued at \$41.6 million with a remaining useful life of 17 years from the commercial launch date of Duaklir®. At 31 December 2017, management performed an impairment review of the IPR&D, using a Net Present Value (NPV) methodology and concluded there was sufficient headroom in the AstraZeneca cash generating unit to not warrant an impairment.

### – Initial valuation and subsequent measurement of Royalties

As part of the transaction, Circassia will pay royalties to AstraZeneca on future sales of Duaklir® in the United States. Under IFRS 3, these royalties have been classified as additional consideration and initially recognised as an IPR&D asset with a corresponding contingent liability. The IPR&D is subsequently amortised over its remaining useful economic life, and the contingent liability is revalued at the end of each period with gains/losses recognised through the profit and loss. The value of the IPR&D asset was calculated by management using a tax-effected NPV of the future royalty cash outflows at the date of the transaction and at 31 December 2017. An IPR&D asset and corresponding contingent liability of \$49.7 million was recognised on the balance sheet at the date of acquisition. At 31 December 2017 the contingent liability was revalued at \$45.3 million due to a reduction in the cash flows used in the NPV model.

## 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 was tested for impairment. Impairment assessments were performed on each CGU (NIOX®, Respiratory and AstraZeneca) and Management concluded no impairment to be required after comparing the carrying values of each CGU to their individual value in use calculation. In addition Management performed an impairment analysis at each identifiable individual intangible asset level. Impairment triggers were identified relating to three intangible assets and impairment charges were recognised on each. See note 16 for further details.

## Going concern and cash flow

Following review of Group cash flows over a three year period to 31 December 2020, 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 2020.

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 2020.

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.

The Group's annual budget was approved by the Board at its December 2017 meeting and the 10 year plan was reviewed at the same meeting.

In addition, after the year end, the Board reviewed a revised 10 year plan and approved the further cost containment measures as part of a focused investment strategy aimed at commercial expansion and refocusing of R&D expenditure as explained in the operating review. This also included the changes in the payment terms of the R&D AstraZeneca collaboration which have been recently negotiated.

This has been built from the bottom up and 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, there was sufficient headroom to ensure the solvency and liquidity of the Group to at least 31 December 2020. In addition, further mitigating actions could be taken to increase the size of the contingency.

This 10 year plan was reviewed by the Board and approved on 23 April 2018.

As part of this review, the Board considered the implications of the Company's collaboration agreement with AstraZeneca which 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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# Corporate governance continued

## Audit and Risk Committee report continued

### **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 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 2016, the Board had asked the management team to carry out a review of the operations of the Group's representative office in China. This resulted in a report, prepared with the assistance of PricewaterhouseCoopers' Beijing office which was provided to the Board late in 2016. One of the recommendations of the report was that there be a follow up audit in 2017, and this was duly carried out, and the results passed on to the Committee in December 2017.

### **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 Compliance team or directly with the Chair of the Audit and Risk Committee.

### **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.

### **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 2017 or up to the date of this report.

At the end of the audit for the year ended 31 December 2017 the Committee formally evaluated the performance of PwC (who had been reappointed as auditors following a tender carried out in 2016).

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 2017 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 (corporate finance services)	173
No	Other assurance services	18

The total fees paid to the Auditor are shown in note 9 of the financial statements. Services were provided during the year in connection with corporate advisory services and other assurance 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.

Corporate advisory fees related to services provided in connection with the preparation of the Prospectus required for the transaction which was completed with AstraZeneca. Other assurance services related mainly to the fees for the follow up 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 2017 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 internal review of the effectiveness of the Committee was carried out in December 2017 as part of the process of evaluating Board effectiveness. The findings of the evaluation were debated by the Board and a list of actions agreed.

## Lota S Zoth

Chair of the Audit and Risk Committee

24 April 2018

# Corporate governance continued

## Nomination Committee report

### 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 2017. 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, Dr Tim Corn and Mr Charles Swingland departed from the Board. Their contributions have been greatly appreciated. Subsequently the Board decided that it should seek to appoint additional independent Non-Executive Directors to the Board, and that search, which was initiated in the course of 2017, resulted in the appointments of Ms Jo Le Couiliard, Ms Sharon Curran, and Dr Heribert Staudinger in February 2018.

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

#### Dr Francesco Granata

Chair of the Nomination Committee

24 April 2018

#### 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

From 1 January 2017 until 26 May 2017, 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, the composition of the Nomination Committee did not comply fully with the recommendations of the Code which requires the majority of members to be independent.

Dr Tim Corn did not stand for re-election at the 2017 Annual General Meeting, and his position was taken, from 26 May 2017, by Mr Marvin Samson. Also, on 26 May 2017 Dr Jean-Jacques Garaud resigned from the Committee and his position was taken up by Ms Lota Zoth. As both Mr Samson and Ms Zoth are independent Non-Executive Directors, the Committee did therefore comply with the Code in respect of its composition of independent Non-Executive Directors from 26 May 2017 onwards.

The Committee met three times during the year ended 31 December 2017 and all members except Mr Marvin Samson 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	3 (3)
Dr Tim Corn (resigned 26 May 2017)	21 February 2014	1 (1)
Dr Jean-Jacques Garaud (resigned 26 May 2017)	21 February 2014	1 (1)
Mr Marvin Samson	26 May 2017	1 (2)
Ms Lota Zoth	26 May 2017	2 (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 search activities which are described below.

#### 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);
- Annual performance evaluation of the Board, its members and its Committees;
- Approval of the initiation of a search for new Non-Executive Directors; and
- Proposal for appointment of new Non-Executive Directors.



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# Remuneration committee report

## 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 2017. This report will be presented for the consideration and approval of Shareholders at the Annual General Meeting on 30 May 2018.

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 will be put to a binding Shareholder vote at the AGM on 30 May 2018; 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 2017 financial year. This latter report is subject to an advisory vote at the AGM.

### Remuneration policy

The existing remuneration policy which was first approved by 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 2017 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, the Group established a transformational commercial collaboration with AstraZeneca in the United States and made significant progress in developing its NIOX business and building its commercial infrastructure. In spite of achievement of a number of the Corporate Objectives set by the Board in excess of 75%, the Executive Directors and the Board considered it appropriate to limit their bonuses to 75% to align with bonus payments to employees.

The Performance Share Plan awards made throughout 2015 have vested in relation to performance ending in 2017. The criteria are set out on page 70.

### Application of policy for 2018

The proposed new Remuneration policy set out in this report will be subject to a binding vote by Shareholders at the Annual General Meeting on 30 May 2018 and, if approved, will be applied with effect from 1 January 2018.

The salaries of the Executive Directors were reviewed with effect from 1 January 2018 and increased in line with increases to the general workforce of 3%. The annual fee for the Chairman, Dr Francesco Granata, will increase from £138,400 to £142,550.

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

Chair of the Remuneration Committee

24 April 2018

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# Remuneration committee report continued

## Directors' remuneration policy report (DRP)

### Directors' remuneration policy report (DRP)

The proposed policy will be presented at the AGM on 30 May 2018 for a binding Shareholder vote and will be expected to remain in force until the AGM in 2021. The bar charts on page 63 have, however, been updated to reflect possible scenarios for remuneration in 2018.

The key policy changes proposed are as follows:

- Introduction of holding period requirement of two years for Executive Directors following exercise of PSP options
- Increase minimum holding of shares in the company for Executive Directors to 200%

Each of the changes has been introduced in line with best practice.

In addition, the contractual arrangements have been reviewed to ensure that these are in-line with current market and best practice. In doing so we have aligned the notice periods with our policy on future service contracts. This includes an increase in the notice period from 6 to 12 months and the introduction of the ability to make phased payments on termination. The change in notice period for the Executive Directors helps ensure business continuity by allowing time for search and recruitment of replacements.

### 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 create 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 deferral of bonuses in shares, share ownership guidelines and holding periods following the vesting of awards, 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.

Salary	Benefits	Annual bonus
<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.	<b>Purpose and link to strategy</b> Provides market competitive, yet cost-effective employment benefits.	<b>Purpose and link to strategy</b> To incentivise and recognise execution of the business strategy and personal objectives on an annual basis.
<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.  Salaries are periodically benchmarked against a relevant peer group of UK listed companies with similar market capitalisation and operations.	<b>Operation</b> For Executive Directors this includes private medical insurance and life insurance.  Other employment benefits may be provided from time to time on similar terms as those of other employees.  If the Company introduces an all-employee share plan, Executive Directors will be eligible to participate on the same terms as other employees.  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.	<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.  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.  Thereafter, the bonus will be payable as 75% cash and 25% shares.  Bonus shares are deferred for three years from the date of the award and are subject to forfeiture.  Recovery and withholding provisions will apply in the event of misstatement of results, error in performance calculation or gross misconduct.  A dividend equivalent, if payable, will be payable in cash when the shares vest.
<b>Maximum potential value</b> The current base salaries are set out in the implementation of policy section of the Annual report on remuneration.  There is no formal maximum limit, but increases are generally in line with those of the wider workforce.  Larger increases may be permitted to reflect a change in responsibilities or a significant increase in the scale or complexity of the role.	<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.	<b>Maximum potential value</b> The maximum payable for all Executive Directors is 100% of salary.
<b>Performance metrics</b> The overall performance of the individual and Company is a key determinant for salary increases.	<b>Performance metrics</b> None.	<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.  Details of the performance measures for the current year are provided in the Annual report on remuneration.

## Remuneration committee report continued

Performance share plan (PSP)	Pension
<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>
<b>Purpose and link to strategy</b> <i>To align Executives with Shareholders and provide an ongoing incentive for continued performance.</i>
<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.
<b>Maximum potential value</b> Executive Directors are required to build and maintain the following minimum level of shareholding: <ul style="list-style-type: none"> <li>— Chief Executive Officer, 150% of salary</li> <li>— Other Executive Directors, 100% of salary</li> </ul>
<b>Performance metrics</b> None.

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 have vested, based on their original terms and are 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 other progress</b> The growth of the Company and therefore delivery of value to investors is dependent on achievement of certain key commercial and other 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 including tax equalisation 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 fees for the Chairman and 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 twelve 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
Service contracts entered into before 1 January 2018	Termination by notice: six months. Redundancy: six months annual salary payable (reduced accordingly if part of the notice period is worked). Retirement, death and ill-health, injury or disability: no termination payment.
Future service contracts (entered into after 1 January 2018)	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 normally 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. Redundancy: annual salary payable for the relevant notice period (reduced accordingly if part of the notice period is worked). Retirement, death and ill-health, injury or disability: no termination payment. In the event of change of control or merger, the Remuneration Committee of the Company has discretion to determine phasing of payments.
Long-term incentives and deferred bonuses	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. Termination by notice: unvested awards lapse on cessation. 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. Death: unvested awards will vest on the date of death. Performance against the conditions will be measured up to the date of cessation and awards will be pro-rated, unless the Committee determines that pro-rating would be inappropriate in the circumstances. 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.
Annual bonus	Termination by notice by individual: if an individual serves notice and the termination date falls before 31 December, the bonus is normally 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. Redundancy, retirement, death and ill-health, or any other reason the Committee determines: if the termination date falls during the financial year, the bonus is normally paid in cash 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. 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.
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	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. Reasonable legal and outplacement costs will be met if deemed necessary.

# Remuneration committee report continued

## Service contracts

The following Executive Directors have current service agreements with the Company which are effective from 1 January 2018. These supersede service agreements covering earlier periods.

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 contractual arrangements for each Executive Director have been reviewed in order to ensure that these are in-line with market and best practice. The notice period and termination arrangements have been aligned with our policy on future service contracts, i.e. the notice period for each Executive Director has been increased from 6 months to 12 months. In the event of termination by way of a Payment In Lieu of Notice, payment would be phased over 12 months and may be stopped at the discretion of the Remuneration Committee on commencement of new employment. The changes to the notice period align our contract provisions with the wider market and help ensure business continuity by allowing time for search and recruitment of replacements. All Executive and Non-Executive Directors, (except Mr Marvin Samson and Dr Jean-Jacques Garaud) 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 2017 (2016: £Nil) and £32,000 for being on the Board of Woodford Patient Capital Trust during the year to 31 December 2017 (2016: £32,000).

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
Ms Jo Le Couilland	3 months	8 February 2018
Russell Cummings	3 months	25 January 2007
Dr Jean-Jacques Garaud	3 months	1 November 2012
Ms Sharon Curran	3 months	8 February 2018
Dr Heribert Staudinger	3 months	8 February 2018
Lota Zoth	3 months	9 February 2015
Marvin Samson	3 months	8 December 2015

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 2018 and expected pension contribution has been used.
- The actual monetary value of benefits received in 2017 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.





# 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.

# Remuneration committee report

## Annual report on remuneration

### 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 30 May 2018.

### Composition

From 1 January 2017 to 26 May 2017, the Committee was made up of Mr Marvin Samson (Chairman), Dr Tim Corn, and Ms Lota Zoth. Marvin Samson and Lota Zoth are both considered independent by the Board. Dr 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 26 May 2017 Dr Corn retired from the board and was succeeded by Dr Jean-Jacques Garaud as a member of the Committee. Dr Garaud is considered to be an Independent Non-Executive Director and therefore the committee complied with the code from that point. 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 2017. 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 2017 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.

### 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 2017 were £3,395 (2016: £39,150), 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

## Annual report on remuneration continued

### Committee evaluation

A review of the effectiveness of the Committee was carried out in December 2017 as part of the process of evaluating Board effectiveness.

### Audited information

#### Total remuneration – year ended 31 December 2017

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 2017.

		Salary or fees <sup>6</sup> £'000	Benefits <sup>7</sup> £'000	Bonus <sup>8</sup> £'000	Long-term incentives <sup>9</sup> £'000	Pension <sup>10</sup> remuneration £'000	Total £'000
<b>Executive Directors</b>							
Steven Harris	2017	410	1	307	45	62	825
	2016	398	1	–	–	60	459
Julien Cotta	2017	257	2	193	23	38	513
	2016	249	1	–	–	37	287
Rod Hafner	2017	278	1	209	36	42	566
	2016	270	1	–	–	41	312
<b>Non-Executive Directors</b>							
Francesco Granata	2017	147	–	–	–	–	147
	2016	142	–	–	–	–	142
Tim Corn	2017 <sup>1</sup>	26	–	–	–	–	26
	2016	60	–	–	–	–	60
Russell Cummings	2017 <sup>2</sup>	46	–	–	–	–	46
	2016 <sup>2</sup>	42	–	–	–	–	42
Paul R Edick	2016 <sup>3</sup>	17	–	–	–	–	17
Jean-Jacques Garaud	2017	64	–	–	–	–	64
	2016	63	–	–	–	–	63
Cathrin Petty	2016 <sup>4</sup>	45	–	–	–	–	45
Lota Zoth	2017	65	–	–	–	–	65
	2016	60	–	–	–	–	60
Marvin Samson	2017	63	–	–	–	–	63
	2016	54	–	–	–	–	54
Charles Swingland	2017 <sup>5</sup>	19	–	–	–	–	19
	2016 <sup>5</sup>	45	–	–	–	–	45
<b>Total 2017</b>		<b>1,375</b>	<b>4</b>	<b>709</b>	<b>104</b>	<b>142</b>	<b>2,334</b>
<b>Total 2016</b>		<b>1,445</b>	<b>3</b>	<b>–</b>	<b>–</b>	<b>138</b>	<b>1,586</b>

<sup>1</sup> Retired from the Board on 26 May 2017 having not submitted himself for re-election.

<sup>2</sup> All fees for Russell Cummings were paid to Touchstone Innovations Limited.

<sup>3</sup> Retired from the Board on 18 May 2016 having not submitted himself for re-election.

<sup>4</sup> Resigned from the Board on 16 December 2016.

<sup>5</sup> Retired from the Board on 26 May 2017 having not submitted himself for re-election.

<sup>6</sup> This is the amount earned as salary or fees in the financial year.

<sup>7</sup> 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.

<sup>8</sup> 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 2017. 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.

<sup>9</sup> The amount shown relates to the gain, being the market value on date of vesting, less exercise price, on PSP 2014 share option awards that vested during the year.

<sup>10</sup> 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 2017 Steven Harris received £61,410 of this pension amount as supplementary cash (2016: £59,625). In 2017 Rod Hafner received £41,767 of this pension amount as supplementary cash (2016: £30,417).

# Annual bonus for the year to 31 December 2017

For the year ended 31 December 2017, 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 2017, the Executive Directors elected to limit payment to a maximum of 75% of the total potential bonus. This was to align with the maximum bonus payable to all employees being limited to 75% of their potential bonus.

Objective 2017	Achievement	% Achievable			% Achieved		
		Steven Harris	Rod Hafner	Julien Cotta	Steven Harris	Rod Hafner	Julien Cotta
<b>1 Commercial</b> — Global NIOX sales growth — Regional sales growth targets for key markets — US — China — UK — Germany — US Tudorza net in market revenues — Gross margin — Cash — Full team hired, trained and promoting Tudorza by June 1, 2017 — Implement system to report Tudorza P&L	Global NIOX sales growth – 60% achieved Regional sales growth for key markets — US – 76% achieved — China – 144% achieved — UK – 134% achieved — Germany – Nil Tudorza in market revenues – 94% achieved Gross margin – 120% achieved Cash – 99% achieved Full commercial team promoting Tudorza – 100% complete. System implementation – 100% complete	35%	25%	40%	14%	10%	16%
<b>2 Progress R&amp;D programmes to achieve the following key milestones</b>		25%	40%	25%	25%	40%	25%
<b>2a Duaklir phase II study to confirm formoterol 12µg is optimal dose.</b>	100% complete						
<b>2b Duaklir phase III study meets co-primary endpoints with acceptable difference in fine particle dose between treatment arms.</b>	100% complete						
<b>2c Tudorza safety study complete and confirms cardiovascular safety</b>	100% complete						
<b>2d Conduct an investigation into Seretide substitute pilot PK study results and begin a further exploratory PK study.</b>	Investigation 100% complete and results awaited.						
<b>2e Complete HDM-SPIRE Phase 2b and Cat-SPIRE two year follow up studies and make a decision on the SPIRE portfolio by mid-May.</b>	100% complete						
<b>2f Preparation of respiratory product candidates for clinical studies.</b>	100% complete						

# Remuneration committee report continued

## Annual report on remuneration continued

Objective 2017	Achievement	% Achievable			% Achieved		
		Steven Harris	Rod Hafner	Julien Cotta	Steven Harris	Rod Hafner	Julien Cotta
<b>3 R&amp;D – To expand NIOX indications</b>		10%	15%	5%	10%	15%	5%
3a – Label change	100% complete						
– Feasibility study for prototype device with instant response sensor and improved flow controller	100% complete						
– Connectivity hub development	100% complete						
– Complete CE mark on Primary Ciliary Dyskinesia screening application	100% complete						
<b>4 Acquisitions</b>		20%	10%	20%	20%	10%	20%
Board approval to pursue at least two acquisition/licensing opportunities; target source and process weightings applied.	100% complete						
<b>5 Other functions – People, Quality and Compliance</b>		10%	10%	10%	10%	10%	10%
Alignment, recruitment and retention of the required workforce for timely and effective delivery of business objectives.	100% complete R&D headcount reduced post Cat-SPIRE and HDM-SPIRE results to reduce overall R&D expenditure. U.S. commercial expansion complete.						
Establish systems and processes to support current products and organisation.	100% complete New eQMS being rolled out with first module for complaints handling complete. Evaluation of proposed new ERP system begun.						
Maintain and manage a global system to ensure the Group is fully compliant with all applicable laws.	100% complete Existing systems and processes operating effectively.						
<b>Total</b>		<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>79%</b>	<b>85%</b>	<b>76%</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 2017 bonus was paid in cash. Julien Cotta has not yet met the shareholding guidelines and so 50% of his 2017 bonus was paid in cash and 50% in shares.

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

On 17 May 2017 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	99.7% of salary of £409,400	£0.96	425,000	12.5%	£408	3 years from date of grant
Julien Cotta	Nominal cost option	93.5% of salary of £256,700	£0.96	250,000	12.5%	£240	3 years from date of grant
Rod Hafner	Nominal cost option	86.2% of salary of £278,450	£0.96	250,000	12.5%	£240	3 years from date of grant

The number of options in the 2017 PSP that ultimately vest will be determined according to the following performance criteria:

#### Criterion 1: Relative TSR

For options granted in 2017, 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 2017, 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:

- In-licensing of one product or product candidate by end 2019 (12.5%);
- File one product in a major market by end of 2019 (12.5%);
- Launch new product in a major market by end 2019 (12.5%);
- Average sales growth for 2017–2019 greater than 20% per annum (12.5%).

# Remuneration committee report continued

## Annual report on remuneration continued

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

#### 2014

The total number of options that ultimately vested in the 2014 PSP scheme was 380,255. The tables below show the vesting by performance criteria.

#### Criterion 1: Relative TSR

For options granted in 2014, none of the total awards vested in relation to Criterion 1 as the Company TSR ranking was below the FTSE 250 index.

#### Criterion 2: Clinical and strategic business objectives

For options granted in 2014, the following awards vested based on achievement of the performance criterion.

Business objective	% weighting of full award <sup>1</sup>		Achieved?	Number of vested options
	Senior employees	Other		
Cat allergy phase III results (CP007) by 30 Sept 2016	9%	15%	Yes	162,966
Ragweed allergy – phase II results (TR006) by 31 December 2015	3%	5%	Yes	54,322
Ragweed allergy – regulatory and IRB approval for commencement of phase III study by 31 March 2016	3%	5%	No	Nil
HDM allergy – phase II study fully recruited by 31 March 2016	6%	10%	Yes	108,645
Grass allergy – end of phase II meeting by 31 December 2015	3%	5%	Yes	54,322
Regulatory and IRB approval for commencement of new clinical programme by 31 March 2017	3%	5%	No	Nil
Signed agreement for out-licensing deal/partnership for development and commercialisation by end 31 December 2016	3%	5%	No	Nil

<sup>1</sup> Percentage weighting dependent on seniority of employee to whom awards were made. The difference in awards arises because a greater weighting of options was awarded under Criterion 1 to more senior employees.

#### 2015

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 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 (20%);
- Establishment of country-specific sales and sales operations infrastructures including US sales force by end of 2017 (10%);
- House Dust Mite regulatory and IRB approval for commencement of Phase III by Q4 2017 (10%);
- Grass regulatory and IRB approval for commencement of Phase III by Q2 2016 (10%).



## 2016

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%).

### Deferred bonus share awards made during the year

During 2017 no awards were made under the Circassia Pharmaceuticals plc Deferred Share Bonus Plan (the DSBP) to the Executive Directors in respect of the deferred portion of their 2016 bonus.

### Directors' pensions

For the financial year ended 31 December 2017 the Company contributed £141,682 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 2017, a total of £61,410 (2016: £59,625) was paid to Steven Harris as supplementary cash due to him exceeding such a statutory limit. During the financial year ended 31 December 2017, a total of £41,767 (2016: £30,417) 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 2017 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 2017 and the date of this report.

Directors holding office at 31 December 2017 with LTIP awards and options outstanding over Ordinary shares of 0.08p were as follows:

# Remuneration committee report continued

## Annual report on remuneration continued

Plan	Date of grant	Awards granted and options held as at 1 January 2017 <sup>1</sup>	Awards and options granted, exercised, lapsed, or cancelled during year	Awards and options held at 31 December 2017 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	(198,389)	52,736
2015 PSP	26 February 2015	214,444	–	214,444
2016 PSP	19 May 2016	212,946	–	212,946
2017 PSP	17 May 2017	–	425,000	425,000
<b>Total</b>		<b>1,213,890</b>	<b>(308,764)</b>	<b>905,126</b>
<b>J Cotta</b>				
2013 Unapproved Scheme	22 October 2013	149,250	–	149,250
2014 PSP	12 March 2014	131,125	(103,589)	27,536
2015 PSP	26 February 2015	112,037	–	112,037
2016 PSP	19 May 2016	111,272	–	111,272
2017 PSP	17 May 2017	–	250,000	250,000
<b>Total</b>		<b>503,684</b>	<b>146,411</b>	<b>650,095</b>
<b>R Hafner</b>				
2014 PSP	12 March 2014	204,750	(161,752)	42,998
2015 PSP	26 February 2015	121,528	–	121,528
2016 PSP	19 May 2016	120,703	–	120,703
2017 PSP	17 May 2017	–	250,000	250,000
<b>Total</b>		<b>446,981</b>	<b>88,248</b>	<b>535,229</b>
<b>Non-Executive Directors</b>				
<b>JJ Garaud</b>				
2007 Unapproved Scheme	12 November 2012	77,500	(77,500)	–
<b>Total</b>		<b>77,500</b>	<b>(77,500)</b>	<b>–</b>

Vesting during year	Vested as at year end	Unvested as at year end	Exercise price (p)	Date from which first exercisable	Expiry date
-	-	-	0.08	2 August 2010	1 August 2017
-	-	-	0.08	18 March 2014	14 August 2021
52,736	52,736	-	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
-	-	425,000	0.08	17 May 2020	16 May 2027
<b>52,736</b>	<b>52,736</b>	<b>852,390</b>			
-	149,250	-	242	22 October 2016	21 October 2023
27,536	27,536	-	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
-	-	250,000	0.08	17 May 2020	16 May 2027
<b>27,536</b>	<b>176,786</b>	<b>473,309</b>			
42,998	42,998	-	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
-	-	250,000	0.08	17 May 2020	16 May 2027
<b>42,998</b>	<b>42,998</b>	<b>492,231</b>			
-	-	-	0.08	12 November 2015	11 November 2022
-	-	-			

# Remuneration committee report continued

## Annual report on remuneration 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 no longer hold options under the Circassia Holdings Limited EMI Share Option Scheme 2007 (the "EMI Scheme") due to the final options being exercised during the year. Executive Directors continue to hold options under 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.

### Gain on exercise of share options

Executive Directors	Date of exercise	Number of options exercised	Exercise price (p)	Market value at date of exercise (p)	Gain on exercise of share options (£)
S Harris	17 June 2017	317,500	0.08p	83.75p	£265,652
	17 June 2017	217,875	0.08p	83.75p	£182,296
JJ Garaud	2 June 2017	77,500	0.08p	89.11p	£68,998

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 2017 (104p) and the acquisition price of the shares. The value as a percentage of salary has been calculated using base salary as at 31 December 2017.

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 2017	Value of owned shares as a % of salary	Shareholding requirement met
<b>Executive Directors</b>			
S Harris	5,959,052	1514%	Yes
J Cotta	46,875	19%	No
R Hafner	900,544	336%	Yes
<b>Non-Executive Directors</b>			
F Granata	312,500	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 2017	Vesting	c/f as at 31 December 2017	Value of owned shares as a % of salary
<b>Executive Directors</b>					
J Cotta	4 March 2014	9,375	(9,375)	–	–
R Hafner	4 March 2014	29,500	(29,500)	–	–

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 2016 and 31 December 2017
<b>CEO</b>	
Salary	3% increase
Benefits	nil
Bonus	Not applicable <sup>1</sup>
<b>Average per employee</b>	
Salary	3% increase
Benefits	nil
Bonus	25% increase

<sup>1</sup> A bonus equivalent to 75% of salary was paid in 2017. No bonus was paid in 2016.

**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 2017 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 2017 was 104p. From 1 January 2017 to 31 December 2017 the share price ranged from a high of 109.5p to a low of 77p.

**Total shareholder return**

18 March 2014 – 31 December 2017

# Remuneration committee report continued

## Annual report on remuneration continued

### Total remuneration for the CEO over time

		2017	2016	2015	2014
Total remuneration	(£'000)	3,642	2,817	2,359	1,528
Bonus awarded	(%)	75%	Nil	100%	93%
LTIP vesting	(%)	21%	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.

	2017 £m	2016 £m
Overall expenditure on pay	41.1	29.3
Dividend plus share buyback	Nil	Nil

### Application of remuneration policy to 2018 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, 8 February 2017 and 6 February 2018 and a 3% increase was applied effective 1 January 2015, 2016, 2017 and 2018 respectively. This increase is in line with the average salary increase awarded to UK employees.

	Salary as at 1 January 2018	Salary as at 1 January 2017	% Increase
Steven Harris	421,680	409,400	3
Julien Cotta	264,400	256,700	3
Rod Hafner	286,800	278,450	3

### Performance targets for 2018 bonus and PSP awards

For the financial year 2018, 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 2018 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 2018, 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 2018, up to 50% of the total award will vest subject to achievement of certain strategic business performance criteria.

Award levels for 2018 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 2018. This increase is in line with the average salary increase awarded to UK employees. The fees paid to the Non-Executive Directors in 2017 and the fees proposed to be paid in 2018 are set out below:

	From 1 January 2017 (£)	From 1 January 2018 (£)	Increase %
Chairman	138,400	142,550	3
Non-Executive Director	45,850	47,225	3
Senior Independent Non-Executive Director Fee	52,950	54,540	3
Remuneration and Audit Committee Chairmanship Fee	10,900	11,230	3
Nomination Committee Chair	8,150	8,395	3
Committee Memberships	5,450	5,615	3

### Shareholder voting at the Annual General Meeting on 26 May 2017

The Annual Report on Remuneration was approved by Shareholders at last year's AGM held on 26 May 2017 with the following votes cast for and against.

Voting results at 2017 AGM	For (%)	Against (%)	Withheld (votes)
To approve the Annual report on remuneration	99.99	0.01	998,360

### 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 20 May 2015

The Directors' remuneration policy report was approved by Shareholders at the AGM held on 20 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 24 April 2018

### Marvin Samson

Chair 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 2017.

## Information included in Strategic Report

The Company's Strategic Report is on pages 01 to 39 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	20 to 25
Research and development	20 to 25
Employee involvement	31
Disclosures concerning greenhouse gas emissions	32

## Corporate governance statement

The information that fulfils the requirements of the Corporate Governance Statement can be found in the Corporate Governance Report on pages 42 to 43 and the Strategic Report on pages 33 to 39 (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 2017 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 2017 (2016: £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 Charles Swingland and Tim Corn who left the Board on 26 May 2017 and Ms Sharon Curran, Ms Jo Le Couilliar, and Dr Heribert Staudinger, who all joined on 8 February 2018.

The Board confirms that each of the Directors who served during the year has been subject to evaluation during this period with the exception of Charles Swingland and Tim Corn who left before the Board evaluation took place in December 2017. In accordance with the Code, all Directors of the Company will stand for re-election on an annual basis. At the 2018 Annual General Meeting, Jean-Jacques Garaud and Marvin Samson 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 17 April 2018 the Company had a total of 147 Ordinary Shareholders and 333,466,262 Ordinary shares in issue.

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 share capital of the Company increased by a further 1,221,674 as a result of share issues required to satisfy employee share awards.

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 26 to the financial statements. The Circassia Pharmaceuticals plc Employee Benefit Trust abstains from voting on the shares held by it. 373,299 shares were acquired by the Employee Benefit Trust during the year (2016: 156,035), 32,157 were transferred out (2016: nil) and the balance of shares held at 31 December 2017 was therefore 608,023 (2016: 266,881).

Pursuant to the Articles of Association and vote of Shareholders at the AGM which took place on 26 May 2017 the Company was granted authority to allot shares for cash up to a maximum nominal amount of £26,579 on a non-pre-emptive basis. This nominal amount represents approximately 10% of the issued share capital of the Company as at 17 April 2018. No such allotments using this authority were made during the year to 31 December 2017 or up to the date of this report other than shares issued to satisfy employee share awards. 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 2017 to 31 December 2017 the share price ranged from a high of 109.5p to a low of 77p. The average price for the period was 90.5p. The mid-market price of an Ordinary share on 31 December 2017 was 104p.

## Significant shareholdings

As at 17 April 2018 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	87,763,271	26.3%
Nortrust Nominees Limited	58,832,384	17.6%
State Street Nominees Limited	51,334,357	15.4%
AstraZeneca UK Limited	47,355,417	14.2%
PH Nominees Limited	28,324,296	8.5%
Chase Nominees Limited	23,489,435	7.0%

The Board confirms that, in accordance with LR 9.2.2AR(2)(a) Relationship Agreements were put in place by 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 (by virtue of its shareholding in Touchstone's parent company, IP Group plc) 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 31 March 2018, Invesco and Touchstone Innovations together held 34.3% of the voting rights attached to the issued share capital of the Company.

# Directors' report continued

## **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.

Subject matter	Page reference
Statement by the board on relationship agreements with controlling shareholders	79 (Directors' report)

## **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 2017.

#### **Auditor**

PricewaterhouseCoopers LLP has been re-appointed as auditor and a resolution to approve this re-appointment 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 30 May 2018 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

24 April 2018



# Statement of Directors' responsibilities

## In respect of the Annual report and accounts and financial statements for the year ended 31 December 2017

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 the parent Company 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

24 April 2018



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

## Report on the audit of the financial statements

### 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 2017 and of the group's loss and the group's and the parent company's cash flows for the year then ended;
- have been properly prepared in accordance with IFRSs as adopted by the European Union and, as regards the parent company's financial statements, as applied in accordance with the provisions of the Companies Act 2006; and
- 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.

We have audited the financial statements, included within the Annual report and accounts (the "Annual Report"), which comprise: the Consolidated and parent company statements of financial position as at 31 December 2017; the Consolidated statement of comprehensive income, the Consolidated and parent company statements of cash flows, and 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 description of the significant accounting policies.

Our opinion is consistent with our reporting to the Audit Committee.

### Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) ("ISAs (UK)") and applicable law. Our responsibilities under ISAs (UK) are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Independence

We remained independent of the group in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, which includes the FRC's Ethical Standard, as applicable to listed public interest entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

To the best of our knowledge and belief, we declare that non-audit services prohibited by the FRC's Ethical Standard were not provided to the group or the parent company.

### Our audit approach

#### Overview

- Overall group materiality: £5.7 million (2016: £3.25 million), based on 5% of loss before tax.
- Overall parent company materiality: £5.4 million (2016: £3.0 million), based on 1% of total assets (adjusted so as not to exceed 95% of Group materiality).
- We identified 4 components which, in our view, required a full scope audit based on their size or risk.
- We used component teams in 2 countries to perform 2 full scope audits, with the Group team performing the remaining 2 components.
- Reporting entities where we performed audit procedures accounted for 99% of Group loss before tax; 98% of Group revenue; and 98% of Group total assets. Our audit scope provided sufficient appropriate audit evidence as a basis for our opinion on the Group financial statements as a whole.
- Impairment of goodwill and intangibles (Group).
- Accounting for the collaboration with AstraZeneca (Group).
- Impairment of the parent company's Investment in and intercompany balances with subsidiaries (Parent).

### The scope of our audit

As part of designing our audit, we determined materiality and assessed 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.

We gained an understanding of the legal and regulatory framework applicable to the group and the industry in which it operates, and considered the risk of acts by the group which were contrary to applicable laws and regulations, including fraud. We designed audit procedures at group and significant component level to respond to the risk, recognising that the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion. We focused on laws and regulations that could give rise to a material misstatement in the group and parent company financial statements, including, but not limited to, the Companies Act 2006, the Listing Rules and UK tax legislation. Our tests included, but were not limited to, review of the financial statement disclosures to underlying supporting documentation, review of correspondence with legal advisors, enquiries of management, including those outside of the finance function and review of significant components auditors' work. There are inherent limitations in the audit procedures described above and the further removed non-compliance with laws and regulations is from the events and transactions reflected in the financial statements, the less likely we would become aware of it.

We did not identify any key audit matters relating to irregularities, including fraud. As in all of our audits we also addressed the risk of management override of internal controls, including testing journals and evaluating whether there was evidence of bias by the directors that represented a risk of material misstatement due to fraud.

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

## Key audit matters

Key audit matters are those matters that, in the auditors' professional judgement, were of most significance in the audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by the auditors, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters, and any comments we make on the results of our procedures thereon, were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. This is not a complete list of all risks identified by our audit.

Key audit matter	How our audit addressed the key audit matter
<p>Impairment of goodwill and intangibles</p> <p>IAS 36 requires at least annual impairment assessments in relation to goodwill and intangible assets that are not yet ready for use, with more regular assessment should an impairment trigger be identified. No impairment triggers were considered to have occurred at the cash generating unit level. However, at an individual asset level triggers were identified and impairments were determined to be required for Seriveo (£31.0m), Flixotide pMDI substitute (EU rights) (£4.7m) and Particle-engineered version of salmeterol xinafoate (£1.3m).</p> <p>Goodwill of £10.0m and intangible assets of £199.7m are significant balances to the Group. 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 value-in-use model for both goodwill and intangible asset impairment testing.</p> <p>Refer to page 51 (Audit Committee Report), page 97 (Critical accounting estimates and judgements), and pages 110 to 113 in the notes.</p> <p>Group</p>	<p>We assessed the level at which impairment testing was performed. Based on our knowledge of the business, including the use of assets and internal reporting, we agreed with management's judgement that, for the assessment of the impairment of goodwill and intangible assets, the Group has three CGU's.</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, with no exceptions identified. Management have applied a Value in Use method to calculate the CGU's and individual assets' recoverable amount. We concluded that this approach is appropriate.</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, historical growth rates and the size of the sales force available to promote this product line). We concluded that the terminal growth rates were reasonable based on our market experts' analysis of the asthma market as well as being consistent with the rate used in the prior year. We considered that revenue growth rates were reasonable, taking into account the increased sales force available to promote the product. Despite third party forecasts for the market peak being lower than those of management, sufficient headroom remains after sensitising sales to this level, such that no impairment is indicated;</li> <li>(ii) forecasts for sales of new products, including comparing projected peak sales of certain marketed and in-development pharmaceutical products with third party forecasts and, in the case of in-development products, the probabilities associated with such products reaching the market. Despite third party forecasts for one product being lower than those of management, sufficient headroom remains after reducing sales to be in line with third party expectations such that no impairment is indicated.</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. We identified and corroborated any differences in the historical forecasting accuracy to conclude that forecasting accuracy is appropriate.</p> <p>Discount rate: We used our experts to recalculate management's discount rates and benchmark the rates against companies of a similar nature. We observed that the rates used are at the low end of our expected range.</p> <p>We also obtained management's sensitivity analysis and performed our own sensitivities reflecting what we believed to be a range of reasonably individually possible alternative outcomes over the forecast cash flows and discount rates, the results of which did not indicate an impairment to goodwill or other intangible assets on a CGU basis. We found management assumptions in relation to individual asset impairments to be reasonable.</p>

#### Accounting for collaboration with AstraZeneca

The Group entered into a Development and Commercialisation Agreement ('DCA') with AstraZeneca to acquire the rights to commercialise Duaklir in the United States of America on 12 April 2017. In addition, the Group acquired the right to exercise an option to acquire the remaining contractual rights and economic benefits of Tudorza.

The consideration comprised of 47,355,417 ordinary shares valued at \$50.0m, plus further deferred non-consideration of \$100.0m and contingent royalty consideration on further sales of Duaklir.

Our main area of focus and the area of most complexity and judgement was the assessment of whether control of each product had transferred to the Group, resulting in a business combination. Where a business combination had occurred, we then focused on the identification and valuation of intangible assets, including in relation to future royalties payable to AstraZeneca, for which a corresponding liability for contingent consideration was recognised on initial recognition and subsequently re-measured.

Refer to page 51 (Audit Committee Report), page 97, (Critical accounting estimates and judgements), and pages 126 and 127 in the notes.

Group

We obtained and reviewed the underlying DCA between the Group and AstraZeneca and concurred with management that control of the Duaklir business had passed to the Group and that control of the Tudorza business would not pass to the Group until the option to acquire the remaining contractual rights and economic benefits becomes exercisable. We also concurred that the option is not "substantive" (as defined in IFRS 10) and therefore should not be recognised as a liability of the Group or parent company at the balance sheet date.

We assessed management's accounting for the business combination under IFRS 3 "Business combinations".

We obtained management's valuation models and tested the mathematical accuracy. We did not identify any exceptions in this testing.

We assessed the appropriateness of the relative fair value approach used to determine the split of consideration between Duaklir and Tudorza products and concurred that this was the most appropriate methodology in the circumstances.

We worked with our valuation experts to assess the reasonableness of management's assumptions by using our understanding of the business and the pharmaceutical industry, and performing the following:

We assessed the assumed peak sales and sales profile over the life cycle (taking account of patent expiry dates) for both products; We recalculated management's discount rates and benchmarked the rates against companies of a similar nature;

We obtained an understanding of the anticipated cash flows and costs used in the acquisition model, on which the valuations were based, including discussions with R&D specialists outside of the finance function;

We evaluated the working capital assumptions included within the model; and

We agreed the future royalty rates payable by the Group to other parties to the underlying DCA.

We suggested that cash flows should be modelled over the whole life cycle of the product (rather than only over the licence period) and noted that certain royalty rates used in the model had not been updated to reflect the final agreement. The model utilised by management was updated to take account of these items, and we considered that management's assumptions in the final model were reasonable.

In relation to the re-measurement of contingent consideration in respect of future royalties payable to AstraZeneca, we obtained management's revised forecasts as at 31 December 2017, considered the reasonableness of changes to anticipated royalties, tested the mathematical accuracy of the calculations and checked that the correct royalty rates were applied from the underlying DCA, with no exceptions identified.

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

<p>Impairment of the parent company's investment in and intercompany balances with subsidiaries</p> <p>Investment in subsidiaries of £273.5m is a significant balance. In addition, the parent company has intercompany receivables totalling £327.5m from its subsidiary companies. The market capitalisation of the Group is £289m, indicating the existence of a potential impairment trigger.</p> <p>Judgement is required in the impairment assessment, specifically in forecasting the future results of the subsidiaries. Judgement is also required in determining the discount rates to be applied to future cash flows. Management have utilised value-in-use models, consistent with the models used for goodwill and intangible asset impairment testing, for testing for possible impairment of the investment in and balances with subsidiary undertakings.</p> <p>Refer to page 51 (Audit Committee Report), page 97 (Critical accounting estimates and judgements), and pages 113 and 114 in the notes.</p> <p>Parent</p>	<p>We have leveraged our analysis and understanding of key assumptions and judgements in the value-in-use models used for testing for potential impairment of goodwill and intangible assets in the consolidated financial statements. In assessing the carrying value of investments in and balances with subsidiary companies, we compared the carrying value of these balances with the cash flows expected to be generated from the value-in-use models for each cash generating unit.</p> <p>We found that there was significant headroom between the value of the cash generating units derived from the value-in-use models and the carrying value of the parent company's investments in and balances with subsidiary undertakings.</p> <p>We performed our own sensitivities (reflecting what we believed to be a range of individually reasonably possible alternative outcomes) over the forecast cash flows and discount rates, the results of which did not indicate an impairment.</p>
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## 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 structure of the group and the parent company, the accounting processes and controls, and the industry in which they operate.

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 structure of the Group and the Company, the accounting processes and controls, and the industry in which they operate.

The Group's accounting process is structured around a local finance function in each of the Group's reporting entities. These functions maintain their own accounting records and controls (although transactional processing and certain controls for some reporting units are performed by the head office finance team) and report to the head office finance team through an integrated consolidation system.

In establishing the overall Group audit strategy and plan, we determined the type of work that needed to be performed at the reporting entities by the Group engagement team and by component auditors from other PwC network firms. Where the work was performed by component auditors, we determined the level of involvement we needed to have in the audit work at those reporting entities so as to be able to conclude whether sufficient appropriate audit evidence had been obtained as a basis for our opinion on the Group financial statements as a whole.

For each reporting entity we determined whether we required an audit of their reported financial information ("full scope"). Those where a full scope audit was required included Circassia Inc (incorporated in the USA), determined as individually financially significant because it contributes more than 15% of the Group's underlying loss before tax and Circassia AB (incorporated in Sweden) due to its size or risk. We also undertook the statutory audit of two further reporting units incorporated in the UK, Circassia Pharmaceuticals plc and Circassia Limited. Senior members of the UK engagement team attended planning meetings with each engagement team and attended, either in person or by telephone, the audit closing meetings. A senior member of the Group audit engagement team visited Sweden, to review the work undertaken by component auditors and assess the audit findings of Circassia AB. The Group audit team reviewed the working papers of the US component team remotely.

In addition to the work performed at the in-scope reporting entities, there is a substantial amount of work performed at head office by the Group audit engagement team. The Group consolidation, financial statement disclosures and a number of complex items, prepared by the head office finance function, were audited by the Group engagement team. These included goodwill, other intangible assets, investments, business combinations, bank and other borrowings and related finance costs, current and deferred tax, central adjustments recorded as part of the consolidation process and assessment of impacts of new accounting standards (IFRS 9 and 15).

In aggregate our audit procedures accounted for 99% of Group loss before tax.

As a result of its structure and size, the Group also has a number of small reporting entities that make up the remaining portion of the key coverage metrics. These small reporting units are covered by the work performed by the Group audit engagement team, where we perform analytical review procedures. A significant proportion of these remaining reporting units not selected for local procedures were subject to an analysis of year on year movements, at a level of disaggregation to enable a focus on higher risk balances and unusual movements. Those not subject to analytical review procedures were individually, and in aggregate, immaterial. This gave us the evidence we needed for our opinion on the financial statements as a whole.



## 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 in aggregate on the financial statements as a whole.

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

	Group financial statements	Parent company financial statements
<b>Overall materiality</b>	£5.7 million (2016: £3.25 million).	£5.4 million (2016: £3.0 million).
<b>How we determined it</b>	5% of loss before tax.	1% of total assets (adjusted so as not to exceed 95% of Group materiality).
<b>Rationale for benchmark applied</b>	<p>Auditing standards allow materiality to be based on a variety of measures depending on the nature and business of the entity in question. The most common benchmark is profit or loss before tax, although for R&amp;D companies at the development stage, expenses are sometimes used.</p> <p>As the business has continued to pursue revenue-generating activities such as NIOX trading and the new AZ collaboration, as well as the discontinuation of the Allergy programmes, we considered loss before tax to be the measure of most relevance to users of the accounts. In the prior year we used loss before tax and the exceptional items related to the allergy programme (primarily impairment of intangible assets), as the exceptional items were material one off items not expected to be repeated. While some items have been identified as "non-underlying" in the current year, none are considered "exceptional".</p>	We believe that total assets is the primary measure used by the shareholders in assessing the performance and position of the entity and reflects the Company's principal activity as a holding company.

For each component in the scope of our group audit, we allocated a materiality that is less than our overall group materiality. The range of materiality allocated across components was between £1.6 million and £5.4 million. 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 £0.3 million (Group audit) (2016: £0.2 million) and £0.3 million (Parent company audit) (2016: £0.2 million) as well as misstatements below those amounts that, in our view, warranted reporting for qualitative reasons.

## Going concern

In accordance with ISAs (UK) we report as follows:

Reporting obligation	Outcome
We are required to report if we have anything material to add or draw attention to in respect of the directors' statement in the financial statements about whether the directors considered it appropriate to adopt the going concern basis of accounting in preparing the financial statements and the directors' identification of any material uncertainties to the group's and the parent company's ability to continue as a going concern over a period of at least twelve months from the date of approval of the financial statements.	We have nothing material to add or to draw attention to. However, because not all future events or conditions can be predicted, this statement is not a guarantee as to the group's and parent company's ability to continue as a going concern.
We are required to report if the directors' statement relating to Going Concern in accordance with Listing Rule 9.8.6R(3) is materially inconsistent with our knowledge obtained in the audit.	We have nothing to report.

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

## Reporting on other information

The other information comprises all of the information in the Annual Report other than the financial statements and our auditors' report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except to the extent otherwise explicitly stated in this report, any form of assurance thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If we identify an apparent material inconsistency or material misstatement, we are required to perform procedures to conclude whether there is a material misstatement of the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report based on these responsibilities.

With respect to the Strategic Report and Directors' Report, we also considered whether the disclosures required by the UK Companies Act 2006 have been included.

Based on the responsibilities described above and our work undertaken in the course of the audit, the Companies Act 2006, (CA06), ISAs (UK) and the Listing Rules of the Financial Conduct Authority (FCA) require us also to report certain opinions and matters as described below (required by ISAs (UK) unless otherwise stated).

### Strategic Report and Directors' Report

In our opinion, based on the work undertaken in the course of the audit, the information given in the Strategic Report and Directors' Report for the year ended 31 December 2017 is consistent with the financial statements and has been prepared in accordance with applicable legal requirements. (CA06) In light of the knowledge and understanding of the group and parent company and their environment obtained in the course of the audit, we did not identify any material misstatements in the Strategic Report and Directors' Report. (CA06)

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

We have nothing material to add or draw attention to regarding:

- The directors' confirmation on page 52 of the Annual Report 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.
- The disclosures in the Annual Report that describe those risks and explain how they are being managed or mitigated.
- The directors' explanation on page 39 of the Annual Report 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 to report having performed a review of the directors' statement that they have carried out a robust assessment of the principal risks facing the group and 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 UK Corporate Governance Code (the "Code"); and considering whether the statements are consistent with the knowledge and understanding of the group and parent company and their environment obtained in the course of the audit. (Listing Rules)

### Other Code Provisions

We have nothing to report in respect of our responsibility to report when:

- The statement given by the directors, on page 47, that they consider the Annual Report taken as a whole to be fair, balanced and understandable, and provides the information necessary for the 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 obtained in the course of performing our audit.
- The section of the Annual Report on page 51 describing the work of the Audit Committee does not appropriately address matters communicated by us to the Audit Committee.
- The directors' statement relating to the parent company's compliance with the Code does not properly disclose a departure from a relevant provision of the Code specified, under the Listing Rules, for review by the auditors.

### Directors' Remuneration

In our opinion, the part of the Directors' Remuneration Report to be audited has been properly prepared in accordance with the Companies Act 2006 (CA06).

## Responsibilities for the financial statements and the audit

### Responsibilities of the directors for the financial statements

As explained more fully in the Statement of Directors' Responsibilities set out on page 82, the directors are responsible for the preparation of the financial statements in accordance with the applicable framework and for being satisfied that they give a true and fair view. The directors are also responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the group's and the parent company's ability to continue as a going concern, disclosing as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the group or the parent company or to cease operations, or have no realistic alternative but to do so.

### Auditors' responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on the FRC's website at: [www.frc.org.uk/auditorsresponsibilities](http://www.frc.org.uk/auditorsresponsibilities). This description forms part of our auditors' report.

### Use of this report

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.

## Other required reporting

### Companies Act 2006 exception reporting

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
- certain disclosures of directors' remuneration specified by law are not made; 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.

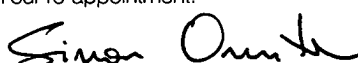
We have no exceptions to report arising from this responsibility.

## Appointment

We were appointed by the directors of the Company (which was unlisted at the time) in September 2007 to audit the financial statements for the year ended 31 December 2007 and subsequent financial periods. The period of total uninterrupted engagement is 11 years, covering the years ended 31 December 2007 to 31 December 2017. In December 2016, the Company held a competitive tender process for the audit of the year ending 31 December 2017, which resulted in our re-appointment.

### Simon Ormiston (Senior Statutory Auditor)

for and on behalf of PricewaterhouseCoopers LLP  
Chartered Accountants and Statutory Auditors  
Cambridge



24 April 2018

# Consolidated statement of comprehensive income for the year ended 31 December 2017

		2017			2016 Restated <sup>1</sup>		
	Notes	Underlying operations £m	Non-underlying items <sup>2</sup> £m	Total £m	Underlying operations £m	Non-underlying items <sup>2</sup> £m	Total £m
<b>Continuing operations</b>							
Revenue	4	46.3	–	46.3	23.1	–	23.1
Cost of sales		(10.0)	–	(10.0)	(8.0)	–	(8.0)
<b>Gross profit</b>		<b>36.3</b>	<b>–</b>	<b>36.3</b>	<b>15.1</b>	<b>–</b>	<b>15.1</b>
Research and development costs		(15.3)	(82.1)	(97.4)	(17.3)	(0.5)	(17.8)
Sales and marketing		(49.6)	–	(49.6)	(27.0)	(0.2)	(27.2)
Administrative expenses		(11.0)	0.1	(10.9)	(14.6)	(0.3)	(14.9)
<b>Operating loss</b>	8	<b>(39.6)</b>	<b>(82.0)</b>	<b>(121.6)</b>	<b>(43.8)</b>	<b>(1.0)</b>	<b>(44.8)</b>
Other (losses) and gains	6	(1.1)	11.5	10.4	5.2	–	5.2
Finance costs	7	(0.1)	(2.7)	(2.8)	(0.1)	–	(0.1)
Finance income	7	0.4	–	0.4	0.9	–	0.9
<b>Loss before tax</b>		<b>(40.4)</b>	<b>(73.2)</b>	<b>(113.6)</b>	<b>(37.8)</b>	<b>(1.0)</b>	<b>(38.8)</b>
Taxation	12	3.5	16.5	20.0	1.9	–	1.9
<b>Loss for the financial year from continuing operations</b>		<b>(36.9)</b>	<b>(56.7)</b>	<b>(93.6)</b>	<b>(35.9)</b>	<b>(1.0)</b>	<b>(36.9)</b>
<b>Discontinued operations</b>							
Loss for the year from discontinued operations attributable to owners of Circassia Pharmaceuticals plc	10	–	(5.5)	(5.5)	–	(100.5)	(100.5)
<b>Loss for the financial year</b>		<b>(36.9)</b>	<b>(62.2)</b>	<b>(99.1)</b>	<b>(35.9)</b>	<b>(101.5)</b>	<b>(137.4)</b>
<b>Loss attributable to:</b>							
Owners of Circassia Pharmaceuticals plc		(36.9)	(62.2)	(99.1)	(35.8)	(101.5)	(137.3)
Non-controlling interests		–	–	–	(0.1)	–	(0.1)
<b>Loss for the financial year</b>		<b>(36.9)</b>	<b>(62.2)</b>	<b>(99.1)</b>	<b>(35.9)</b>	<b>(101.5)</b>	<b>(137.4)</b>
<b>Other comprehensive income</b>							
<b>Items that may be subsequently reclassified to profit or loss</b>							
Share of other comprehensive income of joint venture	18	–	–	–	–	0.1	0.1
Currency translation differences	29	2.2	–	2.2	9.7	–	9.7
<b>Total other comprehensive income for the year</b>		<b>2.2</b>	<b>–</b>	<b>2.2</b>	<b>9.7</b>	<b>0.1</b>	<b>9.8</b>
<b>Total comprehensive expense for the year</b>		<b>(34.7)</b>	<b>(62.2)</b>	<b>(96.9)</b>	<b>(26.2)</b>	<b>(101.4)</b>	<b>(127.6)</b>
<b>Total comprehensive expense attributable to:</b>							
Owners of Circassia Pharmaceuticals plc		(34.7)	(62.2)	(96.9)	(26.1)	(101.4)	(127.5)
Non-controlling interests		–	–	–	(0.1)	–	(0.1)
<b>Total comprehensive expense for the year</b>		<b>(34.7)</b>	<b>(62.2)</b>	<b>(96.9)</b>	<b>(26.2)</b>	<b>(101.4)</b>	<b>(127.6)</b>

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

		2017 £	2016 Restated <sup>1</sup> £
<b>Basic and diluted loss per share</b>			
Loss per share from continuing operations	13	(0.29)	(0.13)
Total loss per share	13	(0.31)	(0.48)

<sup>1</sup> Restated to show the results of the allergy business in discontinued operations, see note 10 for further details

<sup>2</sup> See note 11 for details

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 £1.5 million (2016: £2.4 million).


The notes on pages 96 to 128 are an integral part of these consolidated financial statements.

# Consolidated statement of financial position as at 31 December 2017

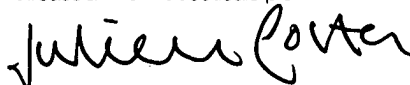
	Notes	2017 £m	2016 £m
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	14	1.4	1.4
Goodwill	15	10.0	9.7
Intangible assets	16	199.7	167.1
Deferred tax assets	24	15.7	16.6
Investment in joint venture	18	0.5	0.9
Prepayment for business combination	35	77.9	–
Non-current tax assets	12	7.3	–
		<b>312.5</b>	<b>195.7</b>
<b>Current assets</b>			
Inventories	19	5.0	4.6
Trade and other receivables	20	18.9	7.7
Current tax assets	12	6.5	8.7
Short-term bank deposits	21	15.0	20.0
Cash and cash equivalents	21	44.5	97.4
		<b>89.9</b>	<b>138.4</b>
<b>Total assets</b>		<b>402.4</b>	<b>334.1</b>
<b>Equity and liabilities</b>			
Ordinary shares	25	0.3	0.2
Share premium	27	602.2	563.8
Other reserves	29	17.2	12.5
Accumulated losses	28	(394.9)	(295.8)
<b>Total equity</b>		<b>224.8</b>	<b>280.7</b>
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Deferred tax liabilities	24	24.1	31.9
Non-contingent consideration	35	68.7	–
Contingent consideration	35	33.6	–
Non-current trade payables	22	20.4	–
		<b>146.8</b>	<b>31.9</b>
<b>Current liabilities</b>			
Trade and other payables	22	30.8	21.5
		<b>30.8</b>	<b>21.5</b>
<b>Total liabilities</b>		<b>177.6</b>	<b>53.4</b>
<b>Total equity and liabilities</b>		<b>402.4</b>	<b>334.1</b>

The notes on pages 96 to 128 are an integral part of these consolidated financial statements. The financial statements on pages 90 to 128 were authorised for issue by the Board of Directors on 24 April 2018 and were signed on its behalf by

**Steven Harris**  
Chief Executive Officer  
Circassia Pharmaceuticals plc  
Registered number: 05822706



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



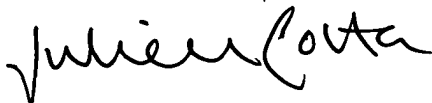
# Parent Company statement of financial position as at 31 December 2017

	Notes	2017 £m	2016 £m
<b>Assets</b>			
<b>Non-current assets</b>			
Investments in subsidiaries	17	273.5	262.0
		<b>273.5</b>	<b>262.0</b>
<b>Current assets</b>			
Trade and other receivables	20	328.2	220.9
Short-term bank deposits	21	15.0	20.0
Cash and cash equivalents	21	0.3	73.0
		<b>343.5</b>	<b>313.9</b>
<b>Total assets</b>		<b>617.0</b>	<b>575.9</b>
<b>Equity and liabilities</b>			
<b>Equity attributable to the owners of the Company</b>			
Ordinary shares	25	0.3	0.2
Share premium	27	602.2	563.8
Other reserves	29	8.6	6.1
Retained earnings	28	1.9	0.4
<b>Total equity</b>		<b>613.0</b>	<b>570.5</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	22	4.0	5.4
		<b>4.0</b>	<b>5.4</b>
<b>Total equity and liabilities</b>		<b>617.0</b>	<b>575.9</b>

The notes on pages 96 to 128 are an integral part of these financial statements. The financial statements on pages 90 to 128 were authorised for issue by the Board of Directors on 24 April 2018 and were signed on its behalf by

**Steven Harris**  
Chief Executive Officer  
Circassia Pharmaceuticals plc  
Registered number: 05822706

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




# Consolidated and parent Company statement of cash flows for the year ended 31 December 2017

		Group		Company	
	Notes	2017 £m	2016 £m	2017 £m	2016 £m
<b>Cash flows from operating activities</b>					
Cash (used in)/generated from operations	30	(66.4)	(68.4)	0.4	1.9
Interest paid		(0.1)	(0.1)	–	(0.1)
Tax credit received		8.9	11.8	–	–
<b>Net cash (used in)/generated from operating activities</b>		<b>(57.6)</b>	<b>(56.7)</b>	<b>0.4</b>	<b>1.8</b>
<b>Cash flows from investing activities</b>					
Acquisition of subsidiaries, net of cash acquired		–	(0.2)	–	(19.0)
Recapitalisation of subsidiary		–	–	(9.0)	–
Purchases of property, plant and equipment	14	(0.8)	(0.7)	–	–
Contingent consideration payment		–	(30.0)	–	(30.0)
Interest received		0.8	0.7	0.7	0.7
Joint venture distributions to owners	18	0.2	–	–	–
Loans granted to subsidiary undertakings		–	–	(68.2)	(29.0)
Decrease in short-term bank deposits		5.0	17.8	5.0	17.8
<b>Net cash generated from/(used in) investing activities</b>		<b>5.2</b>	<b>(12.4)</b>	<b>(71.5)</b>	<b>(59.5)</b>
<b>Cash flows from financing activities</b>					
Costs offset against share premium		(1.6)	–	(1.6)	–
Purchase of treasury shares	34	–	(0.4)	–	–
Transactions with non-controlling interests	29	–	(3.2)	–	–
<b>Net cash used in financing activities</b>		<b>(1.6)</b>	<b>(3.6)</b>	<b>(1.6)</b>	<b>–</b>
<b>Net decrease in cash and cash equivalents</b>		<b>(54.0)</b>	<b>(72.7)</b>	<b>(72.7)</b>	<b>(57.7)</b>
Cash and cash equivalents at 1 January	21	97.4	166.0	73.0	130.7
Exchange gains on cash and cash equivalents		1.1	4.1	–	–
<b>Cash and cash equivalents at 31 December</b>	21	<b>44.5</b>	<b>97.4</b>	<b>0.3</b>	<b>73.0</b>

The notes on pages 96 to 128 are an integral part of these consolidated financial statements.

# Consolidated statement of changes in equity for the year ended 31 December 2017

	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 2016	25, 27, 28, 29	0.2	564.0	2.8	(158.5)	408.5	1.2	409.7
Loss for the financial year	28	–	–	–	(137.3)	(137.3)	(0.1)	(137.4)
Other comprehensive income								
Share of other comprehensive income of joint venture	29	–	–	0.1	–	0.1	–	0.1
Currency translation differences	29	–	–	9.7	–	9.7	–	9.7
Total comprehensive income/(expense)		–	–	9.8	(137.3)	(127.5)	(0.1)	(127.6)
Transactions with owners:								
Purchase of own shares	29	–	–	(0.4)	–	(0.4)	–	(0.4)
Employee share option scheme	29	–	–	2.4	–	2.4	–	2.4
Expenses offset against share premium	27	–	(0.2)	–	–	(0.2)	–	(0.2)
Transactions with non-controlling interests	29	–	–	(2.1)	–	(2.1)	(1.1)	(3.2)
<b>At 31 December 2016</b>	<b>25, 27, 28, 29</b>	<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>
<b>At 1 January 2017</b>	<b>25, 27, 28, 29</b>	<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>
Loss for the financial year	28	–	–	–	(99.1)	(99.1)	–	(99.1)
Currency translation differences	29	–	–	2.2	–	2.2	–	2.2
Total comprehensive expense		–	–	2.2	(99.1)	(96.9)	–	(96.9)
Transactions with owners:								
Issue of ordinary shares	25	0.1	38.4	–	–	38.5	–	38.5
Employee share option scheme	29	–	–	2.5	–	2.5	–	2.5
<b>At 31 December 2017</b>	<b>25, 27, 28, 29</b>	<b>0.3</b>	<b>602.2</b>	<b>17.2</b>	<b>(394.9)</b>	<b>224.8</b>	<b>–</b>	<b>224.8</b>

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

The notes on pages 96 to 128 are an integral part of these consolidated financial statements



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# 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 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.

The exemption from audit has been claimed for the individual financial statements of Circassia Pharma Limited (registered number 6410308) and Prosonix Limited (registered number 05679156) for the year ended 31 December 2017 under section 479A of Companies Act 2006. Circassia Pharmaceuticals plc has given the required guarantee under section 479C in respect of the reporting year. Circassia Pharma Limited and Prosonix Limited results are included in these consolidated financial statements.

### 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 2017 but had no significant impact on the Group:

- IAS 7 (amendment) – Statement of cash flows
- IAS 12 (amendment) – Income taxes

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' (effective 1 January 2018): adopting IFRS 9 will impact hedge accounting and receivables provisions. The basis of documentation and effectiveness testing of hedges under the new standard will be linked more closely to the risk management objectives, which may generate different levels of ineffectiveness than the current testing under IAS 39. The Group currently does not adopt hedge accounting hence the changes are not expected to have any significant impact on the financial statements.

Receivables provisions will move from an incurred to an expected loss model. The Group's largest exposure is trade receivables with the gross value of £4.0 million as at 31 December 2017. The new model will impact the timing and value of provision recognition on higher risk balances. No material impact is anticipated as a result of these changes.

IFRS 15 'Revenue from contract with customers' (effective 1 January 2018): IFRS 15 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 review of the impact of IFRS 15 requires an assessment at contract level to confirm the full impact of adopting this standard. Based on the analysis completed to date, the Directors consider that the new standard will not materially impact the revenue recognition for the Group business activities.

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 and are annotated with an asterisk.

#### 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. In addition, a judgement is made as to determine the point at which control of a business passes to the Group and a business combination occurs. Until control is passed to the Group, consideration paid or payable is presented as a prepayment for the business combination.

#### Accounting for the Collaboration with AstraZeneca

Following the collaboration and profit share arrangement with AstraZeneca, a Purchase Price Allocation exercise was performed focusing on the following key accounting areas:

##### — Determination and allocation of the consideration

Under the terms of the agreement to secure certain US commercial rights to Tudorza® and Duaklir®, a maximum total consideration of \$230 million plus future sales-based royalties is payable to AstraZeneca. For the purposes of IFRS 3, the total consideration included in the valuation consists of \$50 million for shares issued to AstraZeneca, \$100 million deferred non-contingent consideration and the fair value of royalties payable to AstraZeneca. It does not include the amount (up to \$80 million) that would be paid to exercise the Tudorza® option, which will be accounted for once exercised.

Under IFRS 3, it is necessary to determine the amount of consideration which should be allocated to Duaklir®. As this is an unusual scenario, there is no prescribed methodology for performing this exercise. Management has based the allocation of consideration between both products on a relative fair value approach. This was determined using a bottom-up business valuation for both products and allocating the amount expected to be paid for both products proportionately between both products. The valuation model was based on expected cash flows into perpetuity under two separate scenarios with certain key assumptions including the use of discount and terminal growth rates, revenue forecasts to 2034 incorporating a specific growth profile. These assumptions therefore give rise to a number of judgements in the valuation models.

##### — Initial valuation of Duaklir IPR&D

The Excess Earnings Method approach was determined to be the most appropriate methodology to use for the valuation of the In-Process Research & Development (IPR&D). This methodology made use of the same cash flows used in the Duaklir® business valuation with certain key assumptions including a specific rate of return of net working capital, no additional workforce requirement and minimal tangible fixed asset requirements.

##### — Initial valuation of Royalties\*

As part of the transaction, Circassia will pay royalties to AstraZeneca on future sales of Duaklir® in the United States. There is some uncertainty over the final amount of future sales and thus royalties due and therefore actual outcomes could differ significantly from the estimates made. Under IFRS 3, these royalties have been classified as additional consideration and initially recognised as an IPR&D asset with a corresponding contingent liability. The value of the IPR&D asset was calculated by management using a tax-effected NPV of the future royalty cash outflows at the date of the transaction. See note 35 for further details.

#### 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 (CGUs) containing the goodwill taking into account key assumptions (see note 15) 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.

#### Investments\*

Circassia Pharmaceuticals plc holds a number of investment balances in subsidiary companies. Investment 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 (CGUs) containing the investment. If there is a significant impairment of a particular CGU or if the Group's market capitalisation remains below the carrying value of Circassia Pharmaceuticals plc's aggregate investment in subsidiaries, this could result in an impairment of the investment.

# Notes to the financial statements continued

## Other accounting estimates and assumptions

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

Customer Relationships 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

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.

Share based payments

Options are 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 26.

Non-underlying items

The Group presents certain items of income and expense as non-underlying in the consolidated statement of comprehensive income.

Management primarily manage the business and measure performance based on the results of "underlying operations". Significant irregular and exceptional items are classified as "non-underlying" items and are excluded from the underlying measures. This is a judgemental area and is performed by Management.

## 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 four business segments during 2017, Allergy, Respiratory, NIOX® and US AZ collaboration. 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.

The allergy operating segment has been classified as a discontinued operation. Information about this discontinued segment is provided in note 10.

## Discontinued operations

A discontinued operation is a component of the Group's business that represents a separate major line of business or geographical area of operations that will not be progressed in the future. Discontinued operations are presented on the income statement as a separate line and are shown net of tax. Cash flows relating to discontinued operations are disclosed in the notes.

The allergy programme costs and the associated research and development tax credit for the year ended 31 December 2016 have been reclassified as discontinued operations in the consolidated statement of comprehensive income in accordance with IFRS 5 requirements. The decision to treat the allergy business as discontinued was made on 25 April 2017 when the Group announced a decision to cease all further activities on the allergy programmes.

### 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).

### 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 – 16 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 is 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.

# Notes to the financial statements continued

## 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. Write-downs of inventory occur in the general course of business and are recognised in cost of sales.

## 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.

## Business combinations under common control

Transactions relating to asset and liability transfers between two Group entities are accounted for by applying the predecessor value method whereby the acquired assets and liabilities are recorded at their existing carrying values on the date of transfer. No new goodwill arises in predecessor accounting.

## 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
Leasehold improvements	Over the life of the unbreakable 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.

### Deferred non-contingent consideration

Deferred non-contingent consideration is measured by discounting the liability, where the effect of the time value of money is material, using a pre-tax discount rate that reflects current market assessments of the time value of money and, when appropriate, the risks specific to the liability. Where discounting is used, the increase in the liability due to the passage of time is recognised as an interest expense in the income statement.

### Contingent royalty consideration

In a business combination, future royalty payments owed to the seller are treated as contingent consideration. The contingent consideration is recognised as a liability, an asset or equity depending on its terms. A contingent consideration arrangement is initially measured at fair value on the acquisition date based on a tax-effected net present value basis of the future cash outflows. Contingent consideration that is classified as a liability is remeasured to fair value at each reporting date, with changes included in the income statement in the post-combination period until the uncertainty is resolved.

### 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 26. 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 with non-market performance conditions 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.

### 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.

#### Rendering of services

Under the AstraZeneca collaboration agreement, the Group promotes the chronic obstructive pulmonary disease (COPD) treatment Tudorza® in the United States. Revenues recognised are the amounts invoiced to AstraZeneca pursuant to the right to collaborate with AstraZeneca on the commercialisation and development of Tudorza® in the United States. Revenue is recognised in the accounting periods in which the services are rendered.

# Notes to the financial statements continued

## 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 'Other gains and losses'. Previously foreign exchange differences were presented within 'Finance costs or income'. The change in the presentation reflects the fact that historically the foreign exchange differences were to a large extent driven by movements on foreign cash balances whereas following the AstraZeneca collaboration agreement the foreign exchange differences also arise from translation of monetary liabilities and as such the change in presentation to 'Other gains and losses' was deemed appropriate. This constitutes a voluntary change in accounting policy and has been applied retrospectively in the financial statements resulting in 2016 total finance income reducing by £5.2 million and Other gains increasing by £5.2 million. Had the foreign exchange differences for 2017 been presented within 'Finance costs or income', total finance income would have been £7.2 million higher and other gains £7.2 million lower. There has been no impact to total loss for the current or previous financial year as a result of the policy change. Had the current policy been applied to 2015 financial results total finance income would have been £1.8 million lower and other gains £1.8 million higher with no impact on total loss for the financial year.

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 2017, the Company issued 47,355,417 Ordinary shares with a value of \$50 million to AstraZeneca (AZ) as part of the consideration to secure certain US commercial rights to Tudorza® and Duaklir®. The Group's capital is comprised of share capital and share premium, which are disclosed in notes 25 and 27 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 Pound 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.

In relation to foreign currency risk, the Group's policy is to hold the majority of its funds in Sterling, monitor foreign currency rates and purchase foreign currency at spot rates.



The change in foreign exchange rates that is assessed to be reasonably likely for each currency in 2017 is 10% (2016: 15%).

At 31 December 2017, if the Euro had weakened/strengthened by 10% against Sterling with all other variables held constant, the post tax loss for the year would have been £0.4 million (2016: £1.6 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 2017 of a 10% weakening/strengthening of the US dollar against Sterling with all other variables held constant would have been a decrease/increase of £2.7 million (2016: £0.6 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 2017 would have been an increase/decrease of £0.1 million (2016: £0.1 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 2017 the Group placed funds on deposit with 6 banks (2016: 7 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. Financial liabilities outstanding for periods greater than one year in 2017 include non-contingent consideration, contingent royalty consideration and R&D contributions payable to AstraZeneca. There were no financial liabilities outstanding for periods greater than one year in 2016. The amounts disclosed in the table are the contracted cash flows discounted to present value where such impact is material:

At 31 December	Less than 1 year 2017 £m	Over 1 year 2017 £m	Less than 1 year 2016 £m
Non-contingent consideration	–	68.7	–
Contingent consideration	–	33.6	–
Trade and other payables	30.8	20.4	21.5
<b>Total</b>	<b>30.8</b>	<b>122.7</b>	<b>21.5</b>

#### Derivative financial instruments and hedging

There were no derivatives at 31 December 2017 or 31 December 2016.

### 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 2017 operating segments are identified within the Group by product portfolios:

- NIOX® relates to the portfolio of products used to improve asthma diagnosis and management by measuring fractional exhaled nitric oxide (FeNO);
- Respiratory relates to the portfolio of asthma and chronic obstructive pulmonary disease product candidates; and
- US AZ collaboration relates to the US collaboration agreement with AstraZeneca regarding the commercialisation of Tudorza® and of Duaklir® once approved.

The allergy operating segment has been classified as a discontinued operation. Information about this discontinued segment is provided in note 10.

There were no sales between the segments in either reporting year.

An impairment charge of £37.0 million in respiratory segment relates to three IPR&D intangible assets, see note 16 for further detail.

# Notes to the financial statements continued

The table below presents information regarding the Group's operating segments for the years ended 31 December 2017 and 2016. Costs shared between the segments are not allocated to individual segments for decision making purposes. These are disclosed under the column headed 'Unallocated'.

## Segment operating loss

	NIOX® £m	Respiratory £m	US AZ collaboration £m	Unallocated £m	Total £m
<b>Year ended 31 December 2017</b>					
<b>Revenue (from external customers by country, based on the destination of the customer)</b>					
US	9.5	–	19.0	–	28.5
EU	8.4	–	–	–	8.4
Asia Pacific	9.3	–	–	–	9.3
Rest of world	0.1	–	–	–	0.1
<b>Total segment revenue</b>	<b>27.3</b>	<b>–</b>	<b>19.0</b>	<b>–</b>	<b>46.3</b>
Research and development	(4.4)	(39.6)	(45.1)	(8.3)	(97.4)
Sales and marketing	(32.6)	–	(16.8)	(0.2)	(49.6)
Administrative expenses	–	–	–	(10.9)	(10.9)
Other	(10.0)	–	–	–	(10.0)
<b>Operating loss from continuing operations</b>	<b>(19.7)</b>	<b>(39.6)</b>	<b>(42.9)</b>	<b>(19.4)</b>	<b>(121.6)</b>
Depreciation, amortisation & impairment included in the expenditure above	(4.2)	(37.0)	–	(0.7)	(41.9)
<b>Year ended 31 December 2016</b>					
<b>Restated<sup>1</sup></b>	<b>NIOX® £m</b>	<b>Respiratory £m</b>	<b>US AZ collaboration £m</b>	<b>Unallocated £m</b>	<b>Total £m</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
Asia Pacific	7.4	–	–	–	7.4
Rest of world	0.1	–	–	–	0.1
<b>Total segment revenue</b>	<b>23.1</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>23.1</b>
Research and development	(9.7)	(6.8)	–	(1.3)	(17.8)
Sales and marketing	(27.2)	–	–	–	(27.2)
Administrative expenses	(4.8)	–	–	(10.1)	(14.9)
Other	(8.0)	–	–	–	(8.0)
<b>Operating loss from continuing operations</b>	<b>(26.6)</b>	<b>(6.8)</b>	<b>–</b>	<b>(11.4)</b>	<b>(44.8)</b>
Depreciation and amortisation included in R&D, S&M and G&A expenditure above	(4.4)	(0.4)	–	(0.5)	(5.3)

<sup>1</sup> Restated to show the results of the allergy business in discontinued operations, see note 10 for further details

## Assets by segment

	NIOX® £m	Respiratory £m	US AZ collaboration £m	Unallocated £m	Total £m
<b>As at 31 December 2017</b>					
Cash, cash equivalents and short term deposits	3.7	–	–	55.8	59.5
Property, plant and equipment	–	–	–	1.4	1.4
Goodwill	5.4	4.4	0.2	–	10.0
Intangible assets	56.1	70.6	73.0	–	199.7
Deferred tax assets	–	–	–	15.7	15.7
Investment in joint venture	–	–	–	0.5	0.5
Prepayment for business combination	–	–	77.9	–	77.9
Non-current tax assets	–	–	–	7.3	7.3
Inventories	–	–	–	5.0	5.0
Trade and other receivables	–	–	–	18.9	18.9
Current tax assets	–	–	–	6.5	6.5
<b>Total assets</b>	<b>65.2</b>	<b>75.0</b>	<b>151.1</b>	<b>111.1</b>	<b>402.4</b>

As at 31 December 2016	NIOX® £m	Respiratory £m	US AZ collaboration £m	Unallocated £m	Total £m
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>72.1</b>	<b>115.5</b>	<b>–</b>	<b>146.5</b>	<b>334.1</b>

#### 4. Revenue

The Group derives the following types of revenue:

	2017 £m	2016 £m
Sale of goods	27.2	23.0
Rendering of services	19.0	–
Licence and milestone revenue	0.1	0.1
<b>Total revenue</b>	<b>46.3</b>	<b>23.1</b>

#### 5. Employees and directors

The average monthly number of persons (including Executive Directors) employed by the Group during the year was:

By activity	2017 Number	2016 Number
Office and management	42	46
Sales and marketing	256	138
Research and development	68	107
<b>Total average headcount</b>	<b>366</b>	<b>291</b>

The average number of administration staff employed by the Company during the year, including Executive Directors, was 2 (2016: 2).

	Group		Company	
	2017 £m	2016 £m	2017 £m	2016 £m
<b>Employee benefit costs</b>				
Wages and salaries	39.6	28.1	1.4	1.1
Social security costs	3.2	2.8	0.2	0.2
Other pension costs	1.5	1.2	0.1	0.1
Share options expense	2.5	2.4	–	–
<b>Total employee benefit costs</b>	<b>46.8</b>	<b>34.5</b>	<b>1.7</b>	<b>1.4</b>

The Group contributes to defined contribution pension schemes for its Executive Directors and employees. Contributions of £95,356 (included in other payables) were payable to the funds at the year end (2016: £101,236).

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 (to 2 March 2017), Senior VP of Commercial US (from 1 July 2017), the General Counsel and Chief Compliance Officer, VP of Human Resources and the Chief Business Officer. The compensation paid or payable to key management is set out below.

	2017 £m	2016 £m
Short term employee benefits (including bonus)	3.0	2.3
Post-employment benefits	0.2	0.2
Share based payment	0.8	1.5
<b>Total</b>	<b>4.0</b>	<b>4.0</b>

# Notes to the financial statements continued

## 6. Other gains and losses

	2017 £m	2016 Restated <sup>1</sup> £m
Change in fair value of contingent Duaklir® royalty consideration	3.2	–
Net foreign exchange (loss)/gain	(1.1)	5.2
Foreign exchange gain on non-underlying items	8.3	–
<b>Total other gains and losses</b>	<b>10.4</b>	<b>5.2</b>

<sup>1</sup> Restated to show Foreign exchange differences within 'Other gains and losses' (previously shown within 'Finance income and costs')

Foreign exchange gains on non-underlying items of £8.3 million (2016: £nil) is made up of £5.4 million foreign exchange gain on the non-contingent consideration and £2.9 million foreign exchange gain on the contingent royalty consideration. See note 11 and note 35 for further details.

## 7. Finance income and costs

	2017 £m	2016 Restated <sup>1</sup> £m
<b>Finance costs:</b>		
Bank charges and interest payable	(0.1)	(0.1)
Non-contingent consideration: unwinding of discount	(2.7)	–
<b>Total finance costs</b>	<b>(2.8)</b>	<b>(0.1)</b>
<b>Finance income:</b>		
Bank interest receivable	0.4	0.9
<b>Total finance income</b>	<b>0.4</b>	<b>0.9</b>

<sup>1</sup> Restated to show Foreign exchange differences within 'Other gains and losses'

## 8. Operating expenses

Operating loss is stated after charging the following:

	2017 £m	2016 £m
Employee benefit costs (note 5)	46.8	34.5
Externally contracted research and development <sup>1</sup>	52.7	27.6
Marketing costs	10.0	5.8
Legal and professional fees including patent costs	3.6	5.1
Depreciation <sup>2</sup>	0.8	0.7
Amortisation <sup>2</sup>	4.1	4.6
Impairment of goodwill and other intangible assets	37.0	74.8
Operating lease	0.8	1.6

<sup>1</sup> Includes AZ R&D contribution, see note 11

<sup>2</sup> Depreciation and amortisation is included on the face of the statement of comprehensive income within 'Research and development costs', 'Sales and marketing' and 'Administrative expenses'

## 9. 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:

	2017 £m	2016 £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>	0.2	0.3
<b>Total</b>	<b>0.5</b>	<b>0.6</b>

<sup>1</sup> Other assurance services in 2017 and 2016 mainly relate to reporting accountant services performed on prospective acquisitions. 2017 costs were offset against the share premium reserve.

## 10. Discontinued operations

On 25 April 2017, following the receipt of the house dust mite allergy study results, it was announced that Circassia would no longer continue development of the allergy programmes. Therefore, the allergy programme costs and the associated research and development tax credit for the year ended 31 December 2016 have been reclassified as discontinued operations in the consolidated statement of comprehensive income to comply with IFRS 5 requirements.

	Notes	2017 £m	2016 £m
<b>Loss for the year</b>			
Expenditure		(6.3)	(31.9)
Goodwill and intangible assets impairment		–	(74.8)
Share of (loss)/profit of joint venture	18	(0.2)	0.6
Loss before tax		(6.5)	(106.1)
Taxation	12	1.0	5.6
<b>Loss from discontinued operations</b>		<b>(5.5)</b>	<b>(100.5)</b>
<b>Cash flow</b>		<b>2017 £m</b>	<b>2016 £m</b>
Net cash outflow from operating activities		(8.7)	(22.5)
<b>Net decrease in cash from discontinued operations</b>		<b>(8.7)</b>	<b>(22.5)</b>

## 11. Non-underlying items

Management primarily manage the business and measure performance based on the results of "underlying operations". Significant irregular and exceptional items are classified as "non-underlying" items and are excluded from the underlying measures. The following non-underlying items have been recognised in the income statement for the year:

	Notes	2017 £m	2016 Restated <sup>1</sup> £m
<b>Charged to research and development costs</b>			
AZ R&D contribution		(45.1)	–
Intangible assets impairment		(37.0)	–
Restructuring costs		–	(0.5)
		(82.1)	(0.5)
<b>Charged to sales and marketing costs</b>			
Restructuring costs		–	(0.2)
		–	(0.2)
<b>Credited/(charged) to administrative expenses</b>			
Restructuring costs		0.1	(0.3)
		0.1	(0.3)
<b>Credited to other gains and losses</b>			
Foreign exchange movement on non-contingent consideration	35	5.4	–
Revaluation of contingent royalty consideration	35	3.2	–
Foreign exchange movement on contingent royalty consideration	35	2.9	–
		11.5	–
<b>Charged to finance costs</b>			
Non-contingent consideration: unwinding of discount	35	(2.7)	–
		(2.7)	–
<b>Loss before tax</b>		<b>(73.2)</b>	<b>(1.0)</b>
Credited to taxation		16.5	–
<b>Loss from continuing operations</b>		<b>(56.7)</b>	<b>(1.0)</b>
Loss from discontinued operations	10	(5.5)	(100.5)
<b>Total loss</b>		<b>(62.2)</b>	<b>(101.5)</b>
Items that may be subsequently reclassified to profit or loss			
Share of other comprehensive income of joint venture		–	0.1
<b>Total</b>		<b>(62.2)</b>	<b>(101.4)</b>

<sup>1</sup> Restated to show the results of the allergy business in discontinued operations, see note 10 for further details

# Notes to the financial statements continued

## AZ R&D contribution

The cost relates to one-off R&D contribution of £45.1 million for Tudorza® and Duaklir® product development. An R&D tax credit of £10.2 million related to this expenditure is included in the taxation line for non-underlying items.

## Intangible assets impairment

Impairments totalling £37.0 million (2016: £nil) relating to the respiratory portfolio were recognised in the year. Further disclosures are given in note 16. The resulting £6.3 million reduction in a deferred tax liability is included in the taxation line for non-underlying items.

## Restructuring costs

Restructuring costs comprise cost optimisation initiatives including severance payments, compensation for loss of office, property and other contract termination costs.

## Non-contingent consideration

The £5.4 million foreign exchange movement on non-contingent consideration relates to the impact of the weakening Dollar on translation of the \$100 million deferred non-contingent consideration payable to AstraZeneca. The consideration was measured by discounting the liability with £2.7 million increase in the liability due to the passage of time (unwinding of discount) recognised as a finance cost in the year.

## Contingent royalty consideration

Contingent royalty consideration relates to the amount of royalties payable to AstraZeneca on the future Duaklir® sales. The liability was remeasured to fair value at the year end with the resulting £3.2 million gain recorded in other gains in the income statement. The £2.9 million foreign exchange movement relates to the impact of the weakening Dollar on translation of the contingent royalty consideration.

## Loss from discontinued operations

The costs relating to the discontinued allergy operation are deemed to be an exceptional item to be excluded from the underlying operations, see note 10 for further details.

## 12. 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 2017 and 2016 represents the credit receivable by the Group for the year and adjustments to prior years. The 2017 amounts have not yet been agreed with the relevant tax authorities.

	2017 £m	2016 £m
<b>Current tax</b>		
United Kingdom corporation tax research and development credit	(13.8)	(8.6)
Adjustments in respect of prior year	(0.2)	(0.2)
<b>Total current tax</b>	<b>(14.0)</b>	<b>(8.8)</b>
<b>Deferred tax</b>		
Decrease/(increase) in deferred tax assets	0.6	(0.8)
(Decrease)/increase in deferred tax liabilities	(7.0)	0.6
Adjustments in respect of prior year	(0.6)	1.5
<b>Total deferred tax</b>	<b>(7.0)</b>	<b>1.3</b>
<b>Total tax</b>	<b>(21.0)</b>	<b>(7.5)</b>
<b>Tax is attributable to:</b>		
Loss on continuing operations	(20.0)	(1.9)
Loss on discontinued operations	(1.0)	(5.6)
	<b>(21.0)</b>	<b>(7.5)</b>

The tax credit for the year is lower (2016: lower) than the standard rate of corporation tax in the UK of 19.25% (2016: 20%). The differences are explained below:

	2017 £m	2016 £m
Loss from continuing operations before tax	(113.6)	(38.8)
Loss from discontinued operation before tax	(6.5)	(106.1)
<b>Loss before tax</b>	<b>(120.1)</b>	<b>(144.9)</b>
Loss on ordinary activities before tax multiplied by the standard rate of corporation tax in the UK of 19.25% (2016: 20%)	(23.1)	(29.0)
Expenses not deductible for tax purposes (permanent differences)	0.5	15.6
Temporary timing differences on employee share options	–	0.2
Research & development relief uplift	(5.8)	(3.5)
Adjustments in respect of prior year	(0.8)	1.3
Tax losses for which no deferred income tax asset was recognised	8.2	7.9
<b>Tax credit for the year</b>	<b>(21.0)</b>	<b>(7.5)</b>

At 31 December 2017, the Group has tax losses to be carried forward of approximately £354.7 million (2016: £292.8 million).

At 31 December 2017, the Group has tax assets arising from tax credits in the United Kingdom for certain research and development expenditure of £13.8 million (2016: £8.7 million). Of this £7.3 million tax is receivable after more than one year and is classified as a non-current tax asset.

A reduction in the rate of UK corporation tax to 17% from 1 April 2020 has been substantively enacted. UK deferred tax assets and liabilities are recognised at a rate of 17% (2016: 17%).

### 13. 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.

For the year ended 31 December 2017	Continuing operations			Discontinued operations	Total
	Underlying operations	Non-underlying operations	Total		
Loss attributable to ordinary equity owners of the parent company (£m)	(36.9)	(56.7)	(93.6)	(5.5)	(99.1)
Weighted average number of Ordinary shares in issue (Number)	319,541,498	319,541,498	319,541,498	319,541,498	319,541,498
<b>Loss per share</b>	<b>(0.11)</b>	<b>(0.18)</b>	<b>(0.29)</b>	<b>(0.02)</b>	<b>(0.31)</b>

For the year ended 31 December 2016 Restated <sup>1</sup>	Continuing operations			Discontinued operations	Total
	Underlying operations	Non-underlying operations	Total		
Loss attributable to ordinary equity owners of the parent company (£m)	(35.9)	(1.0)	(36.9)	(100.5)	(137.4)
Weighted average number of Ordinary shares in issue (Number)	284,889,171	284,889,171	284,889,171	284,889,171	284,889,171
<b>Loss per share</b>	<b>(0.13)</b>	<b>(0.00)</b>	<b>(0.13)</b>	<b>(0.35)</b>	<b>(0.48)</b>

<sup>1</sup> Restated to show the results of the allergy business in discontinued operations, see note 10 for further details

As net losses from continuing operations were recorded in 2017 and 2016, the dilutive potential shares are anti-dilutive and therefore were excluded from the earnings per share calculation.

### 14. Property, plant and equipment

Group	Leasehold improvements £m	Fixtures and fittings £m	Plant and equipment £m	Total property, plant and equipment £m
<b>At 1 January 2016</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>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>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>1.4</b>
<b>Year ended 31 December 2017</b>				
Opening net book amount	0.2	0.2	1.0	1.4
Additions	0.2	0.2	0.4	0.8
Depreciation	(0.1)	(0.1)	(0.6)	(0.8)
<b>Closing net book amount</b>	<b>0.3</b>	<b>0.3</b>	<b>0.8</b>	<b>1.4</b>
<b>At 31 December 2017</b>				
Cost	0.8	0.5	2.1	3.4
Accumulated depreciation	(0.5)	(0.2)	(1.3)	(2.0)
<b>Net book amount</b>	<b>0.3</b>	<b>0.3</b>	<b>0.8</b>	<b>1.4</b>

# Notes to the financial statements continued

## 15. Goodwill

	2017 £m	2016 £m
<b>At 1 January</b>		
Cost	84.2	81.2
Accumulated impairment	(74.5)	–
<b>Net book amount</b>	<b>9.7</b>	<b>81.2</b>
<b>Year ended 31 December</b>		
Opening net book amount	9.7	81.2
Acquisition of business (note 35)	0.2	–
Impairment	–	(74.5)
Exchange differences	0.1	3.0
<b>Closing net book amount</b>	<b>10.0</b>	<b>9.7</b>
<b>At 31 December</b>		
Cost	84.5	84.2
Accumulated impairment	(74.5)	(74.5)
<b>Net book amount</b>	<b>10.0</b>	<b>9.7</b>

During 2017, Circassia entered into a collaboration agreement with AstraZeneca to commercialise Tudorza® and Duaklir®. The £0.2 million of goodwill relates to the Duaklir® business combination only. In the event that the Option over Tudorza® becomes exercisable, a further business combination is expected to occur, potentially resulting in the recognition of additional goodwill. This collaboration to commercialise Tudorza® and Duaklir® products is considered to be a new CGU.

In 2016, following the cat allergy immunotherapy phase III study results, the Allergy portfolio value was written off in full resulting in the impairment charge 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:

	2017 £m	2016 £m
<b>Cash generating unit</b>		
NIOX®	5.4	5.3
Respiratory	4.4	4.4
AstraZeneca collaboration	0.2	–
	<b>10.0</b>	<b>9.7</b>

The recoverable amount of the CGUs 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 NIOX® CGU valuation basis was changed to a value in use model (2016: a fair value less costs of disposal model) as a result of the changes to the business during the year following the AstraZeneca collaboration agreement. In addition, US operation assets are now shared between the NIOX® and AstraZeneca collaboration CGUs which resulted in assets being allocated between the two CGUs.

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). The calculations use risk-adjusted 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.

The value in use 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). The calculations use pre-tax cash flow projections. Cash flows over ten years have been considered appropriate based on the product lifecycle. 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 value in use for the AstraZeneca collaboration CGU was calculated over a ten year period using a discount factor of 11.5% (being a weighted average cost of capital rate for the CGU). The calculations use risk-adjusted pre-tax cash flow projections. Cash flows over ten years have been considered appropriate based on the product lifecycle. 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 CGUs are as follows:

#### Respiratory CGU

Valuation basis	Value in use
Anticipated launch dates	Group product candidate portfolio 2018 – 2027
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
Period of specified projected cash flows	10 years
Terminal growth rate	Terminal growth rates based on management's estimate of future long-term average growth rate 2017 – 1% 2016 – 1%
Discount rate	Discount rates based on weighted average cost of capital for the CGU, adjusted where appropriate. 2017 – 13% 2016 – 13%

#### NIOX CGU

Valuation basis	Value in use
Research and development costs	Based on management forecasts of testing and development 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
Period of specified projected cash flows	10 years
Terminal growth rate	Terminal growth rates based on management's estimate of future long-term average growth rate 2017 – 1% 2016 – 1%
Discount rate	Discount rates based on weighted average cost of capital for the CGU, adjusted where appropriate. 2017 – 10% 2016 – 10%

#### AstraZeneca collaboration CGU

Valuation basis	Value in use
Anticipated launch dates	2019
Research and development costs	Based on contractual clinical study costs per the Collaboration Agreement with AstraZeneca
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
Period of specified projected cash flows	10 years
Terminal growth rate	Terminal growth rates based on management's estimate of future long-term average growth rate 2017 – 1% 2016 – n/a%
Discount rate	Discount rates based on weighted average cost of capital for the CGU, adjusted where appropriate. 2017 – 11.5% 2016 – n/a%

In each case the valuations of Respiratory, NIOX® and AstraZeneca collaboration 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.

# Notes to the financial statements continued

## Impact of possible changes in key assumptions

Unsuccessful development of two product candidates in the Respiratory CGU

Management have, in their sensitivity analysis, assessed the impact of the possibility that the development of two product candidates in the Respiratory CGU is unsuccessful.

Reduction in revenue growth in the NIOX® and AstraZeneca collaboration CGUs

Management have, in their sensitivity analysis, assessed the impact of the possibility that sales growth in the NIOX® and AstraZeneca collaboration CGUs is less than that of internal forecasts.

No change in the key assumptions mentioned above would have resulted in a goodwill or intangible assets impairment charge.

As discussed in the Strategic Report, the Group's strategy has been changed and it now intends to out-license/partner the rights to the respiratory portfolio and the impact of this change will need to be factored into impairment reviews in the future.

## 16. Intangible assets

Group	IPR&D £m	Customer relationships £m	Technology £m	Other £m	Total intangible assets £m
<b>At 1 January 2016</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>
<b>Year ended 31 December 2017:</b>					
Opening net book amount	88.8	31.4	46.9	–	167.1
Acquisition of business (note 35)	73.0	–	–	–	73.0
Amortisation charge	(0.1)	(1.9)	(2.1)	–	(4.1)
Impairment charge	(37.0)	–	–	–	(37.0)
Exchange differences	0.1	0.3	0.3	–	0.7
<b>Closing net book amount</b>	<b>124.8</b>	<b>29.8</b>	<b>45.1</b>	<b>–</b>	<b>199.7</b>
<b>At 31 December 2017</b>					
Cost	161.9	34.6	50.3	1.6	248.4
Accumulated amortisation and impairment	(37.1)	(4.8)	(5.2)	(1.6)	(48.7)
<b>Net book amount</b>	<b>124.8</b>	<b>29.8</b>	<b>45.1</b>	<b>–</b>	<b>199.7</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.

Key assumptions and sensitivities used in the impairment review at a CGU level are disclosed in note 15. In addition, the Group performs impairment reviews in relation to individual assets.

An impairment of £31.0 million has been recognised for the Seretide® pMDI substitute to reflect updated cash flows used in the valuation of intangibles on the balance sheet following negative PK study results in the previous two years. This resulted from a reduction in the probability of success of the PK study bringing it more in line with analyst expectations. If the launch of the product was delayed by one or two additional years compared to the current assumptions, the impairment would be between £2.0 million and £3.7 million higher. If the probability of success was further reduced by 10%, the impairment would have been £4.6 million higher. If forecast sales were reduced by 10%, the impairment would have been £2.8 million higher.

In addition, an impairment of In-Process Research & Development (IPR&D) of £4.7 million in respect of Flixotide® pMDI substitute (EU rights) has been recognised following the decision to halt further development.

IPR&D of £1.3 million relating to a particle-engineered version of salmeterol xinafoate which is no longer being developed has also been impaired.

### Int-Process Research & Development (IPR&D)

IPR&D comprise a portfolio of asthma and chronic obstructive pulmonary disease product candidates.

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.

### 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 developed 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 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.

## 17. Investments in subsidiaries

Company	2017 £m	2016 £m
Investments in subsidiaries at 1 January	262.0	242.6
Additional investment in Prosonix Limited	9.0	–
Investment in Aerocrine AB	–	3.2
Investment in Circassia Pharmaceuticals Inc (formerly Aerocrine Inc)	–	15.5
Equity settled instruments granted to employees of subsidiaries	2.5	2.4
Impairment of Circassia Limited investment	–	(1.7)
<b>Investments in subsidiaries at 31 December</b>	<b>273.5</b>	<b>262.0</b>

The capital contribution relating to share based payment is for 4,141,200 (2016: 7,660,654) 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 26.

### 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. Consequently, the majority of the Company's investment in Prosonix Limited was reclassified to investment in Circassia Limited.

### Deed of assignment for AstraZeneca collaboration agreement

On 1 September 2017, management enacted a Deed of assignment between Circassia Pharmaceuticals plc and Circassia Limited, transferring all rights, powers, interests and benefits of the transaction. This transfer was accounted for at a book value of £42.1 million on 1 September 2017, with no gain or loss in either entity.

# Notes to the financial statements continued

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	Dormant	100%
Circassia Pharmaceuticals Inc	5151 McCrimmon Parkway, Suite 260, Morrisville, North Carolina 27560, USA	Pharmaceutical research and sale of asthma and respiratory products	100%
Circassia AB	Fyrislundsgatan 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%

As discussed in the Strategic Report, the Group's strategy has been changed and it now intends to out-license/partner the rights to the respiratory portfolio and the impact of this change will need to be factored into impairment reviews in the future.

## 18. Investment in joint venture

	2017 £m	2016 £m
<b>At 1 January</b>	<b>0.9</b>	<b>0.2</b>
Share of (loss) / profit	(0.2)	0.6
Distributions to owners	(0.2)	–
Share of other comprehensive income	–	0.1
<b>At 31 December</b>	<b>0.5</b>	<b>0.9</b>

## Nature of investment in joint venture 2017 and 2016

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

	2017 £m	2016 £m
Current assets		
Trade and other receivables	0.8	1.0
Cash	0.2	0.8
	1.0	1.8
Current liabilities		
Trade payables	–	–
Other payables	–	–
	–	–
<b>Net assets</b>	<b>1.0</b>	<b>1.8</b>

#### Summarised statement of comprehensive income for the year ended 31 December

	2017 £m	2016 £m
Revenue	0.1	1.8
Research & development costs	(1.0)	(1.8)
Administration expense	(0.1)	0.2
(Loss)/profit from operation	(1.0)	0.2
Income tax	0.6	1.0
Post tax profit from operation	(0.4)	1.2
Other comprehensive income:		
Currency translation differences	–	0.2
<b>Total comprehensive income</b>	<b>(0.4)</b>	<b>1.4</b>

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).

The Adiga Life Sciences joint venture managed clinical research organisations (CROs) in Canada in respect of allergy programmes on behalf of Circassia. As the allergy programmes are no longer being continued, the results of the joint venture for the year ended 31 December 2017 and 2016 have been included within discontinued operations in the consolidated statement of comprehensive income, see note 10.

#### 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	2017 £m	2016 £m
<b>Opening net assets 1 January</b>	<b>1.8</b>	<b>0.4</b>
(Loss)/Profit for the year	(0.4)	1.2
Dividends paid	(0.4)	–
Other comprehensive income	–	0.2
<b>Closing net assets</b>	<b>1.0</b>	<b>1.8</b>
Interest in joint venture @ 50%	0.5	0.9
<b>Carrying value</b>	<b>0.5</b>	<b>0.9</b>

#### 19. Inventories

	2017 £m	2016 £m
Finished goods	5.0	4.6

Inventories recognised as an expense during the year ended 31 December 2017 amounted to £8.5 million (2016: £7.1 million). These were included in 'Cost of sales'.

Write-down of inventories to net realisable value amounted to £0.9 million (2016: £0.5 million). These were recognised as an expense during the year and included in 'Cost of sales'.

# Notes to the financial statements continued

## 20. Trade and other receivables

	Group		Company	
	2017 £m	2016 £m	2017 £m	2016 £m
Trade receivables	3.7	3.4	–	–
Prepayments and accrued income	6.0	2.2	–	0.4
Other receivables	9.2	2.1	0.7	1.9
Receivables from subsidiary undertakings	–	–	327.5	218.6
<b>Total trade and other receivables</b>	<b>18.9</b>	<b>7.7</b>	<b>328.2</b>	<b>220.9</b>

The fair value of other receivables are their current book values. Included within receivables is £0.7 million (2016: £1.2 million) of trade receivables that were past due at the end of the reporting year 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 receivables are unsecured, interest free and have 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	
	2017 £m	2016 £m	2017 £m	2016 £m
UK pound	0.2	0.6	263.4	192.1
United States dollar	7.0	2.0	64.8	27.7
Swedish krona	0.1	1.2	–	1.1
Euro	1.6	1.5	–	–
	<b>8.9</b>	<b>5.3</b>	<b>328.2</b>	<b>220.9</b>

## 21. Cash and cash equivalents and short-term bank deposits

	Group		Company	
	2017 £m	2016 £m	2017 £m	2016 £m
Short-term bank deposit, with original maturity: More than 3 months	15.0	20.0	15.0	20.0
<b>Total short-term bank deposits</b>	<b>15.0</b>	<b>20.0</b>	<b>15.0</b>	<b>20.0</b>
Cash and cash equivalents:				
Cash at bank and in hand	44.5	97.4	0.3	73.0
<b>Total cash and cash equivalents</b>	<b>44.5</b>	<b>97.4</b>	<b>0.3</b>	<b>73.0</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	
	2017 £m	2016 £m	2017 £m	2016 £m
AA	0.3	0.8	–	–
AA–	19.3	32.7	0.3	11.9
A+	20.1	35.0	–	35.0
A	19.8	48.9	15.0	46.1
	<b>59.5</b>	<b>117.4</b>	<b>15.3</b>	<b>93.0</b>

The Group and Company cash and cash equivalents and short-term deposits are held in the following currencies at 31 December:

	Group		Company	
	2017 £m	2016 £m	2017 £m	2016 £m
UK pound	39.6	96.0	15.3	90.9
United States dollar	16.6	3.2	–	–
Canadian dollar	0.2	0.6	–	–
Euro	2.6	10.5	–	2.1
Swiss franc	–	2.0	–	–
Swedish krona	0.5	5.0	–	–
Chinese yuan renminbi	–	0.1	–	–
	59.5	117.4	15.3	93.0

## 22. Trade and other payables

	Group		Company	
	2017 £m	2016 £m	2017 £m	2016 £m
<b>Payable within one year</b>				
Trade payables	22.7	9.2	0.1	0.1
Social security and other taxes	0.3	0.5	–	–
Accruals	6.7	8.1	0.2	0.2
Other payables	1.1	3.7	–	–
Payables to subsidiary undertakings	–	–	3.7	5.1
<b>Total trade and other payables</b>	<b>30.8</b>	<b>21.5</b>	<b>4.0</b>	<b>5.4</b>
<b>Payable after one year</b>				
Trade payables	20.4	–	–	–
<b>Total non-current other payables</b>	<b>20.4</b>	<b>–</b>	<b>–</b>	<b>–</b>

Non-current trade payables relate to an R&D contribution payable to AZ in 2019.

## 23. 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:

	2017 £m	2016 £m
<b>Assets</b>		
Cash and cash equivalents	44.5	97.4
Short-term bank deposits	15.0	20.0
Trade and other receivables	8.9	5.3
<b>Loans and receivables</b>	<b>68.4</b>	<b>122.7</b>
<b>Liabilities</b>		
Trade and other payables – current	29.9	18.4
Trade payables – non-current	20.4	–
Non-contingent consideration	68.7	–
Contingent consideration	33.6	–
<b>Financial liabilities</b>	<b>152.6</b>	<b>18.4</b>

# Notes to the financial statements continued

The Company had the following financial instruments at 31 December each year:

	2017 £m	2016 £m
<b>Assets</b>		
Cash and cash equivalents	0.3	73.0
Short-term bank deposits	15.0	20.0
Other receivables	0.7	2.3
Receivable from subsidiary undertaking	327.5	218.6
<b>Loans and receivables</b>	<b>343.5</b>	<b>313.9</b>
	2017 £m	2016 £m
<b>Liabilities</b>		
Trade and other payables - current	0.3	0.3
Payables to subsidiary undertakings	3.7	5.1
<b>Financial liabilities</b>	<b>4.0</b>	<b>5.4</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 2017 or 31 December 2016.

## Fair value

The Directors consider that the fair values of the Group's financial instruments do not differ significantly from their book values except as described below.

Contingent consideration is remeasured to fair value calculated using a discounted cash flow approach. The valuation methodology uses significant inputs which are not based on observable market data (unobservable inputs), therefore this valuation technique is classified as level 3 in the fair value hierarchy. See note 35 for further detail.



## 24. Deferred taxation

	Intangibles £m	Tax losses £m	Net deferred tax liability £m
<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>
<b>As at 1 January 2017</b>	31.9	(16.6)	15.3
(Credit)/charge to the income statement	(7.8)	0.9	(6.9)
<b>As at 31 December 2017</b>	<b>24.1</b>	<b>(15.7)</b>	<b>8.4</b>
		2017 £m	2016 £m
Deferred tax liabilities		24.1	31.9
Deferred tax assets		(15.7)	(16.6)
<b>Total deferred tax position</b>		<b>8.4</b>	<b>15.3</b>

The Group has the following unrecognised potential deferred tax assets as at 31 December:

	2017 £m	2016 £m
Losses	60.3	51.8
Share based payments and provisions	–	1.3
<b>Total unrecognised deferred tax asset</b>	<b>60.3</b>	<b>53.1</b>

## 25. Share capital

Authorised, called up and fully paid	2017 £m	2016 £m
333,466,262 (2016: 284,889,171) Ordinary shares of 0.08p each	0.3	0.2

On 12 April 2017, the Company issued 47,355,417 ordinary shares with a value of \$50 million to AstraZeneca as part of the consideration to acquire certain US commercial rights to Tudorza® and Duaklir®. Costs relating to the deal were £1.9 million, of which £1.6 million was offset against the Share premium reserve and £0.3 million was charged to the income statement in administrative expenses.

### Movements in ordinary shares

	Number of shares	Par value £m
As at 1 January 2017	284,889,171	0.2
Share issue to AZ	47,355,417	0.1
Employee share scheme issues	1,221,674	–
<b>As at 31 December 2017</b>	<b>333,466,262</b>	<b>0.3</b>

# Notes to the financial statements continued

## 26. 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:

	2017 Number of Ordinary shares ('000)	2016 Number of Ordinary shares ('000)
PSP Scheme <sup>(i)</sup>	8,855	6,610
EMI Scheme <sup>(ii)</sup>	–	535
Unapproved Scheme <sup>(iii)</sup>	187	516
	<b>9,042</b>	<b>7,661</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 have a fixed exercise price and are subject to additional vesting performance conditions. The exercise price of options granted under the 2014 PSP scheme is £nil and all subsequent PSP scheme awards have an exercise price of £0.0008. 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.

The movement in share options outstanding is summarised in the following table:

	2017 Number ('000)	2017 Weighted average exercise price (£)	2016 Number ('000)	2016 Weighted average exercise price (£)
Outstanding at 1 January	7,661	0.06	5,532	0.15
Granted	4,141	0.0008	3,346	0.0008
Expired	–	n/a	–	n/a
Forfeited/lapsed	(1,879)	0.0003	(1,217)	0.29
Exercised	(881)	0.0008	–	n/a
Outstanding at 31 December	<b>9,042</b>	<b>0.05</b>	<b>7,661</b>	<b>0.06</b>
Exercisable at 31 December	<b>535</b>	<b>0.84</b>	<b>1,014</b>	<b>0.36</b>

Share options outstanding at the end of the year have the following expiry and exercise prices:

Scheme	Grant year	Expiry year	Exercise price (£)	2017 Number ('000)	2016 Number ('000)
PSP 2014	2014	2024	0.0	348	1,514
PSP 2015	2015	2025	0.0008	1,925	2,101
PSP 2016	2016	2026	0.0008	2,760	2,994
PSP 2017	2017	2027	0.0008	3,822	–
Unapproved	2010 – 2013	2020 – 2022	0.0008	–	329
Unapproved	2013 – 2014	2023 – 2024	2.416	187	187
EMI	2007 & 2011	2007 & 2011	0.0008	–	536
<b>Total</b>				<b>9,042</b>	<b>7,661</b>

The weighted average remaining contractual life of share options outstanding at the end of the year was 8.4 years (2016: 7.9 years).

Options exercised in 2017 resulted in 880,532 shares being issued at a weighted average price of £0.0008 each. The related weighted average share price at the time of exercise was £0.88 per share.

There were no options exercised during the year ended 31 December 2016.

### Valuation models

The fair value of PSP share options granted during the year 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 (2016: nil), all options granted in previous years were valued using the Black Scholes model.

#### Black Scholes

There were no options granted during the year (2016: 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:

	2017	2016
Exercise price	£0.0008	£0.0008
Share price	£0.96	£2.66
Expected volatility	30%	35%
Expected life	3 years	3 years
Expected dividends	0%	0%
Risk free interest rate	0.1%	0.4%

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 year determined using the Monte Carlo Simulation model at the grant date was £0.75 per option (2016: £1.75).

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 no restricted shares in issue at 31 December 2017 (2016: 0.1 million Ordinary shares of 0.08p).

### Deferred shares

During the year the Group awarded nil (2016: 156,035) deferred shares to Executive Directors as part of a deferred bonus for 2016. 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.

# Notes to the financial statements continued

## 27. Share premium

Group and Company	2017 £m	2016 £m
At 1 January	563.8	564.0
Issue of new shares	40.0	–
Expenses relating to share issue	(1.6)	(0.2)
<b>At 31 December</b>	<b>602.2</b>	<b>563.8</b>

## 28. (Accumulated losses)/retained earnings

	Group		Company	
	2017 £m	2016 £m	2017 £m	2016 £m
At 1 January	(295.8)	(158.5)	0.4	(2.0)
(Loss)/profit for the year	(99.1)	(137.3)	1.5	2.4
<b>At 31 December</b>	<b>(394.9)</b>	<b>(295.8)</b>	<b>1.9</b>	<b>0.4</b>

## 29. Other reserves

Group	Share option reserve £m	Translation reserve £m	Treasury shares reserve £m	Transactions with non-controlling interests <sup>(a)</sup> £m	Total other reserves £m
<b>At 1 January 2016</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 34)	–	–	(0.4)	–	(0.4)
Transactions with non-controlling interests	–	–	–	(2.1)	(2.1)
<b>At 31 December 2016</b>	6.4	12.9	(0.7)	(6.1)	12.5
Employee share option scheme	2.5	–	–	–	2.5
Currency translation differences	–	2.2	–	–	2.2
<b>At 31 December 2017</b>	<b>8.9</b>	<b>15.1</b>	<b>(0.7)</b>	<b>(6.1)</b>	<b>17.2</b>

(a) 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.

Company	Share option reserve £m	Total other reserves £m
<b>At 1 January 2016</b>	3.7	3.7
Employee share option scheme	2.4	2.4
<b>At 31 December 2016</b>	6.1	6.1
Employee share option scheme	2.5	2.5
<b>At 31 December 2017</b>	<b>8.6</b>	<b>8.6</b>

### 30. Cash used in operations

#### Reconciliation of (loss)/profit before tax to net cash used in operations

	Group		Company	
	2017 £m	2016 £m	2017 £m	2016 £m
(Loss)/profit from continuing operations before tax	(113.6)	(38.8)	1.5	2.4
Loss from discontinued operation before tax	(6.5)	(106.1)	–	–
(Loss)/profit before tax	(120.1)	(144.9)	1.5	2.4
Adjustment for:				
Interest income	(0.4)	(0.9)	(0.3)	(0.9)
Interest expense	2.8	0.1	1.5	0.1
Depreciation	0.8	0.7	–	–
Amortisation	4.1	4.6	–	–
Impairment	37.0	74.8	–	1.7
Share of joint venture profit	0.2	(0.6)	–	–
Fair value gain on contingent royalty consideration	(3.2)	–	–	–
Share based payment charge	2.5	2.4	–	–
Foreign exchange on non-operating cash flows	(8.5)	(7.8)	(3.5)	–
Changes in working capital:				
(Increase)/decrease in trade and other receivables	(11.6)	(1.4)	1.2	(1.6)
Increase in inventories	–	(1.2)	–	–
Increase in trade and other payables	30.0	5.8	–	0.2
<b>Net cash (used in)/generated from operations</b>	<b>(66.4)</b>	<b>(68.4)</b>	<b>0.4</b>	<b>1.9</b>

### 31. Contingent liabilities

There were no contingent liabilities at 31 December 2017 or at 31 December 2016.

During the year the Group received a notification about an arbitration claim raised for up to \$4 million for the non-performance of certain obligations of the contract against one of the subsidiary companies. At the date these accounts were issued, details of the claim are yet to be presented by the claimant. Given the lack of detail at the early stage of the claim, it is not possible to make a reasonable estimate of the expected financial effect, if any, that will result from ultimate resolution of the proceedings. Hence, the nature and facts of the case are disclosed but no provision is made.

# Notes to the financial statements continued

## 32. 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:

	2017 £m	2016 £m
Due within one year	0.8	1.0
Due between one and five years	1.8	1.7
Over five years	0.5	0.7

The Group leases various offices and warehouses under non-cancellable operating leases expiring within one to over five years.

The total of future minimum sublease payments expected to be received for the Chicago property no longer utilised by the Group is £1.5 million.

## 33. Capital commitments

The Group had no capital commitments at 31 December 2017 or at 31 December 2016.

## 34. 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 2017 are as follows: Invesco Asset Management (28.37% of total voting rights); Woodford Investment Management (22.40% of total voting rights); AstraZeneca PLC (14.20% of total voting rights); Touchstone Innovations (7.95% of total voting rights); Neptune Investment Management (6.90% of total voting rights); OppenheimerFunds Inc (7.05% of total voting rights).

Transactions with related parties during the year and balances with related parties at 31 December are as follows:

Related party	2017 Purchases £'000	2016 Purchases £'000	2017 Payables £'000	2016 Payables £'000
Adiga Life Sciences (Joint venture)	330	1,929	–	–
Touchstone Innovations <sup>1</sup>	46	42	–	–

<sup>1</sup> Purchases<sup>1</sup> include compensation paid or payable in respect of services provided by Russ Cummings as Non-Executive Director of the Company.

## Company

The following transactions with subsidiaries occurred in the year:

Related party	2017 £m	2016 £m
Rendering of services to Circassia Limited <sup>1</sup>	1.2	0.8
Settlement of liabilities on behalf of the subsidiaries	(2.8)	(5.5)
Net transfer of funds to subsidiaries	69.8	33.6
Deed of assignment transfer (note 17)	42.1	–
	110.3	28.9

<sup>1</sup> Remuneration costs (excluding share options charges) relating to Steven Harris and Julien Cotta in respect of services rendered to Circassia Limited.

	2017 £m	2016 £m
Balances due from subsidiary companies	327.5	218.6
Balances due to subsidiary companies	(3.7)	(5.1)

The amounts due are unsecured, interest free and have 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. No funding was paid into the Trust by the Company during the year ended 31 December 2017 (2016: £414,729).

No shares were purchased by the Trust during the year ended 31 December 2017 (2016: 156,035). As at 31 December 2017 a cash balance of £4,733 (2016: £5,068) was held by the Trust.

# Notes to the financial statements continued

## 35. Business combinations

On 12 April 2017, Circassia's collaboration and profit share arrangement with AstraZeneca became unconditional. Under the agreement, Circassia secured certain US commercial rights to Tudorza® and Duaklir®. On that day Circassia issued 47,355,417 ordinary shares with a value of \$50 million to AstraZeneca. In addition, 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; and royalties on sales of Duaklir® in the United States.

Under the terms of the agreement, Circassia will have the option to secure the remaining commercial rights and economic benefits of Tudorza®. This will become exercisable from H2 2018 based on the sales performance of Tudorza® in the preceding 12 month period, or if Duaklir® gains FDA approval before 31 December 2019. Until the option becomes exercisable Circassia does not have control over the Tudorza® business hence the consideration paid and payable represents a prepayment for the business combination.

Following positive results from the AMPLIFY Phase III study, the filing of a New Drug Application (NDA) for Duaklir® with the United States Food and Drug Administration (FDA) is planned in the first half of 2018. Circassia has exclusive commercialisation rights to Duaklir® in the United States and as such it is considered that the Group assumed control over the Duaklir® business when the collaboration agreement became unconditional.

The future royalty payments to AstraZeneca on Duaklir® are recognised as an additional intangible asset and contingent consideration liability. A contingent consideration arrangement is initially measured at fair value on the acquisition date based on discounted future cash outflows. Contingent consideration that is classified as a liability is remeasured to fair value at each reporting date, with changes taken to the income statement. The amount of royalties payable as determined in the collaboration agreement is based on the future Duaklir® sales. As the valuation methodology uses this significant input which is not based on observable market data, this valuation technique is classified as level 3 in the fair value hierarchy. The fair values are calculated using the discount rate of 20.5%.

Consideration	2017 £m
Ordinary share capital 47,355,417 shares at £0.0008	–
Share premium	40.0
Deferred non-contingent consideration	71.4
Contingent Duaklir® royalty consideration	39.7
	<b>151.1</b>
<b>Recognised amounts of identifiable assets acquired</b>	<b>£m</b>
Duaklir® IPR&D	33.3
Duaklir® royalty IPR&D	39.7
<b>Total identifiable net assets</b>	<b>73.0</b>
AZ collaboration goodwill	0.2
Prepayment for Tudorza® business combination	77.9
	<b>151.1</b>

R&D contribution of £45.1 million for Tudorza® and Duaklir® product development was recognised in the income statement during the year.

Transaction costs totalling £1.9 million were incurred on the collaboration arrangement with AstraZeneca, of which £0.3 million is included within the operating loss (administrative expenses line) for the year ended 31 December 2017 and £1.6 million has been offset against the Share premium reserve.

The consideration for the Duaklir business was determined to be £73.2 million. Intangible assets (IPR&D) of £73.0 million have been recognised in the accounts. The difference between total value of the business and identifiable assets resulted in a recognition of £0.2 million goodwill.



### Tudorza® option

If the option to secure the remaining commercial rights and economic benefits of Tudorza® is taken, Circassia will make further payments to AstraZeneca of up to \$80 million dependent on the level of Tudorza® sales in the United States and if Duaklir® gains FDA approval. Such payments are not considered to be a present obligation until the option becomes exercisable therefore this has not been recognised as a liability in the financial statements for the year ended 31 December 2017.

Until the Tudorza® option is exercised, the Group promotes the chronic obstructive pulmonary disease (COPD) treatment Tudorza® in the US in accordance with the collaboration and profit share arrangement. The commission fees receivable are based on Tudorza® product in-market sales and promotion activities performed by Circassia. In 2017 revenue recognised for rendering this service was £19.0 million.

Deferred non-contingent consideration	£m
At 12 April 2017	71.4
Unwinding of discount	2.7
Foreign exchange movement	(5.4)
At 31 December 2017	68.7

The value of the non-contingent consideration was calculated by discounting the liability using a pre-tax discount rate of 5.5%.

Contingent Duaklir® royalty consideration	£m
At 12 April 2017	39.7
Change in fair value	(3.2)
Foreign exchange movement	(2.9)
At 31 December 2017	33.6

Change in fair value and foreign exchange movements relating to contingent Duaklir® royalty consideration are included in Other (losses)/gains in the income statement.

The changes in future Duaklir® sales might result in a significantly higher or lower fair value of contingent Duaklir® royalty consideration (see the table below for list of key inputs used in the fair value measurement). 10% higher or lower Duaklir® sales would result in £3.4 million lower or higher fair value of the liability.

### Significant estimates relating to contingent royalty consideration valuation

The assessment of the fair value of the contingent Duaklir® royalty consideration requires the selection of an appropriate valuation model at the date of acquisition, consideration as to the inputs necessary for the valuation model chosen and the estimation of the future cash flows of the product discounted at the risk adjusted rate. Key assessments and judgements included in the calculation of deferred royalty consideration are as follows:

Valuation model	Discounted cash flow
Anticipated launch date	2019 – reviewed and amended to take into account development, regulatory and marketing risks
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
Period of specified projected cash flows	16 years
Discount rate	20.5%

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## Notes to the financial statements continued

### 36. Events occurring after the reporting date

During 2018, the Company plans to implement its refocused investment strategy. As a result, there will be no further development of the respiratory pipeline which may result in an impairment in the carrying value of the respiratory cash generating unit assets as detailed in note 3.

Circassia intends to issue further ordinary share capital to AstraZeneca, subject to shareholder approval, such that AstraZeneca's holding will increase from 14.2% to a maximum of 19.9%. Circassia will use the proceeds to fund a deferred R&D contribution of \$20 million, which is payable by the end of 2018 under the agreement with AstraZeneca, and part fund a final R&D contribution of \$25 million payable by the end of 2019. AstraZeneca has agreed to include any remaining R&D contribution not paid by the end of 2019 in the loan arrangements in the existing development and commercialisation agreement.

# Glossary

**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

**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

**DPI**

Dry powder inhaler

**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

**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

**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

**pMDI**

Pressurised meter dose inhaler

**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

**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

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## Advisors and contact details

### Financial calendar

- Annual General Meeting:  
30 May 2018
- Interim results for the  
six months ending  
30 June 2018: Q3 2018

### 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.

### Addresses for correspondence

#### Head office

Circassia Pharmaceuticals plc  
Northbrook House  
Robert Robinson Avenue  
The Oxford Science Park  
Oxford OX4 4GA  
United Kingdom

Tel: +44 (0)1865 405560

Fax: +44 (0)7092 987560

General enquiries: [info@circassia.com](mailto:info@circassia.com)

Investors: [IR@circassia.com](mailto:IR@circassia.com)

Website: [www.circassia.com](http://www.circassia.com)

#### Registered office

The Magdalen Centre  
Robert Robinson Avenue  
Oxford Science Park  
Oxfordshire  
England  
OX4 4GA

#### Registrars

Equiniti Limited  
Aspect House  
Spencer Road  
Lancing  
West Sussex BN99 6DA  
United Kingdom

Shareholder support: 0371 384 2030  
Calls to this number are charged at 8p  
per minute plus network extras.  
Lines are open 8:30am to 5:30pm  
Monday to Friday.

#### Bankers

HSBC Bank plc  
Apex Plaza  
Reading  
RG1 1AX

#### Independent Auditors

PricewaterhouseCoopers LLP  
Chartered Accountants and Statutory  
Auditors  
1 Embankment Place  
London  
WC2N 6RH

**Forward-looking statements**

This Annual report 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 Annual report 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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**Circassia Pharmaceuticals plc**

Northbrook House  
Robert Robinson Avenue  
The Oxford Science Park  
Oxford OX4 4GA  
United Kingdom

Tel: +44 (0)1865 405560

[www.circassia.com](http://www.circassia.com)