

Building on our progress

Circassia Pharmaceuticals plc
Annual Report and Accounts 2018



Circassia in brief

Circassia is a world-class specialty pharmaceutical business focused on respiratory disease. The Company sells its novel, market-leading NIOX[®] asthma management products directly to specialists in the United States, United Kingdom, China and Germany, and in a wide range of other countries through its network of partners. In the United States, Circassia has a commercial collaboration with AstraZeneca in which it has the commercial rights to chronic obstructive pulmonary disease (COPD) treatments Tudorza[®] and Duaklir[®]. Circassia also has the US and Chinese commercial rights to the late-stage ventilator-compatible nitric oxide product AirNOvent. For more information please visit www.circassia.com.

Investment proposition



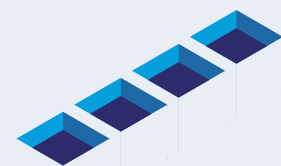
Strengthening our portfolio

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Advancing our COPD partnership

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Expanding our global footprint

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Transforming our business

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We are broadening and strengthening our portfolio of innovative products as part of our strategy to build a successful specialty pharmaceutical company. We made good progress during 2018, which we have continued in the first quarter of 2019.

Acquiring full US commercial rights to Tudorza®

Building on our profit share arrangement with AstraZeneca for chronic obstructive pulmonary disease (COPD) treatment Tudorza®, we exercised our option to acquire the product's full US commercial rights at the end of 2018. This followed a filing in the first half of the year to include positive clinical data from the ASCENT study in the product's label, which was recently approved by the US Food and Drug Administration (FDA). We are now looking forward to the transfer of Tudorza®'s licence from AstraZeneca to Circassia in the coming weeks.

Preparing Duaklir® for launch

As part of our original collaboration with AstraZeneca, we acquired the US commercial rights to COPD combination therapy Duaklir®. During 2018, AstraZeneca submitted a New Drug Application for the product, which was recently approved by the FDA. As a result, we plan to launch the product during the second half of the year, further strengthening our portfolio of respiratory medicines in the United States.

Adding AirNOvent to the portfolio

In early 2019, we announced the acquisition of the US and Chinese commercial rights to the ventilator-compatible nitric oxide product AirNOvent from AIT Therapeutics Inc ("AIT"). Following a successful pre-submission meeting with the FDA, AIT plans to submit the product for approval in the US for use in the treatment of hypoxic respiratory failure associated with persistent pulmonary hypertension of the newborn. Once approved, we anticipate launching AirNOvent in the United States in the first half of 2020.

Approved products

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We have NIOX®, Tudorza® and Duaklir® approved in the US and have the potential for a fourth approval with AirNOvent

Strengthening our portfolio



Advancing our COPD partnership



During 2018, we built on our transformational US commercial collaboration with AstraZeneca for chronic obstructive pulmonary disease (COPD) treatments Tudorza® and Duaklir®. In 2018 we amended our original agreement, AstraZeneca subscribed for additional new ordinary shares in Circassia and we exercised our option to take full US commercial control of Tudorza®.

Establishing a dedicated COPD sales force

Taking full commercial control of Tudorza® in the United States provides us with additional flexibility in managing the composition of our sales force, customer targeting, product detail prioritisation, territory definition, distribution strategy, pricing and market access priorities. As a result, we have launched a dedicated COPD sales force to promote Tudorza®, and following its launch later in the year, Duaklir®. Alongside this sales force our device promotional team will focus on NIOX® and prepare for the launch of AirNOvent, which we anticipate in 2020, once approved.

Presenting new clinical data

At the prestigious 2018 American Thoracic Society conference scientists presented positive clinical data from the Tudorza® phase IV ASCENT and Duaklir® phase III AMPLIFY studies. Both studies met their primary endpoints, with ASCENT demonstrating Tudorza® is effective at reducing COPD exacerbations with no increase in major cardiovascular adverse events, and AMPLIFY showing Duaklir® achieved significantly greater improvements in lung function compared with its individual monotherapy components.

COPD exacerbations



In the ASCENT study Tudorza® significantly reduced the rate of moderate to severe COPD exacerbations during the first year of treatment

COPD hospitalisations



Tudorza® also significantly reduced hospitalisations due to COPD exacerbations in the same period

During 2018 we grew our commercial footprint around the world, significantly expanding our team in China and adding new partners in a number of countries. We aim to leverage this commercial platform, increasing sales of our existing products and adding further products via in-licensing, acquisition or partnering.

Launching our direct sales team in China

In the second half of 2018, we made great progress recruiting, training and launching our new NIOX® direct sales team in China. This built on, and significantly expanded, our established Beijing-based commercial team, which previously focused on supporting local partners. With NIOX® already installed in approximately 400 top hospitals in China, our new commercial team is targeting the approximately 2,000 leading institutions where the product was not available previously.

Expanding our network of partners

Alongside our direct sales teams in the United States, United Kingdom, Germany and China, we sell our products in more than 35 additional countries through our international network of partners. During 2018, we strengthened this network, with the addition of new partners in several territories, including Malaysia, Mexico and Thailand.

Growing our European presence

During 2018, we expanded our direct sales capabilities in the UK with the addition of new key account managers and further training expertise. Our European sales teams based in the UK and Germany are supported by dedicated commercial operations functions, which we are strengthening with additional marketing and analytics experts. Complementing our direct presence in the UK and Germany, we recently appointed a commercial Director in Italy, who will play a key role in finalising our commercial strategy in the country.

China team

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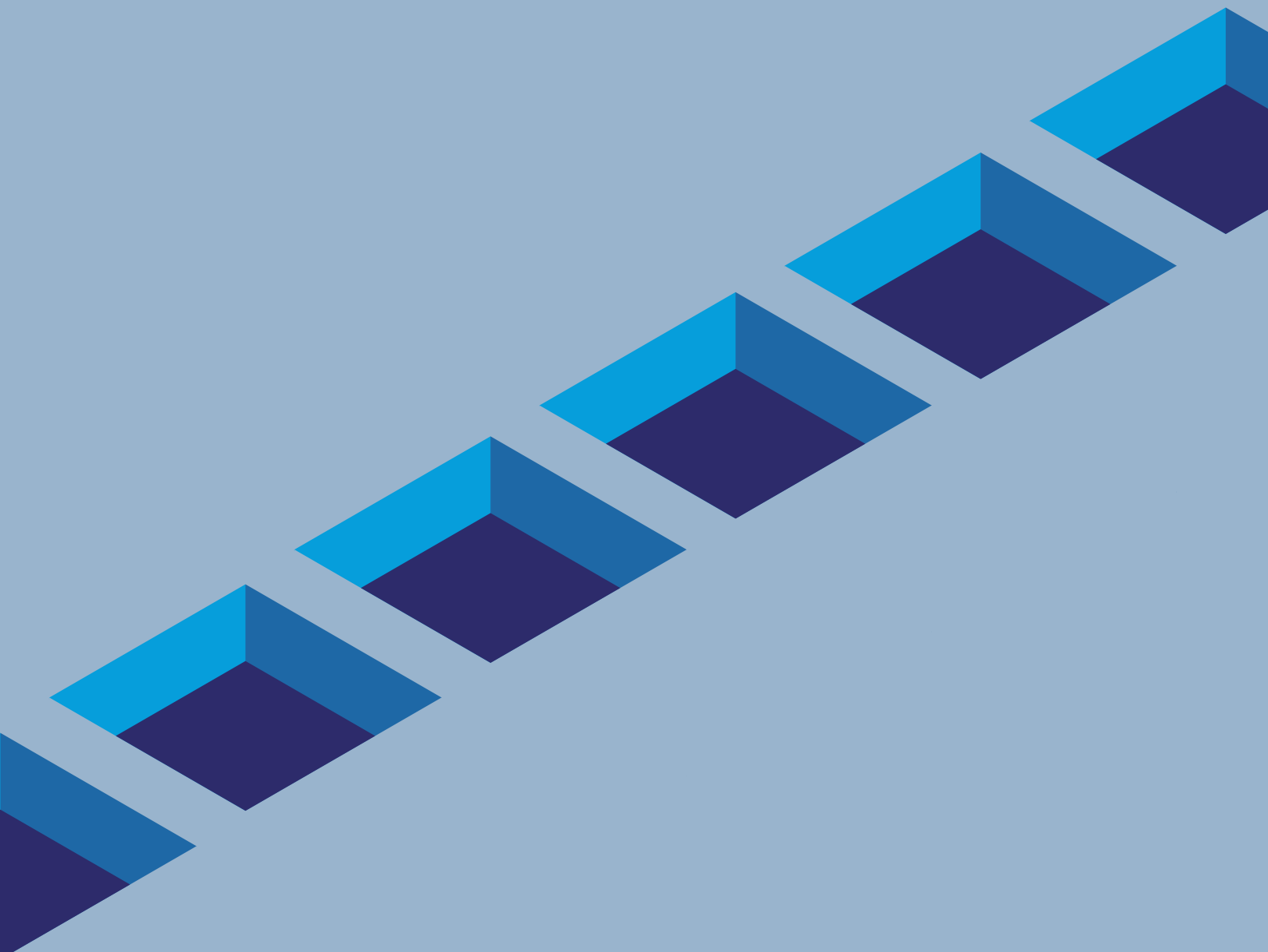
We significantly expanded our commercial organisation in China and most of our approximately 100-strong team is now in place

Direct sales territories

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We are expanding our direct sales capabilities, and have the potential to add Italy to our direct markets

Expanding our global footprint



Transforming our business



During 2018, we continued our transition into a commercially-focused specialty pharmaceutical business. We maintained our focus on controlling costs, reduced R&D expenditure, contained administrative spending and invested in our commercial platform. With our revenues continuing to grow, despite headwinds in the second half of the year, we continued our trajectory towards profitability.

Growing revenues

During 2018 we continued to grow our revenues, which increased by approximately 4% to £48.3 million, despite higher Tudorza® rebates in US federal channels and disruption in China following the establishment of the Company's new direct sales team in the second half. In the coming year, we look forward to building on the progress of 2018, as we take full control of Tudorza®'s commercialisation in the US and our commercial team in China sells NIOX® direct.

Containing costs and commercial investment

In April 2018, we announced a refocused investment strategy designed to accelerate our transition into a commercially-focused business. As part of this strategy we halted spending on our in-house respiratory pipeline and focused R&D expenditure on product support, while containing corporate costs and increasing investment in our commercial platform. During the year we have implemented this approach, with our underlying R&D costs reducing by 19% and only modest growth in administrative expenditure due to increased support for our expanded China commercial team. With these combined costs reduced during the period, we grew our underlying sales and marketing investment by 10%, reflecting our commercial team in the United States and expansion in China.

Revenues

£48.3m

We grew our revenues to £48.3m during 2018 and aim to build on this in the coming year

Reduction in R&D spend

£2.5m

We reduced our underlying R&D expenditure by 19% as part of our cost containment strategy

Operational and financial highlights

NIOX® progress

- Sales increased 5% to £27.4 million (2017 CER¹: £26.2 million)
- Clinical (non-research²) revenues increased 7% compared with 2017 CER¹
- China sales decreased 11% vs 2017 CER¹ following destocking and disruption during transition to direct sales; new sales model now in place
- Q1 2019 unaudited revenues increased 38% vs Q1 2018 CER¹

US COPD portfolio progress

- Tudorza® profit share revenues increased 11% to £20.9 million (2017 CER¹: £18.8 million)
- Q1 2019 unaudited revenues increased 31% vs Q4 2018 CER¹ following option exercise at year end; prescriptions stable
- Tudorza® option exercised acquiring product's full commercial rights
- Tudorza® ASCENT study data filed for inclusion in label; FDA approved March 2019
- Duaklir® NDA filed; FDA approved March 2019

Commercial platform progress

- China direct sales force launched; commercial team expansion to approximately 100 near completion
- UK team expanded; Commercial Director hired in Italy; European commercial operations strengthened
- US dedicated COPD and device teams launched to prepare for product launches

Corporate progress

- AstraZeneca subscription raising \$26.7 million completed

Post-period highlights

- US and China commercialisation rights to novel nitric oxide product AirNOvent³ acquired January 2019
- Move to AIM completed February 2019
- AstraZeneca five-year loan addresses outstanding COPD transaction consideration, option and R&D payments

+5%

NIOX® sales increased 5% to £27.4 million (2017 CER¹: £26.2 million)

+11%

Tudorza® profit share revenues increased 11% to £20.9 million (2017 CER¹: £18.8 million)

Financial highlights

Key performance indicators	2018 underlying continuing operations	2017 underlying continuing operations	2018 total	2017 total
Revenue	£48.3m	£46.3m	£48.3m	£46.3m
R&D	(£10.8m)	(£13.3m ⁴)	(£89.4m)	(£103.0m)
G&A	(£11.4m)	(£10.7m ⁴)	(£11.8m)	(£11.1m)
S&M	(£54.4m)	(£49.5m ⁴)	(£57.3m)	(£50.1m)
Loss for the year	(£25.9m)	(£34.5m ⁴)	(£117.1m)	(£99.1m)
Net cash ⁵ outflow	(£18.8m)	(£57.9m)	(£18.8m)	(£57.9m)
Cash ⁵ at year end	£40.7m	£59.5m	£40.7m	£59.5m

- ¹ Constant exchange rates (CER) for 2017 represent reported numbers re-stated using 2018 average exchange rates; management believes CER comparisons better represent underlying performance due to currency fluctuations against sterling
- ² Clinical revenues represent sales to clinicians, hospitals and distributors; research revenues represent sales to pharmaceutical companies for use in clinical studies
- ³ AirNOvent is not an approved name and may not be the final name submitted for approval
- ⁴ Underlying operations restated to show the results of in-house respiratory development in discontinued operations
- ⁵ Cash, cash equivalents and short-term deposits

£48.3m

Revenues increased by £2.0 million to £48.3 million (2017: £46.3 million)

£40.7m

Cash⁵ at year end was £40.7 million (2017: £59.5 million)

£18.8m

Net cash out flow reduced to £18.8 million (2017: £57.9 million)

Strategic overview

In 2018 Circassia made good progress implementing its strategy. The Company completed its transition into a commercially-focused specialty pharmaceutical business, and has continued to build on this positive momentum. The Company has refocused its R&D expenditure, with device development, regulatory, medical affairs, quality and supply chain functions focused on supporting its commercial products, and spending on its in-house respiratory pipeline halted. In parallel, Circassia has maintained investment in its commercial platform, dramatically increasing its presence in China and strengthening its team in Europe. The Company also expanded its product portfolio, exercising its option to take full US commercial control of chronic obstructive pulmonary disease (COPD) treatment Tudorza® at the end of 2018, and acquiring the US and Chinese commercial rights to late-stage ventilator-compatible nitric oxide product AirNOvent at the start of 2019.

Circassia also made good corporate progress. It amended its commercialisation agreement with AstraZeneca for COPD products Tudorza® and Duaklir®, and AstraZeneca increased its equity stake in Circassia to 19.9% following a subscription of new shares. As part of the approval process for this related-party transaction, the Company agreed with the UK Financial Conduct Authority (FCA) to seek shareholder approval to move to AIM if the percentage of its shares held in public hands did not reach the level required for the Main Market. Circassia's shareholders subsequently approved this move to AIM and it was completed in early 2019. The move also provides potential strategic advantages as AIM's more flexible regulatory regime may help the Company acquire, partner or in-license additional products more efficiently to leverage its commercial platform.

Alongside the Company's strategic and corporate progress, the past year was also a period of financial transition. Circassia continued to grow its revenues despite headwinds in the second half, controlled its non-commercial costs, reduced the net loss in its underlying business and dramatically decreased its net cash outflow. As a result, Circassia is continuing to advance towards its strategic objective of building a self-sustaining specialty pharmaceutical business.



Steven Harris
Chief Executive Officer

“We made good progress in 2018 completing our strategic transition into a commercially-focused specialty pharmaceutical business focused on respiratory disease. Our revenues continued to grow and we maintained our commercial investment and broad cost control activities. As a result, we dramatically reduced our net cash outflow and decreased the loss in our underlying business.”

NIOX® asthma management products

NIOX® is the leading point-of-care system for measuring fractional exhaled nitric oxide (FeNO), an important biomarker of the major underlying cause of asthma, type 2 airway inflammation. NIOX® is used around the world to improve asthma diagnosis and management, and Circassia sells the product directly in the United States, UK and Germany, and following the recent launch of its local sales team, in China also. In addition, the Company promotes NIOX® through its network of international partners, which extends across more than 35 countries.

Sales growth

NIOX® sales continued to grow during 2018. Global revenues of £27.4 million were 5% (CER) higher than the year before, with sales for clinical use increasing 7% and less predictable sales for use in pharmaceutical company clinical studies declining 6%. Overall growth was held back by lower sales in China, which decreased 11% with destocking and distributor disruption during the transition to the Company's direct sales model. In Germany and the UK, revenues grew 8% and 27% (CER) respectively, while in the United States sales declined by 1% (CER) due to disruption at the end of the year caused by territory realignment as the Company launched dedicated COPD and NIOX® sales teams.

With much of this disruption now complete, NIOX® revenue growth has accelerated significantly during the first quarter of 2019, and global sales were 38% higher at CER compared with the same period the year before.

Increasing access

Circassia is working to increase NIOX® market access in a number of countries. In the United States, payor coverage grew significantly during 2018 and the market access team is targeting a number of additional healthcare plans to increase this further. In the US and UK, the Company's commercial teams are working with pharmacy chains to explore the potential of providing NIOX® testing in convenient locations. In China, reimbursement for FeNO testing was recently granted in Beijing, providing an opportunity to target the more than 100 top level hospitals in the city. In Australia, the Company's partner plans to grow the local market following the introduction of reimbursement for FeNO testing alongside spirometry.

Geographic expansion

Outside its direct sales territories, Circassia sells NIOX® through a network of international partners. During 2018 the Company added new partners in Malaysia, Mexico, Saudi Arabia and Thailand and has now received approvals in each of these countries.



NIOX® revenues continued to grow during 2018



During 2018 the Company added new partners in Malaysia, Mexico, Saudi Arabia and Thailand and has now received approvals in each of these countries

NIOX® support

Circassia supports its partners' NIOX® promotion via a dedicated commercial team. During 2018, the team launched a new NIOX® marketing campaign at the European Respiratory Society International Congress, where it also held a partner meeting to provide training on the new materials. The Company also provided training in South Korea and recently held training sessions at the Chest World Congress in Thailand.

During 2018 Circassia's commercial team also continued NIOX® brand building activities in its direct markets, including the roll out of its digital strategy with online advertising, e-shots, refreshed web resources and the launch of a new NIOX.com web portal. In the UK, Circassia is providing healthcare professionals with training via its Asthma Masterclass programme, which is delivered by a specialist respiratory nurse advisor. It is also working with the Primary Care Respiratory Society to offer members exclusive benefits when purchasing NIOX®.

In the US, the Company has partnered with reimbursement specialists to provide support for NIOX® customers. This new service offers coding and reimbursement support via a dedicated hotline team of certified coders. Additionally, Circassia has launched a dedicated NIOX® promotional team in the US to improve targeting and promotional efficiency. The team includes telesales and customer service professionals working alongside the dedicated field-based sales force.

US collaboration with AstraZeneca

In 2017, Circassia established a US commercial collaboration with AstraZeneca for COPD products Tudorza® and Duaklir®. Under the agreement, Circassia acquired the commercialisation rights to Duaklir® and entered a profit share arrangement for Tudorza® in which the Company was responsible for the product's promotion and AstraZeneca its manufacture, distribution, pharmacovigilance and regulatory activities.

Agreement amendment and option exercise

During 2018, the companies amended the original agreement, and AstraZeneca increased its shareholding in Circassia to 19.9% via subscription for newly-issued ordinary shares. Circassia used the \$26.7 million consideration to pay a \$20.0 million R&D contribution due to AstraZeneca by 31 December 2018 and to part settle the final \$25.0 million payable by the end of 2019. The remaining \$18.3 million of this final R&D payment is addressed by a five-year loan provided by AstraZeneca.

At the end of 2018, Circassia issued a notice of option exercise to acquire the full US commercialisation rights to Tudorza®. This completed as anticipated on 31 December 2018, and from 1 January 2019 Circassia has recorded Tudorza®'s in-market sales and costs and retained the full profits from commercialisation. The option exercise triggered an initial payment obligation of \$5 million, and following the approval of Duaklir® a final option payment of \$20 million became payable to AstraZeneca. These payment obligations are addressed by a five-year loan provided by AstraZeneca under the companies' agreement. This loan facility provided by AstraZeneca also addresses the final consideration of \$100 million due under the companies' agreement, in addition to the R&D payment outlined above.

The team launched a new NIOX® marketing campaign at the European Respiratory Society International Congress, where it also held a partner meeting to provide training on the new materials



“During 2018, our global NIOX® business continued to grow, and following the launch of our direct sales team in China we look forward to expanding our presence in this significant market.”

Tudorza® collaboration

Tudorza® contains the long-acting muscarinic antagonist (LAMA) acclidinium bromide, which is administered twice-daily via the easy-to-use inhaler Pressair® for the maintenance treatment of COPD. In the United States, the market for LAMA therapies totalled an estimated \$2 billion in 2018 presenting a significant opportunity for Tudorza®. With the product's prescriptions making up approximately 2.6% of the market, a modest increase in volumes or uptake in higher value channels could substantially grow the product's sales, which would be of material importance to the Company.

Commercial progress

Following the establishment of the Tudorza® collaboration in 2017, Circassia's sales force rapidly achieved its target call volumes as part of the Company's plan to turn round the product's previously declining prescriptions. During 2018 the prescription rate continued to stabilise, although the £20.9 million profit share revenues for the year were impacted by higher rebates in federal channels during the second half. In the final quarter of the year the Company refined its physician targeting strategy and during piloting the new prescription rate per call responded positively.

Circassia plans to build on this progress during the coming year. Following the exercise of its option to acquire the full US commercial rights to Tudorza® at the end of 2018, first quarter revenues in 2019 increased 31% at CER compared with the final quarter the previous year. With the imminent transfer of the product's licence to Circassia, the Company will have significant additional flexibility in managing its sales force composition, customer targeting, product detail prioritisation, territory definition, distribution strategy, pricing and market access activities. Circassia is leveraging this increased flexibility and recently refocused its US sales capabilities launching a dedicated COPD sales force to improve targeting and promotional efficacy.

Regulatory progress

Following the successful completion of the phase IV ASCENT study at the end of 2017, Tudorza® has made good regulatory progress. The study met both its primary endpoints, and during the first half of 2018 a supplemental New Drug Application (sNDA) was submitted to the FDA requesting inclusion of the data in the product's prescribing information. The FDA recently completed its review of the filing and approved the sNDA at the end of March.

As a result, Tudorza®'s expanded label now includes unique data from ASCENT. The study, which was conducted in patients with moderate to very severe COPD and cardiovascular disease and / or significant cardiovascular risk factors, demonstrated that Tudorza® is effective at reducing COPD exacerbations with no increase in major cardiovascular events and at reducing hospitalisations due to COPD exacerbations in this at-risk population. Cardiovascular disease is the most common and significant co-morbidity of COPD, with approximately 30% of COPD patients dying from cardiovascular conditions. Tudorza® is the only LAMA in the United States with these data in its label, which Circassia plans to use in payor discussions as part of its market access strategy.

Circassia recently refocused its US sales capabilities launching a dedicated COPD sales force to improve targeting and promotional efficacy



In the United States, the market for LAMA therapies totalled an estimated \$2 billion in 2018 presenting a significant opportunity for Tudorza®

Duaklir[®] collaboration

Duaklir[®] is a fixed-dose combination of the LAMA aclidinium bromide and long-acting beta agonist (LABA) formoterol fumarate, which is administered twice-daily via the breath-actuated Pressair[®] inhaler for the maintenance treatment of COPD. Duaklir[®] targets the rapidly growing \$850 million US LAMA / LABA market, which represents an important commercial opportunity for the Company.

Regulatory progress

During 2018, Duaklir[®] made good regulatory progress following the successful completion of the AMPLIFY phase III study the prior year. In the first half of 2018, a New Drug Application was submitted for Duaklir[®], which was approved in March 2019 by the FDA. The approval is based on a broad clinical database, including data from AMPLIFY and two earlier phase III studies, ACLIFORM and AUGMENT. The label also includes clinical data from the phase IV ASCENT study, which shows aclidinium therapy is effective at reducing COPD exacerbations. As a result, Duaklir[®] is the only twice-daily LAMA / LABA in the United States with COPD exacerbation data included in its prescribing information.

Commercial progress

Circassia plans to launch Duaklir[®] in the second half of 2019 through its dedicated COPD sales force. The Company is making good progress with its preparations and is working with specialist agencies and an advisory board of medical experts as it finalises its launch plans. The team has completed market research to inform the product's value proposition, brand messaging and creative campaign, and is developing Duaklir[®]'s market access contracting strategy and payor value propositions while public relations specialists finalise the communications strategy.

Commercial infrastructure progress

During 2018 Circassia continued to develop its commercial infrastructure to increase revenues from its existing portfolio and provide a platform to attract additional products. In China it significantly expanded its team, launching a direct sales team at the end of the year. This represents a significant change to the Company's business model in the country, with Circassia's previously modest team focusing solely on distributor support, marketing and market access activities. During the second half of the year, the Company recruited a full range of commercial and back office functions to support its direct sales field force, and by the end of the year the vast majority of the 100-strong commercial team was in place. Following the launch of this direct sales capability, Circassia now commercialises NIOX[®] using a mixed business model in China. In major cities the sales force works with logistics providers to supply customers directly, while in secondary cities the team works alongside distributors and in remoter regions the Company uses distribution partners. This new approach represents a significant opportunity for the Company to significantly increase its gross margin and expand its overall sales.

The launch and transition to this new model in China resulted in disruption and destocking at the end of 2018 impacting revenues. However, with this now complete and Circassia focusing promotion significantly beyond the 400 hospitals where NIOX[®] was previously installed, as well as capturing additional margin from selling directly, the Company anticipates continued strong sales growth in China.

“We also advanced our US COPD portfolio, and in the first half of 2018 our partner filed for Duaklir[®] approval and an expanded label for Tudorza[®]. We are delighted that both filings were successful and we now look forward to enhancing our Tudorza[®] promotion and launching Duaklir[®] later this year.”



Circassia now commercialises NIOX[®] using a mixed business model in China. In major cities the sales force works with logistics providers to supply customers directly, while in secondary cities the team works alongside distributors and in remoter regions the Company uses distribution partners

Circassia is also strengthening its presence in Europe. The UK sales force expanded to increase coverage in the South East and add dedicated territories in the South West and Republic of Ireland. In Italy, the Company recently appointed a Commercial Director with significant respiratory and market access experience who will play a key role in finalising the commercialisation strategy in the country, including the potential for direct sales. Additionally, the Company is recruiting further marketing, analysis and operations expertise to support local promotional activities.

Investment strategy

In 2018, the Company refocused its investment approach as part of the strategy to transition into a self-sustaining, commercially-focused specialty pharmaceutical business. As a result, Circassia focused investment on its commercial platform while halting R&D expenditure on its in-house respiratory pipeline and aligning its regulatory, medical affairs, quality and supply chain resources to support the Company's marketed and late-stage products. The Company reduced its underlying R&D expenditure by nearly 20%, with headcount decreasing by over 50%, and increased its sales and marketing investment by 10% with growth focused in the United States and China. At the same time, the Company controlled its underlying administrative expenditure, which increased only marginally following increased office costs to support the Company's significant expansion in China.

During 2019, Circassia plans to maintain its commercial investment alongside an ongoing focus on cost containment. With the refocusing of its investment strategy now complete, the Company anticipates ongoing control of non-commercial expenditure, and sales and marketing costs reflecting the larger team in China and upcoming launch of Duaklir® in the United States.

Post-period highlights

Portfolio expansion

As part of its strategy to leverage its commercialisation platform, Circassia is actively pursuing opportunities to add to its portfolio through partnering, in-licensing or acquisition. The Company continued its business development programme throughout 2018, and at the beginning of 2019 announced the acquisition of the exclusive US and Chinese commercialisation rights to AirNOvent from AIT Therapeutics Inc. AirNOvent is a late-stage, ventilator-compatible novel inhaled nitric oxide product, initially targeting use in the treatment of hypoxic respiratory failure associated with persistent pulmonary hypertension of the newborn (PPHN).

Under the terms of the agreement, Circassia paid AIT initial consideration of \$7.35 million, and a further \$3.15 million following the successful completion of a pre-submission FDA meeting. Both payments were satisfied through the issuance of new ordinary shares in the Company to AIT. Further deferred contingent consideration, also payable in Circassia shares, will become due on the achievement of certain milestones, including \$12.6 million following FDA approval, \$8.4 million on US approval of a related indication and \$1.05 million on the product's launch in China. Additionally, the Company will pay tiered royalties based on gross profits from future product sales.



Circassia acquired the exclusive US and Chinese commercialisation rights to AirNOvent from AIT Therapeutics Inc. AirNOvent is a late-stage, ventilator-compatible novel inhaled nitric oxide product



The Company is recruiting further marketing, analysis and operations expertise to support local promotional activities

AirNOvent overview

AirNOvent is a portable system that utilises an electric voltage to produce precise quantities of nitric oxide from the nitrogen and oxygen in air. Inhaled nitric oxide is a pulmonary vasodilator, which is approved in the United States for use as part of a regimen in the treatment of hypoxic respiratory failure associated with PPHN. PPHN is the failure of normal circulatory transition after birth, which occurs in approximately 1,500 – 26,200 newborns in the United States. The condition is potentially fatal and management can be complex involving a number of treatments, which in addition to supplemental oxygen can include the administration of inhaled nitric oxide.

The currently available product, INOMAX[®], is used in neonatal intensive care units (NICUs) and its delivery system administers nitric oxide from pressurised cylinders in conjunction with ventilator systems. The product generated US revenues estimated at over \$400 million in 2018. AirNOvent offers a number of potential benefits over the existing competition. It is cylinder-free and is smaller, significantly lighter and more convenient, and unlike nitric oxide cylinder-based systems does not require special storage and handling. As a result, it has the potential for use by NICUs, as well as smaller clinics without the facilities required to manage nitric oxide cylinders.

Under the companies' agreement, AIT is responsible for the product's development, US regulatory filings and manufacture, with Circassia managing the regulatory process in China. AIT plans to submit AirNOvent to the FDA in the coming weeks for Premarket Approval (PMA) for use in the treatment of PPHN, and Circassia anticipates launching the product in the first half of 2020 following approval.

AirNOvent commercialisation

Circassia intends to leverage its existing commercial platform in the United States to commercialise AirNOvent and anticipates modestly expanding its commercial team, adding further key accounts and medical affairs experts. The Company plans to target top hospitals with NICUs, many of which are called on by the existing dedicated device sales team. Additionally, the team will target facilities that do not currently use inhaled nitric oxide, such as those without the appropriate handling facilities.

Move to AIM

AstraZeneca's subscription for additional equity in 2018 decreased the 'free float' in the Company's shares to approximately 10%. The free float excludes holdings by directors and shareholdings of over 5%, and the Financial Conduct Authority's (FCA) Listing Rules require a level of at least 25%. As a result, the Company committed to the FCA that if the free float did not meet this required level within six months it would seek shareholder approval to move to AIM, which does not have the same requirement.

During the subsequent months, there was little movement in the free float and consequently Circassia sought approval to move to AIM. This was granted at a shareholder meeting on 4 January 2019 and the Company's shares were removed from trading on the London Stock Exchange's Main Market and admitted to trading on AIM on 4 February 2019.



The Company plans to target top hospitals with NICUs, many of which are called on by the existing dedicated device sales team



PPHN is the failure of normal circulatory transition after birth, which occurs in approximately 1,500 – 26,200 newborns in the United States

Board changes

Following six years as Non-Executive Chairman, Dr Francesco Granata has informed the Company of his intention to retire from Circassia's Board in order to focus on his other business commitments. Francesco will continue as Chairman while the Company completes the ongoing search for his replacement. Additionally, following 12 years as Non-Executive Director, Russ Cummings has informed the Company he will not stand for re-election to the Board at the forthcoming Annual General Meeting. The Board wishes to express its sincere appreciation to Francesco for his leadership and significant contribution to the Company's development during his time at Circassia and to Russ for providing strategic insight and extensive financial market experience during his significant time as a Non-Executive Director.

In parallel with the ongoing Chairman search process, the Company is further strengthening its commercial focus through the creation and appointment of a Chief Operating Officer. The COO will lead Circassia's global commercial strategy and operational management and will be appointed to the Company's Board. The Company intends to announce the appointment of both the new Chairman and COO in due course.

Summary and outlook

During 2018, Circassia continued to make good progress implementing its strategy. The Company grew its revenues, despite headwinds in the second half, and maintained its financial strategy focusing on commercial investment and cost containment elsewhere. As a result, it reduced net cash outflow significantly and decreased the loss in its underlying business despite increased investment in its commercial infrastructure.

During the year, the Company's products also made progress, with the NIOX[®] business continuing to grow and filings in the US COPD portfolio resulting in the recent approval of Duaklir[®] and label expansion for Tudorza[®]. With dedicated NIOX[®] and COPD sales teams in the US, direct sales capabilities in China and a broader commercial platform in Europe, Circassia anticipates building on the encouraging Q1 2019 sales with strong revenue growth in the coming year. In the coming months, the Company looks forward to further progress, with the upcoming US filing for AirNOvent and launch of Duaklir[®] in the second half of 2019.

Over the last three years, the Company has completed its transformation from an R&D-based organisation into a strong commercially-focused business. The Company now features a unique commercial platform promoting compelling respiratory products across the world's largest markets. With a clear strategy focused on building a self-sustaining specialty pharmaceutical business, combined with growing revenues, Circassia is well positioned to continue its drive towards profitability.

Steven Harris
Chief Executive Officer

1 May 2019



Circassia anticipates continued strong revenue growth in the coming year. In the coming months, the Company looks forward to further progress, with the upcoming US filing for AirNOvent and launch of Duaklir[®]

“During 2019 we have maintained our momentum, taking full commercial control of Tudorza[®], adding late-stage product AirNOvent to our portfolio, significantly increasing NIOX[®] revenues and boosting our commercial platform. As a result, we are making good progress building a robust business with growing revenue potential and an exciting commercial future.”

Strategy

Our strategy is focused on building a self-sustaining world-class specialty pharmaceutical company, following an efficient business model that leverages our in-house commercialisation capabilities.

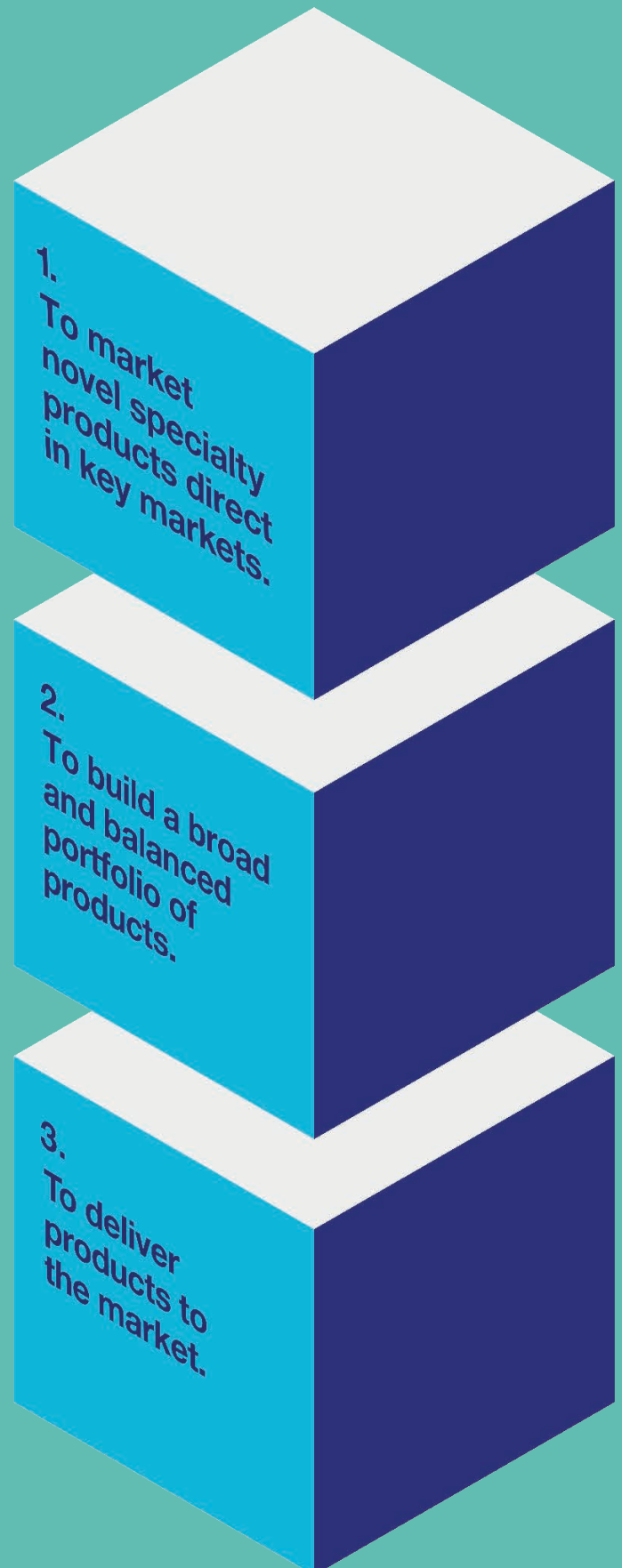
Clear objectives

Our strategy has three clear objectives as part of our ambition to become a leading business in our field.

1. To market novel specialty products direct in key markets.
2. To build a broad and balanced portfolio of products.
3. To deliver products to the market.

Good progress

Since the beginning of 2018, we have continued to make good progress against our objectives. The launch of our direct sales team in China at the end of the year expands our direct sales capabilities, complementing those in the US, UK and Germany. In 2019 we have continued our progress, with the addition of AirNOvent to our portfolio and the recent approval of Duaklir® in the US, which we plan to launch in the second half of the year.



Business model

As a commercially-focused specialty pharmaceutical business, we implement our strategy following an efficient business model.



During 2018 revenues continued to grow, increasing 4% to £48.3 million, while the Company maintained control of overall costs, reducing R&D expenditure, containing administrative costs and investing in the commercial platform.

The table overleaf sets out the Group's results for the year ended 31 December 2018, separated into continuing and discontinued operations. Continuing operations are further divided into underlying and non-underlying operations. Continuing underlying operations include revenues from the Tudorza® collaboration with AstraZeneca and sales of NIOX®, as well as the costs of the underlying business. These key performance indicators are used by management to manage the business and measure performance.

Non-underlying operations include irregular and non-recurring expenditure, such as those relating to restructuring the US field force into dedicated NIOX® and COPD units, the prior year's R&D contribution to AstraZeneca and other non-cash gains and losses relating to the deferred consideration payable to AstraZeneca. Discontinued operations include direct costs and overheads associated with the in-house respiratory pipeline which ceased in April 2018 and residual costs from the allergy programmes for which all development ceased in April 2017.

Revenue

Circassia's revenues of £48.3 million (2017: £46.3 million) include Tudorza® revenues of £20.9 million (2017: £19.0 million) and NIOX® sales of £27.4 million (2017: £27.3 million).

During 2018, Tudorza® revenues derived from the profit share arrangement with AstraZeneca. AstraZeneca recorded in-market sales, cost of sales and other operational costs while Circassia recorded the costs of the field force and promotion and the companies each recorded 50% of the resultant profit. On 31 December 2018, Circassia completed the exercise of its option to take full commercial control of Tudorza® in the United States, and during 2019 will receive the full benefits of commercialisation and will record both the product's sales and costs.

NIOX® revenues include sales for use in clinical practice of £23.4 million (2017: £22.8 million), sales for use in pharmaceutical company research of £3.7 million (2017: £4.1 million) and other revenues such as freight of £0.3 million (2017: £0.4 million).

Gross profit

Gross margin increased from 78% to 82%. This was mainly due to the contribution of revenues from the AstraZeneca collaboration for the full year, which due to the agreement structure have a 100% gross margin. Gross profit on NIOX® sales was £18.5 million (2017: £17.3 million), with a gross margin of 68% (2017: 63%). This increase mainly reflects the weakening of sterling against the dollar.



Julien Cotta
Chief Financial Officer

“During 2018 revenues continued to grow, increasing 4% to £48.3 million, while the Company maintained control of overall costs, reducing R&D expenditure, containing administrative costs and investing in the commercial platform.”

	Underlying operations		Non-underlying operations		Total continuing		Discontinued operations ¹		Total	
	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017
	Restated ²	Restated ²	Restated ²	Restated ²	Restated ²	Restated ²	Restated ²	Restated ²	Restated ²	Restated ²
	£m	£m	£m	£m	£m	£m	£m	£m	£m	£m
Revenue	48.3	46.3	–	–	48.3	46.3	–	–	48.3	46.3
Cost of sales	(8.9)	(10.0)	–	–	(8.9)	(10.0)	–	–	(8.9)	(10.0)
Gross profit	39.4	36.3	–	–	39.4	36.3	–	–	39.4	36.3
Gross margin	82%	78%	–	–	82%	78%	–	–	82%	78%
Research and development	(10.8)	(13.3)	–	(45.1)	(10.8)	(58.4)	(78.6)	(44.6)	(89.4)	(103.0)
Sales and marketing	(54.4)	(49.5)	(2.9)	–	(57.3)	(49.5)	–	(0.6)	(57.3)	(50.1)
Administrative expenditure	(11.4)	(10.7)	(0.3)	0.1	(11.7)	(10.6)	(0.1)	(0.5)	(11.8)	(11.1)
EBITDA	(32.8)	(32.3)	(3.2)	(45.0)	(36.0)	(77.3)	(78.7)	(45.7)	(114.7)	(123.0)
Operating loss	(37.2)	(37.2)	(3.2)	(45.0)	(40.4)	(82.2)	(78.7)	(45.7)	(119.1)	(127.9)
Other gains and (losses)	1.9	(1.1)	(5.6)	11.5	(3.7)	10.4	(0.1)	(0.2)	(3.8)	10.2
Finance costs	(0.1)	(0.1)	(11.9)	(2.7)	(12.0)	(2.8)	–	–	(12.0)	(2.8)
Finance income	0.3	0.4	–	–	0.3	0.4	–	–	0.3	0.4
Loss before tax	(35.1)	(38.0)	(20.7)	(36.2)	(55.8)	(74.2)	(78.8)	(45.9)	(134.6)	(120.1)
Taxation	9.2	3.5	–	10.2	9.2	13.7	8.3	7.3	17.5	21.0
Loss for the financial year	(25.9)	(34.5)	(20.7)	(26.0)	(46.6)	(60.5)	(70.5)	(38.6)	(117.1)	(99.1)
Cash³									40.7	59.5

¹ Disclosed as a single amount in the consolidated statement of comprehensive income.

² Restated to show the results of the respiratory business in discontinued operations, see note 10 to the consolidated financial statements.

³ Includes cash and cash equivalents and short-term deposits.

Gross margin

82%

Gross margin increased from 78% in 2017 to 82%

“Gross margin increased from 78% to 82%. This was mainly due to the contribution of revenues from the AstraZeneca collaboration for the full year, which due to the agreement structure have a 100% gross margin.”

Sales and marketing

Sales and marketing costs increased to £57.3 million (2017: £50.1 million). This was mainly due to a full year of investment in the US field force promoting Tudorza® versus nine months in 2017, as well as significant expansion of commercial operations in China during the second half of the year. Sales and marketing costs of £2.9 million included in non-underlying continuing operations represents the re-organisation costs associated with restructuring the US field force into dedicated NIOX® and COPD teams.

R&D activities

Research and development activities include the costs associated with regulatory, quality and medical affairs support for marketed products, device development, and depreciation and amortisation. Research and development costs from underlying operations decreased to £10.8 million (2017: £13.3 million) mainly as a result of significantly lower headcount.

Discontinued operations include costs relating to the in-house respiratory pipeline of £78.6 million (2017: £44.6 million) most of which relates to an impairment charge of the associated intangible assets as set out below. The impairment costs have no impact on cash.

Impairment of intangibles	£m
Goodwill	4.4
Flixotide substitute	21.1
Seretide substitute	22.1
Spiriva substitute	8.5
Technology	18.9
Total	75.0

Total R&D expenditure reduced to £89.4 million (2017: £103.0 million).

Administrative expenditure

Administrative expenditure, which includes overheads relating to corporate functions, centrally managed support functions and corporate costs, increased to £11.8 million (2017: £11.1 million). This was mainly due to the costs associated with the transfer of the Company's shares to AIM and increased business development costs.

Other gains and losses

Other losses increased to £3.8 million (2017: £10.2 million gain). This was mainly due to unrealised foreign exchange losses relating to deferred consideration payable to AstraZeneca following the weakening of sterling against the dollar.

Net finance costs

Net finance costs were £11.7 million (2017: £2.4 million) for the year. This mainly relates to a non-cash charge to the income statement for the period reflecting the difference in the discounted and actual deferred consideration payable to AstraZeneca recorded on the statement of financial position. The discounted amount reflects the time value of money.

Taxation

Taxation for the year was a credit of £17.5 million (2017: £21.0 million) of which £9.2 million (2017: £3.5 million) relates to underlying continuing operations. Included in underlying continuing operations is an R&D tax credit of £1.0 million (2017: £3.5 million) which is lower than the previous year because of a decrease in qualifying R&D expenditure. Also included is a deferred tax credit of £8.2 million (2017: £nil) which has arisen on an increase in recognised carried-forward tax losses in the Group.

An R&D tax credit of £10.2 million was included in non-underlying continuing operations in 2017, which related to the R&D contribution paid to AstraZeneca.

Revenues

↑ 4%

During 2018 revenues continued to grow, increasing 4% to £48.3 million

“Research and development costs from underlying operations decreased to £10.8 million (2017: £13.3 million) mainly as a result of significantly lower headcount.”

Taxation for discontinued operations increased to a credit of £8.3 million (2017: £7.3 million credit), mainly due to a reduction in the deferred tax liability following the impairment of intangible assets in the respiratory pipeline.

Loss after tax and loss per share

Basic loss per share for the period was 34p (2017: 31p) reflecting a loss of £117.1 million (2017: £99.1 million), with the increase mainly due to impairment of intangible assets in the in-house respiratory portfolio. Loss per share for continuing operations decreased to 14p (2017: 19p) reflecting a loss for the financial period of £25.9 million (2017: £34.5 million).

Statement of financial position

The Group's net assets at 31 December 2018 were £125.9 million (31 December 2017: £224.8 million). The decrease was mainly due to impairment of the in-house respiratory intangible assets and lower trade receivables and deposit balances, combined with an increase in the recognised non-contingent consideration payable to AstraZeneca reflecting the time value of money.

Current liabilities at the end of the period were £124.4 million (31 December 2017: £30.8 million). The increase at 31 December 2018 was mainly due to reclassification of the \$100 million deferred non-contingent consideration payable to AstraZeneca as a current liability payable due within one year.

Current tax assets at 31 December 2018 were £1.0 million (31 December 2017: £6.5 million), representing the R&D tax credit due from HM Revenue and Customs. An R&D tax credit of £10.9 million was received in July 2018.

Cash flow

The Group's cash position, including cash equivalents and short-term deposits, decreased from £59.5 million at 31 December 2017 to £40.7 million at 31 December 2018.

Cash used in operations decreased to £51.3 million (2017: £66.4 million), reflecting higher revenues and a net decrease in the overall cost base of the business. Cash used in operations in 2017 included settlement of the \$17.5 million (£13.1 million) R&D contribution due to AstraZeneca. In 2018, the contribution of \$20.0 million (£15.3 million) was satisfied through the issue of new shares to AstraZeneca.

Other significant cashflows included an R&D tax credit of £10.9 million (2017: £8.9 million) and proceeds from the issue of share capital of £20.4 million (2017: £nil), which were used to pay the AstraZeneca R&D contribution of \$20.0 million and the remainder part paying the final tranche of \$25.0 million due by the end of 2019. The remaining \$18.3 million of this final R&D payment, plus the \$125.0 million consideration payable, is addressed by a five-year loan provided by AstraZeneca.

Outlook

In the coming year, Circassia anticipates significant sales growth with a number of factors expected to contribute to the increase. In particular, the Company expects higher NIOX[®] revenues in China following the implementation of direct sales in the country, increased Tudorza[®] revenues following the exercise of the option at the end of 2018 and initial Duaklir[®] sales later this year following the product's approval by the FDA at the end of March. The Company also plans to continue its cost control and commercial investment strategy and as a result, Circassia looks forward to continuing its trajectory towards profitability.

Julien Cotta
Chief Financial Officer

1 May 2019

Cash position

£40.7m

The Group's cash position, including cash equivalents and short-term deposits, decreased from £59.5 million at 31 December 2017 to £40.7 million at 31 December 2018

“Circassia looks forward to ongoing financial transformation during 2019, as the Company continues its trajectory towards profitability.”

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 2018.

Member	Male	Female	Total	%	
				Male	Female
plc Board including					
Non-Executive Directors	6	3	9	67	33
Employees in other senior executive positions	3	1	4	75	25
Directors of subsidiary companies not included in above	–	–	–	–	–
Total Senior Managers excluding directors	12	4	16	75	25
All other employees	111	98	209	53	47
Total	132	106	238	55	45

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. Feedback is also provided through an annual employee engagement survey.

Employment, training, career development and promotion of disabled persons

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

Health and safety

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

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

Ethical and social policies

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

Sunshine Act

The Group is committed to promoting transparency of its relationships with healthcare providers. It collects, tracks and reports payments to healthcare professionals and organisations in compliance with the US Physician Payment Sunshine Act 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 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 2018 are slightly lower than those in 2017 due to exiting the Solna office in Sweden at the end of March 2017. The Group's emissions are largely a function of the heating and lighting of leased office premises.

	2018	2017
CO ₂ equivalent emissions – scope 2 (tonnes)	194	231
Intensity ratio (kg/m ² of office space)	40	42

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.

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 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 from all areas of the business, and updates the Board on a timely basis where important developments occur. The US Commercial Team, Commercial Team for Rest of the World, the Quality Team, Compliance Committee, and Health and Safety Committee meet regularly. Relevant output or matters arising 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.

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.

Tudorza[®], the long-acting muscarinic antagonist (LAMA) which the Group sells in the United States, competes with other LAMAs. 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 maintain or increase its share of the LAMA market.

Later in 2019, the Group plans to launch Duaklir[®], the fixed-dose combination of the long-acting muscarinic antagonist (LAMA) aclidinium bromide and long-acting beta-agonist (LABA) formoterol fumarate. Duaklir[®] will compete with Stiolto[®] (sold by Boehringer Ingelheim), Anoro[®] (sold by GSK), Bevespi[®] (sold by AstraZeneca) and Utibron[®] from Sunovion. There is no guarantee that the Group will be able to take a share of the LAMA/LABA 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 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. In the United States, Spirosure Inc.'s product has been approved by the FDA and is, therefore, a potential competitor to the Group's NIOX VERO[®] device.

In 2020, the Group plans to launch in the United States AirNOvent, the novel cylinder free system for nitric oxide generation for use as part of the treatment regimen for hypoxic respiratory failure associated with persistent pulmonary hypertension of the newborn. AirNOvent will compete with INOMAX® (sold by Mallinckrodt) and potential future new competitors to the market. There is no guarantee that the Group will be able to take a share of this market in the countries where it has commercial rights, namely the United States and China.

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. For example, it may prove difficult to build a strong enough economic case based on the burden of illness and population impact. Third party payers are increasingly managing costs to both their organisations as well as patients, and as a result pharmaceutical products in competitive markets can be denied or limited in terms of coverage and reimbursement. Moreover, even if the products can be sold profitably, they may not be accepted by patients and the medical community.

The Group has expanded its operations significantly in China and moved to a direct sales model. However, there is no guarantee that this will lead to commercial success in the Chinese market. The economic system of China is very different from the economies of developed countries in many respects, including government involvement, level of development, growth rate, control of foreign trade and allocation of resources. Any changes to the political, economic and social conditions in China or in the policies of the Chinese government may have a material adverse impact on the Group's business in China.

Outside the United States, United Kingdom, China and Germany the Group relies on distributors to sell its NIOX® devices and such relationships must be carefully managed in order to ensure the commercialisation 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.

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 have established a Joint Steering Committee which meets regularly to review the development and commercialisation of Tudorza® and Duaklir®. Promotional efforts are focused on current prescribers of Tudorza® and high volume prescribers of other LAMAs. A dedicated team concentrates on selling the product to larger public and private institutions under fixed term contracts.

Plans put in place in order to mitigate against the risk of the launch of Duaklir® being unsuccessful include, recruitment of managers with the relevant commercial experience, establishment of a dedicated COPD field force, a detailed launch plan identifying the target market, product positioning and messaging, contract negotiation with payers, supply chain strategy, and measurement and monitoring of performance.

To mitigate the risks of termination of the products' 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 significant resources to sales of the device. In the United States there is a dedicated commercial team, including sales representatives, selling NIOX®. The products are also sold directly by the Company's teams in China, the United Kingdom and Germany who manage local commercialisation activities. Distributor markets are managed by an experienced Senior Director of Distributor Management.

The Group is in the process of preparing plans to mitigate against the risk of the launch of AirNOvent being unsuccessful. These will include: recruitment of appropriate managers with the relevant commercial experience; launch by an experienced field force; and preparation of a clear marketing and launch plan.

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 relevant legislation and regulations, including 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 United States, such as China, may result in criminal and civil proceedings against the Group.

In 2019, as a result of the Group exercising its option in December 2018 to take full ownership of Tudorza[®], the provision of Tudorza[®] samples to healthcare practitioners will transition to the Group from AstraZeneca. As a result, in 2019 the Group will need to implement its own sample management programme.

Mitigating activities

The Group has an internal Compliance function, which comprises the General Counsel and Chief Compliance Officer together with dedicated Compliance resources in the United States and China. The General Counsel and Chief Compliance Officer have a direct reporting line to the Chair of the Audit and Risk Committee. Activities in this area are reviewed by the Senior Management Team on a quarterly basis. The Compliance function works with a network of external advisers in the relevant territories to ensure local regulations are understood. 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, compliance oversight of sampling activities, and audits of distributors and suppliers.

Regulatory approvals

The Group may not obtain regulatory approval for its products and devices that 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, and whether it is possible to commercialise products effectively or at all. Moreover, approval in one territory offers no guarantee that regulatory approval will be obtained in any other territory.

If the Group acquires further development-stage products, it may be necessary to successfully complete supporting clinical studies to support applications to regulatory authorities for the grant of regulatory approval. 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 United Kingdom 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.

Regulatory approval for the Group's ventilator-compatible nitric oxide product, AirNOvent, might be delayed or refused in the territories where it has commercial rights, being the United States and China.

The Group relies on partners, such as its AirNOvent partner AIT, third party sub-contractors and service providers for the execution of most aspects of 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 professionals who, where appropriate, will commission advice from external advisers and consult with the regulatory authorities on the design of any pre-clinical and clinical programmes that may be required. These in-house experts would 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 application for AirNOvent approval in the United States will be managed by AIT and follows a recent successful pre-submission meeting with the Food and Drug Administration. The AIT team members have regulatory and device development expertise as well as experience in the development of nitric oxide system technology.

Unforeseen side effects

Unforeseen side effects may result from the use of the Group's products and devices.

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 sales may be adversely impacted, and, in extreme circumstances, it may prove necessary to suspend sale and/or withdraw the product from the market.

Adverse events or unforeseen side effects or device malfunction may also potentially lead to product liability claims being raised against the Group as the seller of the product.

Mitigating activities

The Group's medical devices are subject to rigorous testing procedures. A robust device vigilance 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® and Duaklir®.

AstraZeneca administers the global safety database for Tudorza® and will administer the global safety database for Duaklir® 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, finished products and services, including shipping. 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, products and services either prior to launch or during commercialisation. Some materials may only be available from one source, as is currently the case for the NIOX® devices and the sensors contained in those devices, and regulatory requirements may make substitution costly and time-consuming.

The supply chain for Tudorza® and Duaklir® is controlled by AstraZeneca, and AstraZeneca is the sole source of supply for these products.

Additionally, AIT is responsible for the manufacture and supply of AirNOvent, which it outsources to third-party contract manufacturers.

Mitigating activities

Audits of 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.

Research and development risks

The Group is dependent upon external collaborators for the development of its NIOX[®] and AirNOvent devices. The Group relies upon its collaborations with PHC Corporation for the development of the NIOX[®] device, upon IT Dr. Gambert GmbH for the development of the sensors contained in the NIOX[®] devices, and upon AIT Therapeutics, Inc. for the development of the AirNOvent device.

Mitigating activities

The development collaborations with PHC Corporation and AIT 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 or third-party patents to which it has rights. 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 United States, 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 licences 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[®], and the rights which are licensed to the Group as part of the collaboration with AIT relating to AirNOvent, 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 a range of different patents or patent families 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 belonging to the Group and 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.

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.

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[®] and AirNOvent.

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 income and expenditure is in United States dollar, Swedish krona, euros and Chinese yuan.

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

At the end of each year, the Board reviews and approves a budget for the following year and reviews the 10 year plan. As part of the review the Board considers the robustness of the Group taking into account its current position, potential future developments, the principal risks facing it, and the effectiveness of mitigation plans and controls. The review also encompasses the potential impact of significant credible scenarios on the business model and future performance of the business. 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 HSBC and Investec on a daily basis. If tax credits are lost in the future then action would be taken to reduce discretionary expenditure to help ensure there remained sufficient cash to support the business through to profitability.

Brexit

There continue to be political and economic uncertainties following the United Kingdom's vote to leave the European Union (EU) at the referendum held on 23 June 2016. The Group continues to face 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 United Kingdom has left the EU, to permit sales of the device to continue in the United Kingdom.

Brexit may also result in restrictions on the movement of people which may 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 uncertainties surrounding Brexit also caused a significant depreciation in the value of sterling and continue to result in 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 already has established subsidiaries in Sweden (Circassia AB), where the Group's NIOX[®] inventory for the EU and other markets outside the United States is held and Germany (Circassia AG) and so the Group will still have a presence in the EU even after Brexit comes into effect. In addition, a 3-month supply of NIOX[®] inventory is held in the United Kingdom to help mitigate against the disruption in supply. The risks relating to currency volatility are mitigated through the actions described above under the heading financial operations risk.

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 an advisor at Helsinn Investment Fund S.A. SICAR. Prior to this he was senior advisor at Warburg Pincus International LLC, and before that he was Executive Vice President at Biogen Idec Inc. Previously, he served as Group Vice President and President responsible for Canada and major European markets at Schering-Plough Corporation as Regional President for Northern Europe and Middle East and Africa at Pfizer Inc., and as Managing Director of Pharmacia & Upjohn Inc. in Italy. He is currently a Board member of Diadem, an Italian company developing a test for Alzheimer's disease; Italfarmaco SpA, a leading Italian pharmaceutical group that operates in both the pharma and chemical sectors; Utility Therapeutics Limited, a company focused on developing and commercialising antibiotics in the US; 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 Kirin International plc. Prior to his career in industry, Francesco practised as a medical doctor specialising in cardiology. He holds a degree in medicine and surgery from the University of Pavia, Italy, and was formerly a member of the Board of the European Federation of Pharmaceutical Industry Associations.



2 Steven Harris

Chief Executive Officer

Steven Harris co-founded Circassia on 19 May 2006 and has led the Company as Chief Executive Officer since then. Steven 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). Steven is also a 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 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 is currently a Non-Executive Director of Cello Health plc and Alliance Pharma plc. Previously, she was Non-Executive Director at the Duke NUS Medical School in Singapore. 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.

6 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 is currently Non-Executive Director of British Patient Capital Limited. He holds a BSc (Eng) in Mechanical Engineering from Imperial College, London.

7 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.



Dear shareholders,

On behalf of the Board, I am pleased to present Circassia's Corporate governance report for the year ended 31 December 2018.

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.

During 2018, two of our long-serving Non-Executive Directors, Dr Jean-Jacques Garaud and Mr Marvin Samson, decided not to stand for re-election. We are very grateful to Jean-Jacques and Marvin for their significant contributions over the years. In addition, Ms Lota Zoth and Dr Heribert Staudinger have retired from the Board following the transfer to AIM. We also extend our thanks to Lota and Heribert for the excellent support and guidance they have provided.

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

1 May 2019



Dr Francesco Granata
Chairman

Corporate governance statement

Statement of Compliance with the Quoted Companies Alliance Code (the “Code”)

On 4 February 2019, Circassia Pharmaceuticals plc transferred its shares from the Main Market to Alternative Investment Market (AIM) and adopted compliance with the QCA Corporate Governance Code with effect from this date. This report follows the structure of these guidelines and explains how we have applied the guidance.

1) Establish a strategy and business model which promote long-term value for shareholders

The Group’s values are stated within the Corporate social responsibility report on page 26 and the Group’s strategy and business model are explained in detail in the Strategic report on pages 20 to 21.

2) Seek to understand and meet shareholder needs and expectations

Dialogue with shareholders

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.

Shareholder presentations, which include information on our markets and strategy, are available to all stakeholders on the Group’s website. In addition to statutory reporting of material matters, the Group publishes general news on products, technologies and commercial opportunities on the Group’s website.

The Board maintains regular communication with shareholders. Meetings between material shareholders and the Executive Directors take place throughout the year. The Chairman 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 bi-annual 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 and matters reserved for the Board. 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 Annual General Meeting (AGM) provides an opportunity for all shareholders to meet Board members and ask about the proposed resolutions and the business in general.

Notice of the AGM is posted to shareholders no 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. 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.

3) Take into account wider stakeholder and social responsibilities and their implications for long-term success

The Group is aware of its corporate social responsibilities and the need to maintain effective working relationships across a range of stakeholder groups. These include the Group's employees, partners, suppliers and regulatory authorities. The Group's operations and working methodologies take account of the need to balance the needs of all stakeholder groups while maintaining focus on the Board's primary responsibility to promote the success of the Group for the benefit of its members as a whole.

The Group endeavours to take account of feedback received from stakeholders, making amendments to working arrangements and operational plans where appropriate and where such amendments are consistent with the Group's longer-term strategy.

The Group takes due account of any impact that its activities may have on the environment and seeks to minimise this impact wherever possible. Through the various procedures and systems it operates, the Group ensures full compliance with health and safety and environmental legislation relevant to its activities.

The Group's Corporate social responsibility report can be found on page 26.

4) Embed effective risk management, considering both opportunities and threats, throughout the organisation

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 Group's principal risks are outlined in the Strategic report on page 28.

Internal controls

The Audit and Risk Committee reviews the Group's risks and mitigating actions 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 Code.

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.

5) Maintain the Board as a well-functioning, balanced team led by the chair

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 three Non-Executive Directors. The biographies of the current members of the Board are set out on pages 34 to 35 of this report.

The Executive Directors have direct responsibility for the business operations of the Group. 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.

The Board is supported by three Committees (the Audit and Risk Committee; the Nomination Committee; and the Remuneration Committee) that have the necessary skills and knowledge to discharge their duties and responsibilities effectively.

Chairman

Dr Francesco Granata, the 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 2018.

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.

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.

Independence

The Board considers itself to be sufficiently independent. The Code suggests that a board should have at least two independent Non-Executive Directors. As at the date of signing this report, including the Chairman there are four Non-Executive Directors, of which only Mr Russell Cummings is deemed non-independent on the grounds of being a Board member for over 10 years.

Board meetings

The Board aims to meet at least four times during the year, with monthly conference calls taking place in the intervening period. 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 2018.

	Committee Memberships	Independent status	Board	Nomination Committee	Audit and Risk Committee	Remuneration Committee
Executive Directors						
Steven Harris	n/a	n/a	4 (4)	2 (2) ¹	3 (3) ¹	3 (3) ¹
Julien Cotta	n/a	n/a	4 (4)	2 (2) ²	3 (3) ²	3 (3) ²
Rod Hafner	n/a	n/a	4 (4)	–	–	–
Non-Executive Directors						
Francesco Granata	N(Chair)	Yes	4 (4)	2 (2)	–	–
Russell Cummings	–	No	4 (4)	–	–	–
Jean-Jacques Garaud ³	A, R	Yes	1 (2)	–	0 (1)	2 (2)
Lota Zoth ⁴	N ⁵ , A(Chair) ⁶ , R(Chair) ⁷	Yes	4 (4)	0 (0)	3 (3)	3 (3)
Marvin Samson ⁸	N, A, R(Chair)	Yes	1 (2)	0 (0)	1 (1)	1 (2)
Jo Le Couilliar ⁹	N ⁹ , A(Chair) ¹⁰ , R ¹¹	Yes	4 (4)	2 (2)	2 (2)	1 (1)
Heribert Staudinger ¹²	N ¹³	Yes	4 (4)	1 (2)	–	–
Sharon Curran	A ¹⁴ , R(Chair) ¹⁵	Yes	4 (4)	–	2 (2)	1 (1)

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

Figures in brackets represent the total number of meetings (occurring during the year to 31 December 2018 when the director was in office).

¹ By invitation.

² In the capacity of Secretary to the Committee.

³ Until 30 May 2018, when he retired from the Board (not having put himself forward for re-election at the AGM).

⁴ Until 4 February 2019, when she retired from the Board following the transfer to AIM.

⁵ Until 30 May 2018, when she retired as a member of the Nomination Committee.

⁶ Until 30 May 2018, when she stepped down from Chair of the Audit and Risk Committee. She remained a member of the Audit and Risk Committee until 4 February 2019 when she retired from the Board following the transfer to AIM.

⁷ From 30 May 2018, when she was promoted from member to Chair of the Remuneration Committee, until 4 February 2019, when she retired from the Board following the transfer to AIM.

⁸ Until 30 May 2018, when he retired from the Board (not having put himself forward for re-election at the AGM).

⁹ From 30 May 2018, when she was appointed to the Nomination Committee.

¹⁰ From 30 May 2018, when she was appointed as Chair of the Audit and Risk Committee.

¹¹ From 30 May 2018, when she was appointed to the Remuneration Committee.

¹² Until 4 February 2019, when he retired from the Board following the transfer to AIM.

¹³ From 30 May 2018, when he was appointed to the Nomination Committee until 4 February 2019, when he retired from the Board following the transfer to AIM.

¹⁴ From 30 May 2018, when she was appointed to the Audit and Risk Committee.

6) Ensure that between them the directors have the necessary up-to-date experience, skills and capabilities

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 is led by the Chairman. Shortlisted candidates are interviewed by members of the Nomination Committee before a recommendation is made to the Board.

The biographies of the current members of the Board are set out on pages 34 to 35 of this report.

The Board is satisfied that, between the directors, it has an effective and appropriate balance of skills, experience and time to perform its duties.

Advisors

The Board obtains independent assistance and advice from external advisors if deemed necessary. In the current year, the Remuneration Committee appointed MM&K Limited to observe and review the Group's remuneration policy. Further information can be found within the Remuneration Committee report on page 52.

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.

Further information around the Group's diversity can be found within the Corporate social responsibility report on page 26.

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 Group'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.

7) Evaluate Board performance based on clear and relevant objectives, seeking continuous improvement

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 most recent Board evaluation concluded that the Board was operating effectively. Areas highlighted for improvement included greater formalisation of succession planning across the functions, and a review of the remuneration policy. Steps are currently being taken to formally document succession planning. Additionally, MM&K have been appointed as external advisors to the Remuneration Committee to benchmark Board and Senior Management remuneration and review the remuneration policy following the move to AIM. Further information can be found within the Remuneration Committee report on page 52.

The Nomination Committee is responsible for overseeing succession planning requirements, including the identification and assessment of potential Board candidates and making recommendations to the Board for its approval. All continuing directors stand for re-election on an annual basis. External recruitment is currently the most likely source of immediate replacements for any of the Executive Directors.

8) Promote a corporate culture that is based on ethical values and behaviours

The Board aims to lead by example and do what is in the best interests of the Group, its stakeholders and shareholders. The Executive Directors strive to act in a manner which is professional and ethical and has published its ethical policies for all employees to observe and comply with.

9) Maintain governance structures and processes that are fit for purpose and support good decision-making by the Board

Board Committees

The Board has three Committees to which it delegates specific responsibilities; the Audit and Risk Committee; the Nomination Committee; and the Remuneration Committee. 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. 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.

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.

From 1 January 2018 until 30 May 2018, the Committee was comprised of Dr Francesco Granata (Chairman and Chair of the Committee); Ms Lota Zoth and Mr Marvin Samson. On 30 May 2018, Mr Marvin Samson retired from the Board (not having put himself forward for re-election at the AGM) and Ms Lota Zoth retired as a member of the Nomination Committee. Their positions were taken by Ms Jo Le Couilliar and Dr Heribert Staudinger.

On 4 February 2019, Dr Heribert Staudinger retired from the Board following the transfer to AIM.

The Committee is therefore made up of Independent Non-Executive Directors and complies with the requirements of the Code.

Remuneration Committee

The Code advises that an effective Committee should comprise of Non-Executive Directors, all of whom should be independent.

For the period from 1 January 2018 until 30 May 2018, the Committee members were: Mr Marvin Samson (Chair of the Committee); Dr Jean-Jacques Garaud and Ms Lota Zoth. All members are considered to be independent.

Mr Marvin Samson and Dr Jean-Jacques Garaud did not seek re-election at the 2018 AGM, and their positions were taken effective from 30 May 2018 by Ms Sharon Curran and Ms Jo Le Couilliard. On this date, Ms Lota Zoth was promoted to Chair of the Remuneration Committee. All members are considered to be independent.

On 4 February 2019, Ms Lota Zoth retired from the Board following the transfer to AIM. Her position as Chair of the Remuneration Committee was taken effective on this date by Ms Sharon Curran.

As at the date of signing this report, the Committee is made up of two Non-Executive Directors. The Board considers that the size and composition of the Committee is appropriate for the size of the Company.

The Committee is therefore made up of Independent Non-Executive Directors and complies with the requirements of the Code.

Audit and Risk Committee

The Code recommends that the Committee should be made up of Independent Non-Executive Directors, with the size of the Committee being proportionate to the complexity of the company and its business and the risks it faces.

For the period from 1 January 2018 until 30 May 2018, the Committee members were: Ms Lota Zoth (Chair of the Committee); Mr Marvin Samson and Dr Jean-Jacques Garaud. All members are considered to be independent.

Mr Marvin Samson and Dr Jean-Jacques Garaud did not seek re-election at the 2018 AGM, and their positions on the Audit and Risk Committee were taken effective from 30 May 2018 by Ms Jo Le Couilliard and Ms Sharon Curran, who are both Independent Non-Executive Directors.

Ms Lota Zoth was Chair of the Audit and Risk Committee from 1 January 2018 to 30 May 2018, at which point Jo Le Couilliard was appointed as Chair.

Ms Lota Zoth remained a member of the Audit and Risk Committee until 4 February 2019, when she retired from the Board following the transfer to AIM.

The Committee is therefore made up of Independent Non-Executive Directors and complies with the recommendations of the Code.

10) Communicate how the Company is governed and is performing by maintaining a dialogue with shareholders and other relevant stakeholders

The Board believes that corporate governance is more than just a set of guidelines; rather it is a framework which underpins the core values for running the business in which we all believe. The Board has formal responsibilities and agendas and three sub-committees; in addition, strong informal relations are maintained between Executive and Non-Executive Directors. Non-Executive Directors meet with other senior managers and give advice and assistance between meetings. Board dinners are held from time to time to provide opportunities for broader discussions.

The Chief Executive Officer and Chief Financial Officer regularly meet with investors after results announcements have been made and at other shareholder participant events. They also meet regularly with the Group's Nomad/broker and discuss any shareholder feedback – the Board is briefed accordingly.

All directors attend the AGM and engage both formally and informally with shareholders during and after the meeting. The results of voting at the AGM are communicated to shareholders via RNS and on the Group's website.

The Chief Executive Officer and the Chief Financial Officer make presentations to institutional shareholders and analysts each year immediately following the release of interim and full year results. The slides used for such presentations are made available on the Group's website under the financial reports section.

Dear shareholders,

On behalf of the Board I am pleased to present Circassia's Audit and Risk Committee report for the year ended 31 December 2018.

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

Jo Le Couilliard
Chair of the Audit and Risk Committee

1 May 2019



Jo Le Couilliard
Chair of the Audit and Risk Committee

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 where appropriate challenges the views of the external auditors. If necessary, the Committee 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 after taking full commercial control of Tudorza[®], the Group also promotes this 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; evaluating the need for an internal audit function; 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:

Member	Date of appointment	Meetings attended (held)
L S Zoth (resigned 4 February 2019)	27 February 2015	3 (3)
J-J Garaud (resigned 30 May 2018)	21 February 2014	0 (1)
M Samson (resigned 30 May 2018)	26 May 2017	1 (1)
J Le Couilliard (Chair of the Committee)	30 May 2018	2 (2)
S Curran	30 May 2018	2 (2)

Mr Marvin Samson and Dr Jean-Jacques Garaud did not seek re-election at the 2018 AGM, and their positions on the Audit and Risk Committee were taken effective from 30 May 2018 by Ms Jo Le Couilliard and Ms Sharon Curran, who are both Independent Non-Executive Directors.

Ms Lota Zoth was Chair of the Audit and Risk Committee from 1 January 2018 to 30 May 2018, at which point Ms Jo Le Couilliard was appointed as Chair.

Ms Lota Zoth remained a member of the Audit and Risk Committee until 4 February 2019, when she retired from the Board following the transfer to AIM.

The Code provides that all members of the Audit and Risk Committee should be Independent Non-Executive Directors. The Board considers that all members are independent and therefore this requirement has been satisfied.

The biographies of the current members of the Audit and Risk Committee are set out on pages 34 to 35 of this report.

The Company Secretary acts as the Secretary to the Committee. The Chief Executive Officer attends Committee meetings at the invitation of the Chair. The Committee meet with the external auditors at least once a year in the absence of management.

Corporate governance

Audit and Risk Committee report continued

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:

Area of review	Activities undertaken
Financial reporting	<p>Review of the interim and full year results.</p> <p>Consideration of whether the Annual Report is fair, balanced, and understandable.</p> <p>Review of the external auditors' reports for the full year results.</p> <p>Review of significant accounting judgements and estimates (see overleaf).</p> <p>Review of anticipated changes in accounting standards and their impact.</p> <p>Review of the going concern basis of preparation of the financial statements.</p>
External auditor	<p>Review of external auditors' independence.</p> <p>Review of auditors' compliance with ethical and professional guidance on audit partner rotation.</p> <p>Assess effectiveness of audit process.</p> <p>Recommend re-appointment of auditors.</p>
Risk management and internal control	<p>Review of risk, risk management systems, internal controls, and whistleblowing policy.</p> <p>Review of compliance activities.</p>
Governance	<p>Review of the Committee's terms of reference.</p>

Financial reporting

During the year to 31 December 2018 and up to the date of this report, the Committee reviewed the interim report and accounts for the period ended 30 June 2018 and the preliminary announcement and Annual Report and Accounts for the year ended 31 December 2018.

Significant accounting matters

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

- Accounting for the Tudorza® option exercise
- Goodwill and intangibles impairment assessment
- Investments in subsidiaries impairment assessment
- Going concern and cash flow

Accounting for the Tudorza® option exercise

Following the exercise of the Tudorza® option, a Purchase Price Allocation exercise was performed focusing on the following key accounting areas:

- Determination of the consideration

In the previous accounting period, it was determined that under the collaboration agreement the maximum total consideration payable to AstraZeneca was \$230 million plus future sales-based royalties. For the purposes of IFRS 3, the total consideration included in the valuation consisted of \$50 million for shares issued to AstraZeneca, \$100 million deferred non-contingent consideration and the fair value of royalties payable to AstraZeneca. It did not include the amount (up to \$80 million) that would be paid to exercise the Tudorza® option, which was to 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 proportionately between both products. This resulted in the consideration allocated to Tudorza® being recognised as a prepayment for business combination.

Once the Tudorza® option was exercised, additional consideration of \$25 million became payable of the maximum \$80 million. This amount was added to the prepayment for business combination, giving the total consideration for the Tudorza® option.

- Initial valuation and subsequent measurement of Tudorza® CMP

The Excess Earnings Method approach was determined to be the most appropriate methodology to use for the valuation of the Currently Marketed Product (CMP). The CMP asset was valued at \$122.9 million with a remaining useful life of 13 years. At 31 December 2018, management performed an impairment review of the CMP, using a Net Present Value (NPV) methodology and concluded there was sufficient headroom in the AstraZeneca cash generating unit ("CGU") to not warrant an impairment.

- Initial valuation and subsequent measurement of royalties

As part of the transaction, Circassia will pay royalties to third-parties on future sales of Tudorza® in the United States. Under IFRS 3, these royalties have been classified as additional consideration and initially recognised as CMP asset with a corresponding contingent liability. The CMP 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 statement of comprehensive income. The value of the CMP 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 2018. A CMP asset and corresponding contingent liability of \$3.6 million was recognised on the statement of financial position at the date of acquisition.

Goodwill and intangibles impairment assessment

In line with IAS 36 Impairment of Assets, the carrying value of each CGU including the allocated goodwill was tested for impairment. Impairment assessments were performed on each CGU (NIOX[®], Respiratory and AstraZeneca) and at an individual intangible asset level. Management concluded that impairment was required to the Respiratory CGU due to the inability to find an out-licensing partner for the product candidates in the respiratory portfolio. This resulted in an impairment of £4.4 million to goodwill, and £70.6 million to intangible assets. See notes 15 and 16 for further details.

Investments in subsidiaries impairment assessment

In line with IAS 36 Impairment of Assets, the carrying value of each investment held by Circassia Pharmaceuticals plc in its subsidiaries was tested for impairment. Management concluded that impairment was required to the investments held in Circassia Limited, Prosonix Limited, Circassia Pharmaceuticals Inc and Circassia AB. This is related to the impairment of the in-house respiratory portfolio, and the halting of investment in the allergy programmes in the prior year. This resulted in an impairment of £210.3 million. See note 17 for further details.

Going concern and cash flow

Following a review of Group cash flows for the next 12 months, 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 1 May 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 1 May 2020.

The Group's annual budget was approved by the Board at its December 2018 meeting and the 10 year plan was reviewed at the same meeting.

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.

The directors note that as at 31 December 2018, the Group is in a net current liability position. This is mainly due to the \$125 million consideration payable to AstraZeneca. Payment of these amounts will be addressed by a loan provided by AstraZeneca.

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.

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 Corruption 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 Committee deemed the internal control framework adequate to mitigate financial risks. The Board accepted this recommendation. This decision will be kept under review.

External auditors

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 2018 or up to the date of this report.

At the end of the audit for the year ended 31 December 2018, the Committee formally evaluated the performance of PricewaterhouseCoopers LLP (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 the 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 Group's external auditor, PwC, is engaged to express its opinion on the Group and the Company's financial statements.

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 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.

The total fees paid to the auditor are shown in note 9 of the financial statements. PwC did not undertake any non-audit services for the Group in the course of the year to 31 December 2018.

In summary, the Committee confirms that the Group has received an independent audit service in the year to 31 December 2018 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 ending 31 December 2014 and is due for rotation after the completion of the audit for this 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 AGM.

Committee evaluation

An internal review of the effectiveness of the Committee was carried out in December 2018 as part of the process of evaluating Board effectiveness. The result of the evaluation concluded that the Committee was performing effectively.

Jo Le Couillard
Chair of the Audit and Risk Committee

1 May 2019

Dear shareholders,

On behalf of the Board, I am pleased to present Circassia's Nomination Committee report for the year ended 31 December 2018. 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.

During 2018, two of our Non-Executive Directors, Dr Jean-Jacques Garaud and Mr Marvin Samson, decided not to stand for re-election. We are very grateful to Jean-Jacques and Marvin for their significant contributions over the years. Subsequently the Committee considered and made recommendations to the Board regarding the appointment of Ms Sharon Curran, Ms Jo Le Couilliard, and Dr Heribert Staudinger as Independent Non-Executive Directors and were appointed to the Board on 30 May 2018.

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

Dr Francesco Granata
Chair of the Nomination Committee

1 May 2019

Responsibilities

The Committee reviews 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 Risk and Remuneration Committees.

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

Membership

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

Member	Date appointed	Meetings attended (held)
Dr Francesco Granata (Chair of the Committee)	21 February 2014	2 (2)
Mr Marvin Samson (resigned 30 May 2018)	26 May 2017	0 (0)
Ms Lota Zoth (resigned 30 May 2018) ¹	26 May 2017	0 (0)
Dr Heribert Staudinger (resigned 4 February 2019)	30 May 2018	1 (2)
Ms Jo Le Couilliard	30 May 2018	2 (2)

¹ Ms Zoth resigned from the Nomination Committee only on this date and remained a director of the Company until 4 February 2019, when she retired from the Board following the transfer to AIM.

Dr Heribert Staudinger resigned from the Nomination Committee and the Board on 4 February 2019, following the transfer to AIM.

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.

Dear shareholders,

Introduction

I am pleased to present my first Directors' Remuneration Report and the first for Circassia following its transition from the Main Market to AIM, which was approved by shareholders on 4 January 2019.

It has been an exciting year for Circassia. The Company has taken a number of positive strides towards achieving our vision, strategy, ambitions and aspirations for the business. This was predominantly R&D focused but is now a strongly focused commercial and sales driven operation. The Group continued to strengthen its product portfolio with the FDA approval of Duaklir[®] granted in March 2019, acquiring the full US commercial rights to Tudorza[®], along with the acquisition of the exclusive commercialisation rights to AirNOvent from AIT Therapeutics Inc in early 2019. Circassia's global presence is also expanding, launching a new NIOX[®] direct sales team in China and expanding our network of partners globally.

Remuneration policy review

Last November, in light of Circassia's change of business strategy and impending migration to AIM, the Committee appointed independent remuneration consultants, MM&K Limited to conduct a review of the remuneration policy and advise the Committee. MM&K provides no other services to the Group.

As a result, we are proposing to make changes to the previously approved policy, whilst also retaining some elements of it. The Committee's objective is to ensure that the remuneration policy is fit for purpose throughout the Company and consistent with its current vision, strategy, risk appetite, culture and philosophy. Taking account of the significant changes which have taken place in the business, we also wanted to minimise structural change and disruption.

The key policy changes for Executive Directors are summarised below:

	New policy	Reason for change
Annual bonus	<ul style="list-style-type: none"> – Introduction of “Threshold”; “Target” and “Over-performance” yardsticks. – 25% payable at Threshold; 50 % at Target. – 100% payable only for over-performance against targets set. – Fewer targets in score-card of corporate/team and individual objectives. – Deferral not related to personal shareholding. – Mandatory deferral of 50 % for two years. 	<p>We believe the changes make for a clear, simple bonus policy which can be rolled-out across the whole business, is focused on strategic KPIs, and better reflects and recognises the respective contributions of individual employees.</p>
Long-term incentive	<ul style="list-style-type: none"> – Maximum award level capped at 100% of salary in 2019. – Revised performance targets, based on share price and sales revenue (weighted equally) for 2019 awards. – Technical changes to PSP rules to reflect the Company's status as an AIM constituent (will be the subject of a separate resolution at the AGM). – Awards now have a vesting period of 3 years and a holding period of 2 years other than for the sale of shares to satisfy any tax liability created on exercise. 	<p>The Committee believes that, following these changes, the PSP will provide an appropriate long-term incentive for an AIM constituent. Rule changes will enable the Committee to make awards to the wider workforce and, in the Committee's view, share price and sales revenue are currently the two most important measures of the Company's success in the medium to long-term. The introduction of a 2 year holding period further strengthens the link between compensation and shareholder interests.</p>
Pensions	<ul style="list-style-type: none"> – Company contribution rate reduced to 10 % of salary. 	<p>This contribution rate is consistent with practice among AIM constituents. Following an increase in pension contribution rates for Senior Management Team (SMT) members, contribution rates are now aligned across the whole SMT.</p>

Other important decisions taken by the Committee

The Committee has decided not to increase the Chief Executive's base salary for 2019 and to manage until it reaches market median level. Other Executive Directors' base salaries have been increased by 3% in line with the general level of increase across the business.

Having taken account of the performance levels achieved in relation to corporate targets set for 2018, the Committee has decided to make bonus awards of between 40% and 48% of salary to the Executive Directors.

Philosophy and purpose

Circassia's remuneration policy is designed to attract, retain and motivate the quality of directors and employees required to develop and implement its business strategy and run a successful and sustainable commercially oriented business for the benefit of all stakeholders. Incentives have been designed to reward growth, take account of risks and, through equity participation, align employee rewards with shareholder returns.

Links to culture and strategy

The management culture is to be supportive and focused on successful outcomes. Business strategy is to achieve successful outcomes by completing the transformation of Circassia from a business focused on R&D to a sustainable commercial operation. Incentive remuneration is linked to strategic KPIs by which the Company measures its progress towards the successful delivery of strategy. By linking the vesting of PSP awards to share price and sales growth, long-term incentives align management, employees and shareholders in terms of both risks and rewards.

Application of policy to the wider workforce

This policy flows throughout the business and embraces the wider workforce. Annual incentive programmes are co-ordinated, insofar as all participants are eligible to participate in an annual bonus plan linked to corporate and/or team and individual targets, depending on their level and the focus of their contribution to the business. Substantially all employees will have an opportunity to acquire an equity interest, which provides a sense of ownership and a share in the success of the business as a whole.

Engagement with shareholders

We have engaged with and consulted our principal shareholders, who listened carefully and offered constructive responses to our proposed remuneration policy for 2019 onwards. I am grateful to those with whom we have engaged for their support.

The Committee wishes to continue its shareholder engagement programme and will consult with our principal shareholders on future material changes in policy.

Basis of preparation of this report

As a constituent of AIM, Circassia is not required to prepare a Directors' Remuneration Report in accordance with the Large and Medium-sized Companies and Groups (Accounts and Reports) (Amendment) Regulations 2013. In accordance with AIM Rule 26, Circassia has adopted the Quoted Companies Alliance (QCA) Corporate governance Code for Small and Mid-Size Quoted Companies. A statement of compliance with the principles of the QCA code is available on the Company's website, as required by Rule 26. The UK Corporate Governance Code applied to the Company up until 4 February 2019.

The Board is committed to maintaining high corporate governance standards and in preparing this report, the Committee has taken into account the principles of the QCA Code and of the QCA Remuneration Committee Guide for Small and Mid-Size Quoted Companies.

The Committee operates within its terms of reference which are reviewed from time to time by the Board and are available on the Company's website.

2019 AGM

This Directors' remuneration policy will be the subject of a binding vote at the AGM on 7 June 2019. Additionally, the Annual Report on Directors' Remuneration will be the subject of an advisory vote.

Shareholders will also be asked to vote on a separate ordinary resolution to approve proposed technical amendments to the PSP rules to bring them up to date and to facilitate share awards to the wider workforce. The proposed amendments are described in the AGM notice.

Sharon Curran

Chair of the Remuneration Committee

1 May 2019

Annual Report on Directors' Remuneration

This section describes remuneration outcomes for Executive Directors for the year ended 31 December 2018, in accordance with the remuneration policy applicable to that year. The Company's revised future remuneration policy is described in the following section of this report.

Remuneration Committee membership during the year

The members of the Remuneration Committee, their dates of appointment and the number of meetings attended during the year are as follows:

Member	Date of appointment	Meetings attended (held)
Mr Marvin Samson (resigned 30 May 2018) ¹	26 May 2017	1 (2)
Ms Lota Zoth (resigned 4 February 2019)	27 February 2015	3 (3)
Dr Jean-Jacques Garaud (resigned 30 May 2018)	21 February 2014	2 (2)
Ms Sharon Curran ²	30 May 2018	1 (1)
Ms Jo Le Couilliar	30 May 2018	1 (1)

¹ Mr Marvin Samson was Chair of the Remuneration Committee until 30 May 2018, when he was replaced by Ms Lota Zoth.

² Ms Sharon Curran replaced Ms Lota Zoth as Chair of the Remuneration Committee on 4 February 2019. Ms Lota Zoth remained a member of the Remuneration Committee until she resigned from the Board.

Single total figure of remuneration table for the year ended 31 December 2018 (Audited)

Director	Salaries and fees £'000	Pension £'000	Benefits £'000	Cash bonus £'000	LTIP/PSP ¹ £'000	Total £'000
Executive Directors						
Steven Harris	422	63	2	169	13	669
Julien Cotta	264	40	2	121	7	434
Rod Hafner	284	43	2	122	13	464
Non-Executive Directors						
Francesco Granata	151	–	–	–	–	151
Russell Cummings	47	–	–	–	–	47
Jean-Jacques Garaud	27	–	–	–	–	27
Lota Zoth	71	–	–	–	–	71
Marvin Samson	29	–	–	–	–	29
Jo Le Couilliar	55	–	–	–	–	55
Sharon Curran	49	–	–	–	–	49
Heribert Staudinger	46	–	–	–	–	46
Total	1,445	146	6	412	33	2,042

Single total figure of remuneration table for the year ended 31 December 2017

Director	Salaries and fees £'000	Pension £'000	Benefits £'000	Cash bonus £'000	LTIP/PSP ¹ £'000	Total £'000
Executive Directors						
Steven Harris	410	62	1	307	45	825
Julien Cotta	257	38	1	193	23	513
Rod Hafner	278	42	1	209	36	566
Non-Executive Directors						
Francesco Granata	147	–	–	–	–	147
Tim Corn	26	–	–	–	–	26
Russell Cummings	46	–	–	–	–	46
Jean-Jacques Garaud	64	–	–	–	–	64
Lota Zoth	65	–	–	–	–	65
Marvin Samson	63	–	–	–	–	63
Charles Swingland	19	–	–	–	–	19
Total	1,375	142	4	709	104	2,334

¹ The amount shown relates to the gain, being the market value on the vesting date less the exercise price in respect of awards which vested during the relevant year.

Annual bonus for the year to 31 December 2018

For the year ended 31 December 2018, bonuses up to a maximum of 100% of base salary for Executive Directors 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 Executive Director 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.

Objective 2018	Achievement	% Achievable			% Achieved		
		Steven Harris	Rod Hafner	Julien Cotta	Steven Harris	Rod Hafner	Julien Cotta
1. Commercial		35%	20%	30%	0%	0%	0%
– Global sales growth	– Global sales growth – Achieved						
– Gross margin	– Gross margin – Achieved						
– Cash	– Cash – Achieved						
– Regional NIOX [®] sales growth	– Regional NIOX [®] sales growth – Not achieved						
– Other commercial targets, including:	– Other commercial targets – Not achieved						
– Pricing strategy							
– Market access							
– US field force HCP targeting							
2. Progress R&D programmes to achieve the following key milestones		25%	40%	25%	12.5%	20%	12.5%
2a. File Duaklir [®] NDA H1 2018	Achieved						
2b. File Tudorza [®] sNDA Q3 2018	Achieved						
2c. Further development of in-house respiratory programmes	No further development following decision to cease further investment.						
2d. Support transfer to Adiga if option is exercised	Achieved						
3. R&D – To expand NIOX[®] indications	Achieved	10%	15%	5%	0%	0%	0%
4. Acquisitions	Not achieved	20%	15%	20%	20%	15%	20%
Board approval to pursue at least one acquisition/licensing opportunities; target source and process weightings applied.							

Corporate governance

Remuneration Committee report continued

Objective 2018	Achievement	% Achievable			% Achieved		
		Steven Harris	Rod Hafner	Julien Cotta	Steven Harris	Rod Hafner	Julien Cotta
5. Other functions – People, Quality and Compliance		10%	10%	20%	7.5%	7.5%	15%
Alignment, recruitment and retention of the required workforce for timely and effective delivery of business objectives.	100% complete R&D headcount reduced following cessation of in-house respiratory programme. US field force right-sizing complete. Recruitment of ~ 80 heads in China complete.						
Establish systems and processes to support current products and organisation.	100% complete Systems and processes maintained and no cyber-attacks.						
Implement electronic ordering, tracking and bar-coding	0% complete Subject to implementation of ERP system.						
Selection and implementation of ERP system.	50% complete System selected, implementation in progress. Go-live expected Q2 2019.						
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.						
Total		100%	100%	100%	40%	42.5%	47.5%

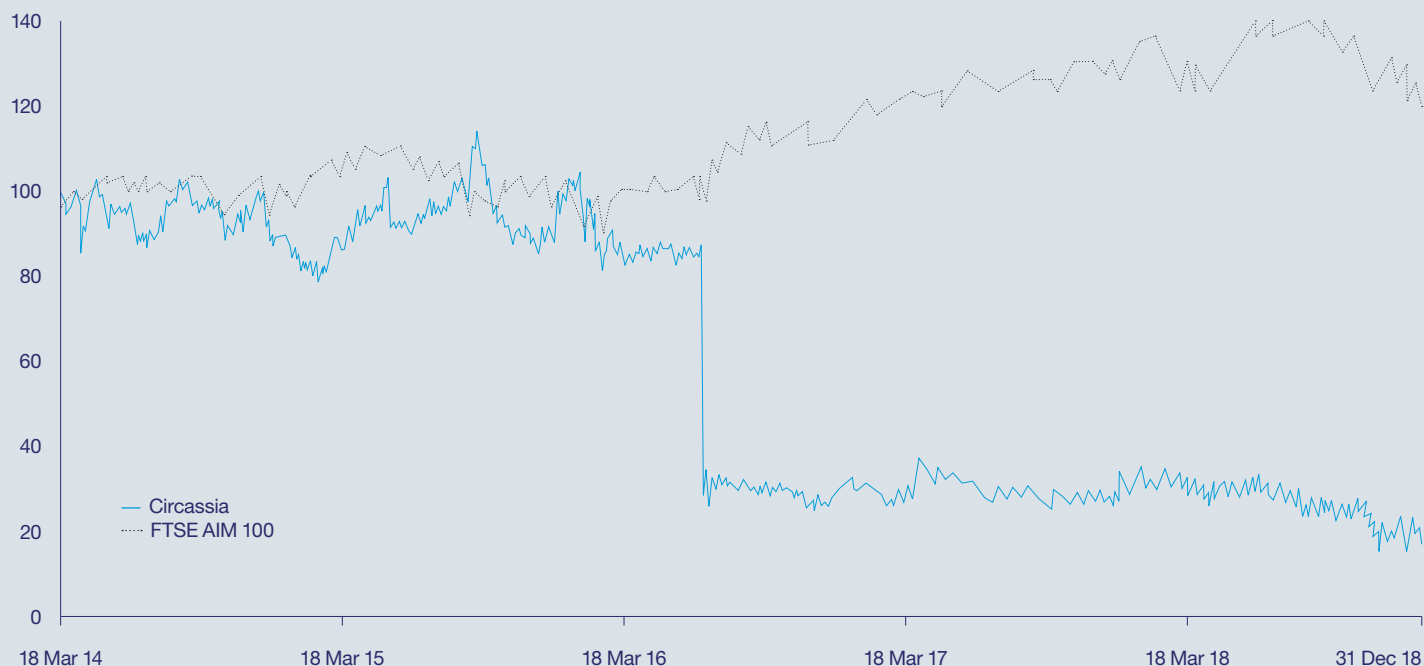
Deferred share bonus awards are structured as conditional awards over shares which vest after three years. The level of deferral is linked to the achievement of the Company's shareholding guidelines as set out in the policy report.

Payments to past directors

There were no payments to past directors and no payments of compensation for loss of office.

TSR performance

The performance of the Company's ordinary shares compared with the FTSE AIM 100 (the "Index") for the period from its IPO on 18 March 2014 up to 31 December 2018 is shown in the graph below:



Historical CEO remuneration

	2018	2017	2016	2015	2014
Total remuneration (£'000)	669	825	458	831	1,528
Bonus awarded	40%	75%	Nil	100%	93%
LTIP vesting	20%	21%	n/a	n/a	100%

Percentage increase in remuneration of the CEO

The CEO's salary increased by 3% between 31 December 2017 and 31 December 2018. This is in line with the average percentage increase per employee.

Relative importance of expenditure on pay (audited)

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.

	2018 £m	2017 £m
Overall expenditure on pay	49.0	41.1
Dividend plus share buyback	Nil	Nil

Executive Directors' share options granted in 2018

Directors	Type of award	Basis of award	Share price at grant	No. of shares over which award was granted	% of shares granted that vest at threshold performance	Face value of shares over which award was made (£'000)	Vesting period
Steven Harris	Nominal cost option	90.6% of salary	£0.90	425,000	12.50%	383	3 years from date of grant
Julien Cotta	Nominal cost option	85.2% of salary	£0.90	250,000	12.50%	225	3 years from date of grant
Rod Hafner	Nominal cost option	78.4% of salary	£0.90	250,000	12.50%	225	3 years from date of grant

No directors exercised share options in the year to 31 December 2018.

Statement of directors' share interests and shareholding requirements

The Executive Directors are required to hold shares worth 200% of salary.

	Shares beneficially owned as at 31 December 2018	Value of owned shares as a percentage of salary as at 31 December 2018	Shareholding requirement met?
Executive Directors			
S Harris	5,959,052	678%	Yes
J Cotta	46,875	9%	No
R Hafner	900,544	151%	No
Non-Executive Directors			
F Granata	312,500	n/a	n/a

Shareholder voting at the Annual General Meeting on 30 May 2018

The Annual Report on Remuneration was approved by Shareholders at last year's AGM held on 30 May 2018 with the following votes cast for and against.

Voting results at 2018 AGM	For (%)	Against (%)	Withheld (votes)
To approve the Annual Report on Remuneration	79.49	20.51	4,455,570

Following a 79.5% vote to approve the Annual Report on Remuneration at the AGM held on 30 May 2018, the Directors appointed MM&K Limited to observe and review the Group's remuneration policy in line with comparable AIM listed entities and make recommendations regarding the remuneration structure for Executive and Non-Executive Directors, along with Key Management.

Shareholder voting at the Annual General Meeting on 26 May 2017

The Annual Report on Remuneration was approved by Shareholders at the 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

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

Statement of directors' shareholding and share interests (audited)

Plan	Date of grant	Awards granted, and options held as at 1 January 2018	Awards and options granted, exercised, lapsed, or cancelled during year	Awards and options held at 31 December 2018 and at the date of this report
Executive Directors				
S Harris				
2014 PSP	12-Mar-14	52,736	–	52,736
2015 PSP	26-Feb-15	214,444	(171,555)	42,889
2016 PSP	19-May-16	212,946	–	212,946
2017 PSP	17-May-17	425,000	–	425,000
2018 PSP	17-May-18	–	425,000	425,000
Total		905,126	253,445	1,158,571
J Cotta				
2013 Unapproved Scheme	22-Oct-13	149,250	–	149,250
2014 PSP	12-Mar-14	27,536	–	27,536
2015 PSP	26-Feb-15	112,037	(89,629)	22,408
2016 PSP	19-May-16	111,272	–	111,272
2017 PSP	17-May-17	250,000	–	250,000
2018 PSP	17-May-18	–	250,000	250,000
Total		650,095	160,371	810,466
R Hafner				
2014 PSP	12-Mar-14	42,998	–	42,998
2015 PSP	26-Feb-15	121,528	(97,222)	24,306
2016 PSP	19-May-16	120,703	–	120,703
2017 PSP	17-May-17	250,000	–	250,000
2018 PSP	17-May-18	–	250,000	250,000
Total		535,229	152,778	688,007

Vesting during year	Vested as at year end	Unvested as at year end	Exercise price (p)	Date from which first exercisable	Expiry date
-	52,736	-	nil	12-Mar-17	11-Mar-24
42,889	42,889	-	0.08	26-Feb-18	25-Feb-25
-	-	212,946	0.08	19-May-19	18-May-26
-	-	425,000	0.08	17-May-20	16-May-27
-	-	425,000	0.08	17-May-21	16-May-28
42,889	95,625	1,062,946			
-	149,250	-	242	22-Oct-16	21-Oct-23
-	27,536	-	nil	12-Mar-17	11-Mar-24
22,408	22,408	-	0.08	26-Feb-18	25-Feb-25
-	-	111,272	0.08	19-May-19	18-May-26
-	-	250,000	0.08	17-May-20	16-May-27
-	-	250,000	0.08	17-May-21	16-May-28
22,408	199,194	611,272			
-	42,998	-	nil	12-Mar-17	11-Mar-24
24,306	24,306	-	0.08	26-Feb-18	25-Feb-25
-	-	120,703	0.08	19-May-19	18-May-26
-	-	250,000	0.08	17-May-20	16-May-27
-	-	250,000	0.08	17-May-21	16-May-28
24,306	67,304	620,703			

Future policy table

Introduction

This section on future directors' remuneration policy will be the subject of a binding vote at the AGM on 7 June 2019.

Remuneration policy table

Remuneration element	Purpose, link to strategy and operation	Opportunity and performance metrics	Remuneration Committee discretion
Salary	<p>Essential to attract and retain key executives.</p> <p>Reviewed annually based on:</p> <ul style="list-style-type: none"> — role, experience and individual performance; — pay awards elsewhere in the Group; — external market; and — general economic environment. 	<p>Salary is benchmarked to the relevant market median.</p> <p>Normally, salary increases for Executive Directors will be generally in line with those of the wider workforce.</p>	<p>The Committee will also consider pay and employment conditions in the wider workforce when determining Executive Directors' salaries.</p>
Benefits	<p>Helps attract and retain key executives.</p> <p>For Executive Directors this includes private medical insurance and life insurance.</p> <p>Other employment benefits may be provided from time to time on similar terms as those of other employees.</p> <p>The Committee may provide additional benefits, where appropriate in the individual's particular circumstances (for example relocation costs).</p>	<p>There is no formal maximum limit as the value of insured benefits will vary from year to year based on the cost from third-party providers.</p>	<p>If an Executive Director is based outside the UK additional benefits and assistance with relocation may be provided which reflect local market norms.</p>
Pensions	<p>Helps attract and retain key executives.</p> <p>Executive Directors are eligible to join a defined contribution pension scheme.</p>	<p>Up to 10% of base salary (may be provided as a cash allowance).</p> <p>Pension allowances are not included in base salary for annual bonus or other executive rewards.</p>	
Annual Bonus	<p>Rewards achievement of annual key performance indicators.</p> <p>"Threshold", "Target" and "Over-performance" achievement levels are designed to encourage above-target growth.</p>	<p>Up to 100% of salary; 25% of the maximum is payable for Threshold performance and 50% at Target.</p> <p>Targets and weightings are set annually; performance is measured over a single year.</p> <p>Bonus awards are determined after the year-end based on achievement against targets.</p> <p>50% of any award is deferred for two years and paid in shares!</p> <p>Malus and clawback provisions apply.</p>	<p>The Remuneration Committee has discretion to make adjustments upwards and downwards to ensure bonus awards are consistent with the underlying performance of the business.</p>

Remuneration element	Purpose, link to strategy and operation	Opportunity and performance metrics	Remuneration Committee discretion
LTIP (Performance Share Plan)¹	<p>Aligns the interests of management and shareholders and encourages retention.</p> <p>Conditional awards or options may be granted annually.</p> <p>Subject to performance against strategic KPIs, awards vest after a minimum period of three years and have a holding period of two years.</p>	<p>Up to 150% of salary, however capped at 100% in 2019.</p> <p>The first awards will vest subject to share price and sales revenues targets, which are weighted equally.</p> <p>Malus and clawback provisions apply.</p>	<p>The Committee may make an award of up to 300% of salary in exceptional circumstances (eg if necessary to recruit an additional Executive Director). The Committee has discretion to make adjustments upwards and downwards to ensure the value of vested awards is consistent with the underlying performance of the business.</p>

¹ Deferred bonus will be awarded in the form of conditional share awards or options to acquire shares in the Company. A resolution to approve technical amendments to the rules of the PSP to facilitate this, provide the flexibility to make share awards to the wider workforce and to bring the rules up to date will be put to shareholders at the AGM on 7 June 2019.

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.

Remuneration scenarios for Executive Directors based on current policy

The charts illustrate remuneration for the current Executive Directors in 2019 for "Fixed", "Expected" and "Maximum" scenarios.

The illustrations are based on the following assumptions:

- The Fixed scenarios show the fixed level of remuneration, assuming there is no performance-related pay;
- The Expected scenarios illustrate the amounts receivable if performance is in line with expectations. Bonus awards are 50% of maximum bonus opportunity. PSP awards are 50% of maximum opportunity; and
- The Maximum scenarios illustrate the levels of remuneration which would be payable if maximum bonus awards (100% of base salary) and maximum PSP awards (100% of base salary) are made.

As no awards will be made until after the AGM, it is not feasible to estimate the effects of future share price growth in this report.

Executive Directors' recruitment policy

Remuneration packages for new Executive Directors are determined by the Remuneration Committee and designed in accordance with the approved remuneration policy.

Terms of the Executive Directors' service contracts

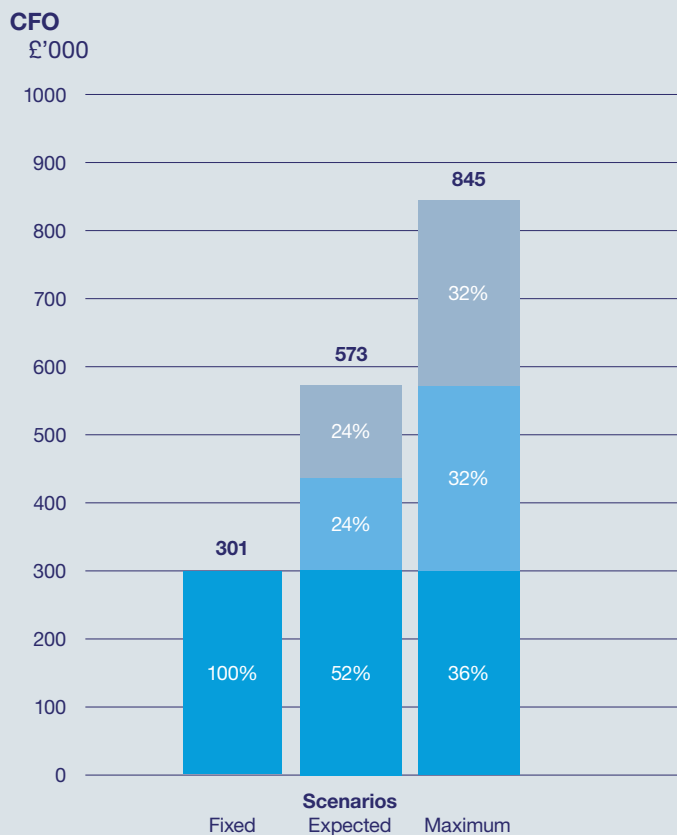
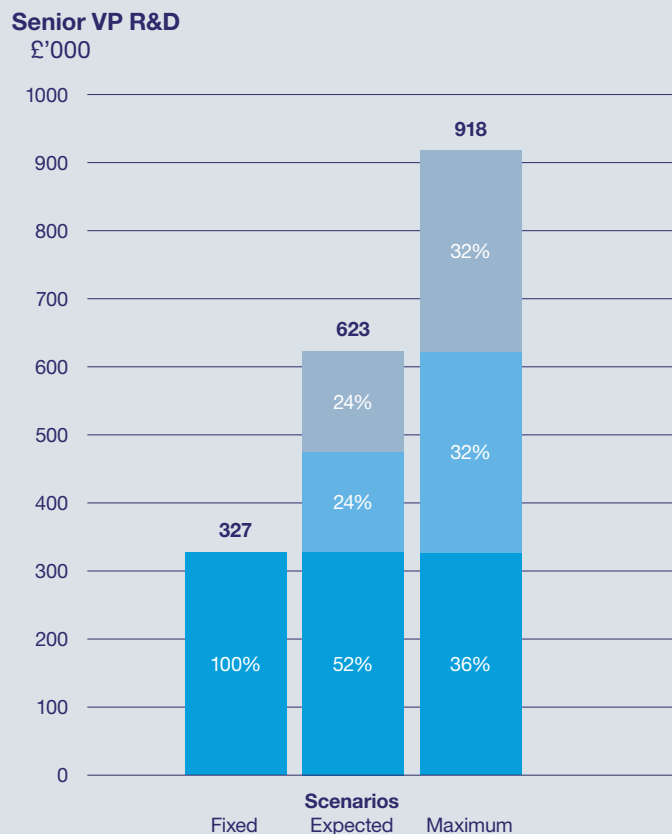
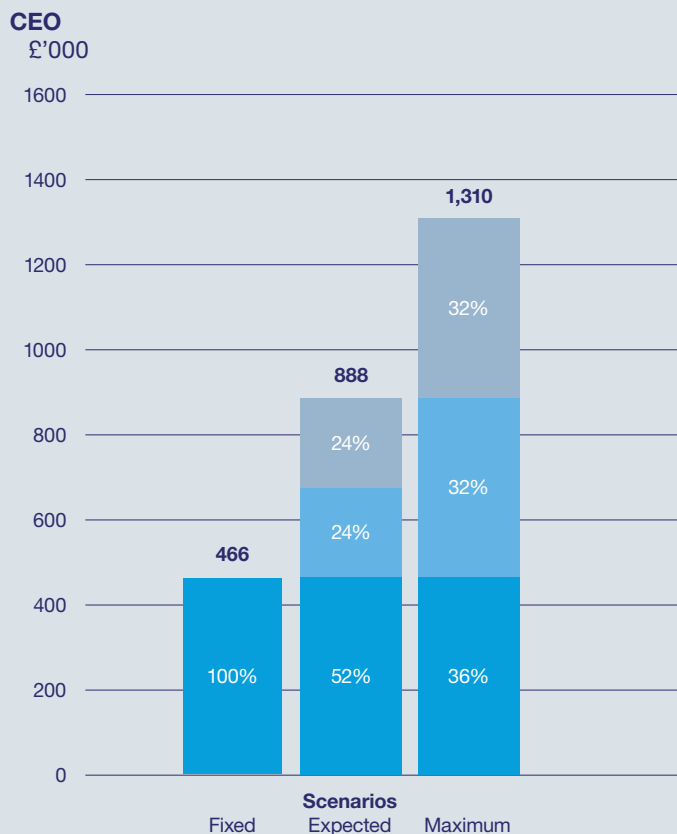
Executive Directors are engaged on rolling service contracts, which provide for 12 months' written notice of termination from either the individual or the Company.

Non-Executive Directors' letter of appointment

Non-Executive Directors are engaged by letter of appointment terminable on three month's written notice from either the individual or the Company.

Termination policy

Any compensation payment made to an Executive Director for termination of employment will be determined with reference to the terms of the individual's service agreement and the rules of any incentive plan in which the individual is a participant.



- Fixed
- Annual bonus
- Long-term variable remuneration

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 fees	To attract and retain a high calibre individual with the requisite experience and knowledge.	<p>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 fees	To attract and retain high calibre individuals with the requisite experience and knowledge.	<p>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>

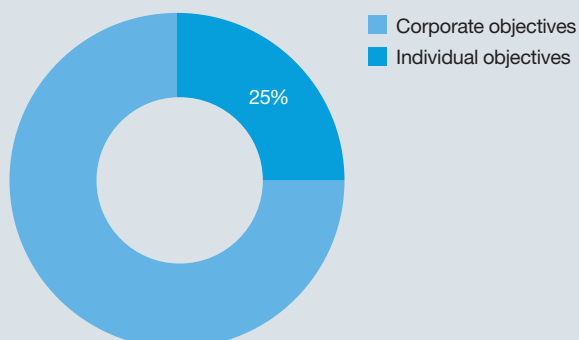
Implementation of the future remuneration policy in 2019

Base salaries and benefits

There will be no change to the CEO's salary. The salaries of the other Executive Directors will be increased by 3% in line with increases to the wider workforce.

Annual bonus – summary of KPIs for 2019

2019 Bonus Structure



2019 Corporate and Individual KPIs

2019 corporate performance measures (75% of total potential award) are:

KPI	% of corporate element of bonus
Sales revenue	50%
Year-end cash	25%
EBITDA	25%

Individual performance measures (25% of total potential award) are specific to each role. Additional details, including achievement against targets will be disclosed in next year's report.

LTIP (PSP)

Awards may be made annually; the maximum award level for all Executive Directors in 2019 is 100% of base salary. The first awards will be made following the 2019 AGM. These awards will have a three year vesting period, dependent on growth in share price and sales revenue followed by an additional two year holding period thereafter.

This Directors' Remuneration Report was approved by the Board on 1 May 2019 and signed on its behalf by:

Sharon Curran
Chair of the Remuneration Committee

1 May 2019

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 2018.

Information included in Strategic report

The Company's Strategic report is on pages 1 to 33 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	12 to 19
Research and development	12 to 19
Employee involvement	26
Disclosures concerning greenhouse gas emissions	27
Events occurring after the reporting date (note 36)	123

Corporate governance statement

The information that fulfils the requirements of the Corporate governance statement can be found in the Corporate governance report on pages 36 to 43 and the Strategic report on pages 10 to 33 (and is incorporated into this Directors' report by reference).

Results and dividend

The results for the year and the financial position as at 31 December 2018 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 2018 (2017: £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 Dr Jean-Jacques Garaud and Mr Marvin Samson who left the Board on 30 May 2018; Ms Sharon Curran, Ms Jo Le Couilliard, and Dr Heribert Staudinger, who 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. In accordance with the Quoted Companies Alliance Code (the "Code"), all directors of the Company will stand for re-election on an annual basis. Dr Heribert Staudinger and Ms Lota Zoth retired from the Board following the transfer to AIM on 4 February 2019.

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 1 January 2018 the Company had 333,466,262 ordinary shares in issue.

The share capital of the Company increased by 23,725,800 ordinary shares on 18 July 2018 as a result of shares issued to AstraZeneca such that AstraZeneca's holding increased from 14.2% to 19.9%. The share capital of the Company increased by a further 94,372 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. No shares were acquired by the Employee Benefit Trust during the year (2017: 373,299), 63,672 were transferred out (2017: 32,157) and the balance of shares held at 31 December 2018 was therefore 544,351 (2017: 608,023).

Pursuant to the Articles of Association and vote of Shareholders at the AGM which took place on 30 May 2018 the Company was granted authority to disapply pre-emption rights in respects of the Company's issued share capital.

Lock up arrangements

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

Share price

From 1 January 2018 to 31 December 2018 the share price ranged from a high of 103p to a low of 48p. The average price for the period was 56.8p. The mid-market price of an ordinary share on 31 December 2018 was 48p.

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 2018.

Auditor

PricewaterhouseCoopers LLP (PwC) 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 7 June 2019 at 12:00 p.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

1 May 2019

Statement of directors' responsibilities in respect of the financial statements

The directors are responsible for preparing the Annual Report and the financial statements in accordance with applicable law and regulation.

Company law requires the directors to prepare financial statements for each financial year. Under that law the directors have prepared the Group financial statements in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union and Parent Company financial statements in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union. 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 the profit or loss of the Group for that period. In preparing the financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- state whether applicable IFRSs as adopted by the European Union have been followed for the Group financial statements and IFRSs as adopted by the European Union have been followed for the Company financial statements, subject to any material departures disclosed and explained in the financial statements;
- make judgements and accounting estimates that are reasonable and prudent; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group and Parent Company will continue in business.

The directors are also responsible for safeguarding the assets of the Group and Parent Company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Group and Parent Company's transactions and disclose with reasonable accuracy at any time the financial position of the Group and Parent Company and enable them to ensure that the financial statements comply with the Companies Act 2006.

The directors are responsible for the maintenance and integrity of the Parent Company's website. Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

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 2018 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 International Financial Reporting Standards (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.

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 2018; 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 and Risk 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.

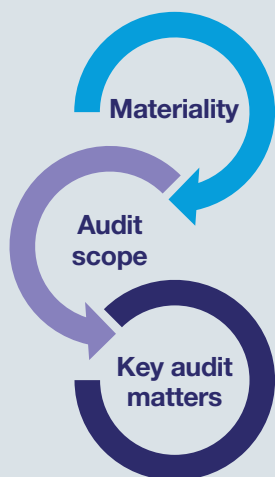
To the best of our knowledge and belief, we declare that non-audit services prohibited by the FRC's Ethical Standard were not provided to the Group or the Parent Company.

Other than those disclosed in note 9 to the financial statements, we have provided no non-audit services to the Group or the Parent Company in the period from 1 January 2018 to 31 December 2018.

Our audit approach

Overview

- Overall Group materiality: £3.0 million (2017: £6.0 million), based on 5% of loss before tax and exceptional items.
- Overall Parent Company materiality: £2.8 million (2017: £5.4 million), based on 1% of total assets restricted so as not to exceed 95% of Group materiality.
- The Group's accounting process is structured around local finance functions 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 reporting entities where a full scope audit was required included Circassia Inc (incorporated in the USA) and Circassia AB (incorporated in Sweden), determined as individually financially significant because they both individually contribute more than 15% of the Group's revenue. We also undertook the statutory audit of two further reporting units incorporated in the UK, Circassia Pharmaceuticals plc and Circassia Limited. Circassia Pharmaceuticals plc is not a financially significant component of the Group. Senior members of the UK engagement team attended planning meetings with each engagement team and attended the audit closing meetings. The Group audit team reviewed the working papers of the Swedish and US component team.



-
- 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, share-based payments, current and deferred tax and central adjustments recorded as part of the consolidation process.
 - In aggregate our audit procedures accounted for 95% of Group revenue.
 - 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.
-
- Impairment of goodwill and intangibles (Group).
 - Accounting for business combinations (Group).
 - Impairment of investment in subsidiaries and intercompany balances (Parent Company).

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.

Capability of the audit in detecting irregularities, including fraud

Based on our understanding of the Group and industry, we identified that the principal risks of non-compliance with laws and regulations related to the Medicines and Healthcare Product Regulatory Agency (MHRA) and, in the US, the Food and Drug Administration (FDA), and we considered the extent to which non-compliance might have a material effect on the financial statements. We also considered those laws and regulations that have a direct impact on the preparation of the financial statements such as the Companies Act 2006 and UK tax legislation. We evaluated management's incentives and opportunities for fraudulent manipulation of the financial statements (including the risk of override of controls), and determined that the principal risks were related to posting inappropriate journal entries to increase revenue or reduce expenditure, unauthorised extractions of cash from the business and management bias in accounting estimates. The Group engagement team shared this risk assessment with the component auditors so that they could include appropriate audit procedures in response to such risks in their work. Audit procedures performed by the Group engagement team and/or component auditors included:

- review of the financial statement disclosures to underlying supporting documentation, review of correspondence with legal advisers, enquiries of management, including those outside of the finance function and review of significant component auditors' working papers.

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. Also, 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.

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

Impairment of goodwill and intangibles (Group)

IAS 36 requires at least annual impairment assessments in relation to goodwill and intangible assets, with more regular assessment should an impairment trigger be identified.

An impairment trigger was identified for the Respiratory cash generating unit due to the inability to find an out-licensing partner for the product candidates in the respiratory portfolio. This resulted in an impairment of £4.4 million to goodwill and £70.6 million to intangible assets.

No other impairment triggers were considered to have occurred at the cash generating unit level.

Goodwill of £9.3 million and intangible assets of £221.4 million 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, including the growth rates applied. 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.

Refer to pages 44 to 50 (Audit and Risk Committee report), page 82 (Significant accounting estimates and judgements), and pages 102 to 105 in the notes.

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 four cash generating units (CGU's).

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.

We assessed the key assumptions, including:

- Future revenue streams: We used our experts to compare the forecast revenues with market expectations for the NIOX® and AstraZeneca CGUs, where available. We observed that the management sales forecasts, including the growth rates applied, are close to market expectations.

- 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.

- 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.

- 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 concluded management's recognised impairment in relation to individual assets is reasonable.

Accounting for business combinations (Group)

On 12 April 2017 the Group entered into a Development and Commercial Agreement ('DCA') with AstraZeneca to acquire the rights to commercial Duaklir® in the United States of America and the right to acquire an option to the rights remaining contractual rights and economic benefit of Tudorza®. The option to acquire Tudorza® became substantive on 23 October 2018.

Our main area of focus and the area of most complexity and judgement was the date on which the option to acquire Tudorza® became substantive, 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 pages 44 to 50 (Audit and Risk Committee report), page 82, (Significant accounting estimates and judgements), and pages 120 to 122 in the notes.

We obtained and reviewed the underlying DCA between the Group and AstraZeneca and concurred with management that control of the Tudorza® business had passed to the Group on 23 October 2018.

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 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);

- 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.

In relation to the re-measurement of contingent consideration in respect of future royalties payable to third-parties, we obtained management's revised forecasts as at 31 December 2018, 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.

Key audit matter**How our audit addressed the key audit matter**

Impairment of investment in subsidiaries and intercompany balances (Parent Company)

Investment in subsidiaries of £67.6 million is a significant balance. In addition, the Parent Company has net intercompany receivables totalling £281.7 million from its subsidiary companies. The market capitalisation of the Group on 31 December 2018 was £171.1 million, indicating the existence of a potential impairment trigger. 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.

Refer to pages 44 to 50 (Audit and Risk Committee report), page 82 (Significant accounting estimates and judgements), and pages 106 and 110 in the notes.

The market capitalisation of the Group is lower than the value of the company's investment in subsidiaries and intercompany receivables balances, which is a trigger for management to perform a review of the balances for potential impairment.

After performing this review, management have recorded impairments of £210.3 million and £91.4 million against the investment in subsidiaries balance and intercompany receivables balances respectively in the year.

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 subsidiaries and intercompany receivables balances, 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.

We concluded that the impairments of £210.3 million to investments in subsidiaries and £91.4 million to intercompany receivables recorded by management are appropriate.

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.

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
Overall materiality	£3.0 million (2017: £6.0 million).	£2.8 million (2017: £5.4 million).
How we determined it	5% of loss before tax and exceptionals.	1% of total assets restricted so as not to exceed 95% of Group materiality.

Rationale for benchmark applied

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/loss before tax, although for R&D companies at the development stage, expenses are sometimes used.

As the business has continued to pursue revenue generating activities such as NIOX® trading and the AstraZeneca collaboration, we consider a profit/loss-based metric to be the measure of most relevance to users of the accounts. However, during the year there was an impairment charge of £75 million in relation to intangible assets in the discontinued Respiratory business, which is a material one-off item that is not expected to be repeated. We consider this item to distort the view of materiality for the users of the accounts and we have therefore excluded this exceptional item to arrive at our adjusted profit-based benchmark which is 'Loss before tax and exceptionals'.

We highlight that there are a number of other items that have been identified by management as "non-underlying" in the current year, but none of these are considered to be "exceptional".

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 £2.3 and £2.8 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 £149,500 (Group audit) (2017: £300,000) and £142,000 (Parent Company audit) (2017: £270,000) as well as misstatements below those amounts that, in our view, warranted reporting for qualitative reasons.

Conclusions relating to going concern

ISAs (UK) require us to report to you when:

- the directors' use of the going concern basis of accounting in the preparation of the financial statements is not appropriate; or
- the directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the Group's and Parent Company's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

We have nothing to report in respect of the above matters.

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. For example, the terms on which the United Kingdom may withdraw from the European Union are not clear, and it is difficult to evaluate all of the potential implications on the Group's trade, customers, suppliers and the wider economy.

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) and ISAs (UK) 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 2018 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)

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 67, 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. 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 are not in agreement with the accounting records and returns.

We have no exceptions to report arising from this responsibility.

Appointment

Following the recommendation of the audit committee, we were appointed by the members on 30 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 12 years, covering the years ended 31 December 2007 to 31 December 2018.

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

1 May 2019

Consolidated statement of comprehensive income for the year ended 31 December 2018

		2018			2017		
	Notes	Underlying operations £m	Non- underlying items £m	Total £m	Underlying operations Restated ¹ £m	Non- underlying items Restated ¹ £m	Total £m
Continuing operations							
Revenue from contracts with customers	4	48.3	–	48.3	46.3	–	46.3
Cost of sales		(8.9)	–	(8.9)	(10.0)	–	(10.0)
Gross profit		39.4	–	39.4	36.3	–	36.3
Research and development costs		(10.8)	–	(10.8)	(13.3)	(45.1)	(58.4)
Sales and marketing		(54.4)	(2.9)	(57.3)	(49.5)	–	(49.5)
Administrative expenses		(11.4)	(0.3)	(11.7)	(10.7)	0.1	(10.6)
Operating loss	8	(37.2)	(3.2)	(40.4)	(37.2)	(45.0)	(82.2)
Other gains and (losses)	6	1.9	(5.6)	(3.7)	(1.1)	11.5	10.4
Finance costs	7	(0.1)	(11.9)	(12.0)	(0.1)	(2.7)	(2.8)
Finance income	7	0.3	–	0.3	0.4	–	0.4
Loss before tax		(35.1)	(20.7)	(55.8)	(38.0)	(36.2)	(74.2)
Taxation	12	9.2	–	9.2	3.5	10.2	13.7
Loss for the financial year from continuing operations		(25.9)	(20.7)	(46.6)	(34.5)	(26.0)	(60.5)
Discontinued operations							
Loss for the year from discontinued operations attributable to owners of Circassia Pharmaceuticals plc	10	–	(70.5)	(70.5)	–	(38.6)	(38.6)
Loss for the financial year		(25.9)	(91.2)	(117.1)	(34.5)	(64.6)	(99.1)
Other comprehensive (expense)/income items that may be subsequently reclassified to profit or loss							
Currency translation differences	29	(4.8)	–	(4.8)	2.2	–	2.2
Total other comprehensive (expense)/income for the year		(4.8)	–	(4.8)	2.2	–	2.2
Total comprehensive expense for the year		(30.7)	(91.2)	(121.9)	(32.3)	(64.6)	(96.9)

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

		2018	2017
		£	Restated ¹ £
Basic and diluted loss per share			
Loss per share from continuing operations	13	(0.14)	(0.19)
Total loss per share	13	(0.34)	(0.31)

¹ Restated to show the results of the respiratory business in discontinued operations, see note 10 for further 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 notes on pages 80 to 123 are an integral part of these financial statements.

Consolidated statement of financial position
as at 31 December 2018

	Notes	2018 £m	2017 £m
Assets			
Non-current assets			
Property, plant and equipment	14	0.5	1.4
Goodwill	15	9.3	10.0
Intangible assets	16	221.4	199.7
Deferred tax assets	24	19.1	15.7
Investment in joint venture	18	0.1	0.5
Prepayment for business combination	35	–	77.9
Non-current tax assets	12	3.0	7.3
		253.4	312.5
Current assets			
Inventories	19	4.2	5.0
Trade and other receivables	20	8.1	18.9
Current tax assets	12	1.0	6.5
Short-term bank deposits	21	–	15.0
Cash and cash equivalents	21	40.7	44.5
		54.0	89.9
Total assets		307.4	402.4
Equity and liabilities			
Equity			
Ordinary shares	25	0.3	0.3
Share premium	27	622.5	602.2
Other reserves	29	15.1	17.2
Accumulated losses	28	(512.0)	(394.9)
Total equity		125.9	224.8
Liabilities			
Non-current liabilities			
Deferred tax liabilities	24	10.9	24.1
Non-contingent consideration	35	–	68.7
Contingent consideration	35	46.2	33.6
Non-current trade payables	22	–	20.4
		57.1	146.8
Current liabilities			
Non-contingent consideration	35	80.3	–
Contingent consideration	35	15.4	–
Trade and other payables	22	28.7	30.8
		124.4	30.8
Total liabilities		181.5	177.6
Total equity and liabilities		307.4	402.4

The notes on pages 80 to 123 are an integral part of these financial statements.

The financial statements on pages 74 to 123 were authorised for issue by the Board of Directors on 1 May 2019 and were signed on its behalf by

Steven Harris
Chief Executive Officer
Circassia Pharmaceuticals plc

Julien Cotta
Chief Financial Officer
Circassia Pharmaceuticals plc

Registered number: 05822706

**Parent Company statement of financial position
as at 31 December 2018**

	Notes	2018 £m	2017 £m
Assets			
Non-current assets			
Investments in subsidiaries	17	67.6	273.5
		67.6	273.5
Current assets			
Trade and other receivables	20	282.6	328.2
Short-term bank deposits	21	–	15.0
Cash and cash equivalents	21	0.1	0.3
		282.7	343.5
Total assets		350.3	617.0
Equity and liabilities			
Equity attributable to the owners of the Company			
Ordinary shares	25	0.3	0.3
Share premium	27	622.5	602.2
Other reserves	29	11.3	8.6
(Accumulated losses)/retained earnings	28	(289.9)	1.9
Total equity		344.2	613.0
Liabilities			
Current liabilities			
Trade and other payables	22	6.1	4.0
		6.1	4.0
Total equity and liabilities		350.3	617.0

The loss for the Parent Company for the year was £291.8 million (2017: £1.5 million profit).

The notes on pages 80 to 123 are an integral part of these financial statements.

The financial statements on pages 74 to 123 were authorised for issue by the Board of Directors on 1 May 2019 and were signed on its behalf by

Steven Harris
Chief Executive Officer
Circassia Pharmaceuticals plc

Julien Cotta
Chief Financial Officer
Circassia Pharmaceuticals plc

Registered number: 05822706

Consolidated and Parent Company statements of cash flows
for the year ended 31 December 2018

	Notes	Group		Company	
		2018 £m	2017 £m	2018 £m	2017 £m
Cash flows from operating activities					
Cash (used in)/generated from operations	30	(51.3)	(66.4)	11.7	0.4
Interest paid	7	(0.2)	(0.1)	–	–
Tax credit received	12	10.9	8.9	–	–
Net cash (used in)/generated from operating activities		(40.6)	(57.6)	11.7	0.4
Cash flows from investing activities					
Recapitalisation of subsidiary	17	–	–	–	(9.0)
Purchases of property, plant and equipment	14	(0.1)	(0.8)	–	–
Purchases of intangible assets	16	(0.3)	–	–	–
Proceeds from sale of property, plant and equipment	14	0.5	–	–	–
Interest received	7	0.2	0.8	–	0.7
Joint venture distributions to owners	18	0.3	0.2	–	–
Loans granted to subsidiary undertakings	20	–	–	(45.5)	(68.2)
Decrease in short-term bank deposits		15.0	5.0	15.0	5.0
Net cash generated from/(used in) investing activities		15.6	5.2	(30.5)	(71.5)
Cash flows from financing activities					
Proceeds from issuance of ordinary shares	25	20.4	–	20.4	–
Share issue costs offset against share premium	27	(0.1)	(1.6)	(0.1)	(1.6)
Acquisition of interest in a subsidiary	17	–	–	(1.7)	–
Net cash generated from/(used in) financing activities		20.3	(1.6)	18.6	(1.6)
Net decrease in cash and cash equivalents					
Cash and cash equivalents at 1 January	21	44.5	97.4	0.3	73.0
Exchange gains on cash and cash equivalents		0.9	1.1	–	–
Cash and cash equivalents at 31 December	21	40.7	44.5	0.1	0.3

The notes on pages 80 to 123 are an integral part of these financial statements.

Consolidated statement of changes in equity for the year ended 31 December 2018

	Notes	Ordinary shares £m	Share premium £m	Other ¹ reserves £m	Accumulated losses £m	Total equity £m
At 1 January 2017		0.2	563.8	12.5	(295.8)	280.7
Loss for the financial year	28	–	–	–	(99.1)	(99.1)
Currency translation differences	29	–	–	2.2	–	2.2
Total comprehensive income/(expense)		–	–	2.2	(99.1)	(96.9)
Transactions with owners:						
Issue of ordinary shares	25	0.1	38.4	–	–	38.5
Employee share option scheme	29	–	–	2.5	–	2.5
At 31 December 2017		0.3	602.2	17.2	(394.9)	224.8
At 1 January 2018		0.3	602.2	17.2	(394.9)	224.8
Loss for the financial year	28	–	–	–	(117.1)	(117.1)
Currency translation differences	29	–	–	(4.8)	–	(4.8)
Total comprehensive expense		–	–	(4.8)	(117.1)	(121.9)
Transactions with owners:						
Issue of ordinary shares	25	–	20.3	–	–	20.3
Employee share option scheme	29	–	–	2.7	–	2.7
At 31 December 2018		0.3	622.5	15.1	(512.0)	125.9

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

The notes on pages 80 to 123 are an integral part of these financial statements.

Parent Company statement of changes in equity
for the year ended 31 December 2018

	Notes	Ordinary shares £m	Share premium £m	Share option reserve £m	(Accumulated losses)/ Retained earnings £m	Total equity £m
At 1 January 2017		0.2	563.8	6.1	0.4	576.9
Profit and total comprehensive income	28	–	–	–	1.5	1.5
Transactions with owners:						
Issue of ordinary shares	25, 27	0.1	38.4	–	–	38.5
Employee share option scheme	29	–	–	2.5	–	2.5
At 31 December 2017		0.3	602.2	8.6	1.9	613.0
At 1 January 2018		0.3	602.2	8.6	1.9	613.0
Loss and total comprehensive expense	28	–	–	–	(291.8)	(291.8)
Transactions with owners:						
Issue of ordinary shares	25, 27	–	20.3	–	–	20.3
Employee share option scheme	29	–	–	2.7	–	2.7
At 31 December 2018		0.3	622.5	11.3	(289.9)	344.2

The notes on pages 80 to 123 are an integral part of these 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 company limited by shares which is listed on the Alternative Investment Market (AIM) and incorporated and domiciled in the United Kingdom. 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 results shown for the years ended 31 December 2018 and 2017 are audited. Statutory accounts of the Company in respect of the financial year ended 31 December 2018 were approved by the Board of Directors on 1 May 2019 and will be delivered to the Registrar of Companies in due course. The report of the auditors on those accounts was unqualified and did not contain an emphasis of matter paragraph nor any statement under Section 498 of the Companies Act 2006.

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 2018 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.

The directors note that as at 31 December 2018, the Group is in a net current liability position. This is mainly due to the \$125 million consideration payable to AstraZeneca. Payment of this amount will be addressed by a loan provided by AstraZeneca.

New and amended standards adopted by the Group

The Group has applied the following standards and amendments for the first time for their annual reporting period commencing 1 January 2018:

- IFRS 9 – Financial Instruments
- IFRS 15 – Revenue from Contracts with Customers

The new standards listed above did not have any impact on the amounts recognised in prior periods or the current period and are not expected to significantly affect future periods.

New standards and interpretations not yet adopted

Certain new accounting standards and interpretations have been published that are not mandatory for 31 December 2018 reporting periods and have not been early adopted by the Group. The Group's assessment of the impact of these new standards and interpretations is set out below.

IFRS 16 – Leases

This new standard was issued in January 2016. It will result in almost all leases being recognised on the balance sheet by lessees, as the distinction between operating and finance leases is removed. Under the new standard, an asset (the right to use the leased item) and a financial liability to pay rentals are recognised. The only exceptions are short-term and low-value leases.

The Group has reviewed all leasing arrangements considering the new lease accounting rules in IFRS 16. The standard will affect primarily the accounting for the Group's operating leases.

As at the reporting date, the Group has non-cancellable operating lease commitments of £3.7 million, see note 32. Of these commitments, approximately £0.1 million relates to low value leases which will be recognised on a straight-line basis as expense in profit or loss.

For the remaining lease commitments, the Group expects to recognise right-of-use assets of approximately £2.3 million on 1 January 2019, lease liabilities of £2.5 million (after adjustments for prepayments and accrued lease payments recognised as at 31 December 2018). The related deferred tax asset is immaterial. Overall net assets will be approximately £0.1 million lower, and net current assets will be £0.6 million lower due to the presentation of a portion of the liability as a current liability.

The Group expects that loss after tax will increase by approximately £0.1 million for 2019 as a result of adopting the new rules.

Operating cash flows will increase, and financing cash flows decrease by approximately £1.6 million as repayment of the principal portion of the lease liabilities will be classified as cash flows from financing activities.

The Group's activities as a lessor are not material and hence the Group does not expect any significant impact on the financial statements. However, some additional disclosures will be required from next year.

The Group will apply the standard from its mandatory adoption date of 1 January 2019. The Group intends to apply the simplified transition approach and will not restate comparative amounts for the year prior to first adoption.

There are no other standards that are not yet effective and that would be expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

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 historical experience and other factors, including expectations of future events that are believed to be reasonable in the circumstances.

Significant accounting estimates and judgements

The preparation of financial statements requires the use of accounting estimates which, by definition, will seldom equal the actual results. Management also needs to exercise judgement in applying the Group's accounting policies. This note provides an overview of the areas that involved a higher degree of judgement or complexity, and of items which are more likely to be materially adjusted due to estimates and assumptions being revised.

The areas involving significant estimates are listed below:

Recognition of deferred tax asset for carried-forward tax losses

The deferred tax assets include an amount of £8.2 million which relates to carried-forward tax losses of Circassia AB (previously known as Aerocrine AB). These losses were generated before the company was acquired by Circassia Pharmaceuticals plc. The Group has concluded that the deferred assets will be recoverable using the estimated future taxable income based on the approved business plans and budgets for the subsidiary. The subsidiary has generated taxable income in both years ended 2017 and 2018 is expected to continue generating taxable income from 2019 onwards. The losses can be carried forward indefinitely and have no expiry date. The judgement is how much of the asset can be recognised based on probable future profits. Changes in the expected future profits of Circassia AB might result in a significantly higher or lower deferred tax asset. A 10% higher or lower taxable profit generated by Circassia AB would result in a £0.8 million higher or lower deferred tax asset recognised.

Accounting for collaboration with AstraZeneca

Following the collaboration and profit share arrangement with AstraZeneca in the previous year, a Purchase Price Allocation exercise was performed in relation to the Duaklir[®] acquisition. It was considered that the Group assumed control over the Duaklir[®] business only on this date, as the acquisition of Tudorza[®] was contingent on net sales achievement. The following key accounting areas were of focus:

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.

As at 31 December 2018, the carrying amount of the Duaklir[®] IPR&D was £33.3 million (2017: £33.3 million). The Group estimates the useful life of this IPR&D to be 17 years, based on the expected future cash flows that the asset is expected to generate. However, the actual useful life might be shorter or longer than 17 years, depending on product innovations and competitor actions. As at 31 December 2018, the asset is not yet ready for use as the Duaklir[®] product has not been launched, and therefore this estimate has no impact on the carrying amount in the current year.

Valuation of Duaklir[®] royalties

As part of the collaboration, 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 and corresponding liability was calculated by management using a tax-effected NPV of the future royalty cash outflows at the date of the transaction.

As at 31 December 2018, the royalty liability has been remeasured using sales projections based on financial budgets approved by management covering a ten-year period. Expected sales beyond the ten-year period are extrapolated using estimated growth rates. See note 35 for further details.

Accounting for the Tudorza[®] option exercise

Following the Tudorza[®] option becoming substantive in October, a Purchase Price Allocation exercise was performed focusing on the following key accounting area:

Initial valuation of Tudorza[®] CMP

The Excess Earnings Method approach was determined to be the most appropriate methodology to use for the valuation of the Currently Marketed Product (CMP). This methodology made use of the cash flows associated with the Tudorza[®] business with certain key assumptions including a specific rate of return of net working capital, workforce requirements and minimal tangible fixed asset requirements. In addition, the Cost Approach was used to value the Assembled Workforce. As per IAS 38, the fair value of the Assembled Workforce has not been recognised as a separate intangible asset. The valuation of the Assembled Workforce was solely used for allowing a return on the Assembled Workforce in the valuation analyses of the CMP.

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. Please see note 17 for sensitivity analysis and further information.

The areas involving judgement are listed below:

Date of acquisition regarding Tudorza® option exercise

The business combination relating to the exercise of the Tudorza® option has been accounted for on 23 October 2018. This is determined to be the point at which there were no barriers to prevent Circassia from exercising the option, rather than 11 December 2018, being the date at which formal notice of exercise was served to AstraZeneca.

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 and losses on transactions between Group companies are eliminated. Accounting policies of subsidiaries are consistent with the policies adopted by the Group. Acquisition-related costs are expensed as incurred.

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 2018, 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 and respiratory operating segments have been classified as discontinued operations. Information about these discontinued segments 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 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. As such, the allergy programme costs and the associated research and development tax credit for the year ended 31 December 2017 and 31 December 2018 are classified as discontinued operations in the Consolidated Statement of Comprehensive Income in accordance with IFRS 5 requirements.

The respiratory programme costs and the associated research and development tax credit for the year ended 31 December 2017 have been reclassified as discontinued operations in the Consolidated Statement of Comprehensive Income in accordance with IFRS 5 requirements. The decision to treat the in-house respiratory pipeline as discontinued was made in April 2018 when the Group announced a decision to cease investment in the respiratory pipeline and to seek an out-license partner.

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. Payment of the \$125 million consideration payable and the \$18.3 million R&D payment will be addressed by a loan provided by AstraZeneca. 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).

Trade and other receivables

Trade receivables are amounts due from customers for goods sold or services performed in the ordinary course of business. They are generally due for settlement within 30 days and therefore are all classified as current. Trade receivables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method, less credit loss allowance. In respect of 2018 and subsequent years, the Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables and contract assets. In respect of 2017, the Group applied an incurred loss methodology, in accordance with IAS39.

Trade receivables are written off when there is no reasonable expectation of recovery.

Other receivables are recognised initially at fair value and subsequently measured at amortised cost, using the effective interest method, less provision for impairment.

Trade and other payables

Trade and other 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.

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, intellectual property rights and currently marketed products acquired through licensing or assigning patents and know-how are carried at historical 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 – 17 years
CMP	13 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.

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.

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
Fixtures and fittings	20%
Plant and equipment	10% - 33%

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.

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.

Deferred contingent consideration

Deferred contingent consideration is recognised as a liability and measured at fair value on the acquisition date. It 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. The liability is subsequently measured at fair value at each reporting date, with changes in fair value recognised as other gains or losses in the income statement. 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 is accounted for under IFRS 15. 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. Revenue is recognised when a contractual promise to a customer (performance obligation) has been fulfilled by transferring control of the product to the customer, substantially all of which is on confirmation of delivery to the customer.

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.

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'.

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 assets are recognised only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilised.

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 2018, the Company issued 23,725,800 ordinary shares with a value of £20.4 million to AstraZeneca (AZ). 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 through forecasting 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 British pound sterling, but a significant proportion of its expenditure and subsidiary results are in various currencies including United States dollar, Swedish krona, euro and Chinese yuan. 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 British pound sterling, United States dollar, Swedish krona or euro. 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 2018 is 10% (2017: 10%).

At 31 December 2018, 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 £0.5 million (2017: £0.4 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 2018 of a 10% weakening/strengthening of the US dollar against British pound sterling with all other variables held constant would have been a decrease/increase of £0.7 million (2017: £2.7 million), as a result of net foreign exchange gains/losses on translation of dollar denominated payables, receivables and foreign exchange losses/gains on translation of dollar denominated bank balances.

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 2018 would have been an increase/decrease of £0.0 million (2017: £0.1 million) due to changes in the amount of interest receivable.

Credit risk

Credit risk arises from cash and cash equivalents, deposits with banks and financial institutions, as well as credit exposures to customers, including outstanding receivables.

i) Risk management

The Group's policy is to place funds with financial institutions which have a minimum credit rating with Fitch IBCA of A- long-term/F1 short-term. During 2018, the Group opened a bank account with China Merchant Bank which has a Fitch IBCA rating of BBB. This is a short-term arrangement until a permanent solution is implemented.

During 2018 the Group placed funds on deposit with 8 banks (2017: 6 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.

ii) Impairment of financial assets

The Group only has one type of financial asset that is subject to the expected credit loss model being trade receivables. The Company only has one type of financial asset that is subject to the expected credit loss model being receivables from subsidiary undertakings. While cash and cash equivalents are also subject to the impairment requirements of IFRS 9, the identified impairment loss was immaterial.

The Group and Company applies the IFRS 9 simplified approach to measuring expected credit losses which uses an expected loss allowance for all trade receivables and receivables from subsidiary undertakings. To measure the expected credit losses, trade receivables and receivables from subsidiary undertakings have been grouped based on the days past due.

The expected loss rates are based on the payment profiles of sales over a period of 36 months before 31 December 2018 and the corresponding historical credit losses experienced within this period. The historical loss rates are adjusted to reflect current and forward looking information on macroeconomic factors affecting the ability of the customers to settle the receivables.

On that basis, the loss allowance as at 31 December 2018 was determined as follows:

Group	Current £m	More than 30 days past due £m	More than 60 days past due £m	More than 90 days past due £m	Total £m
31 December 2018					
Expected loss rate	2%	12%	10%	8%	
Gross trade receivables carrying amount	3.4	0.1	0.1	0.2	3.8
Loss allowance	(0.1)	–	–	–	(0.1)

Company	Current £m	More than 30 days past due £m	More than 60 days past due £m	More than 90 days past due £m	Total £m
31 December 2018					
Expected loss rate	24%	0%	0%	0%	
Gross receivables from subsidiary undertakings carrying amount	373.1	–	–	–	373.1
Loss allowance	(91.4)	–	–	–	(91.4)

Notes to the financial statements continued

The closing loss allowance for trade receivables as at 31 December 2018 reconciles to the opening loss allowances as follows:

	Group		Company	
	2018 £m	2017 £m	2018 £m	2017 £m
Opening loss allowance as at 1 January	–	(0.2)	–	–
Increase in loss allowances recognised in profit or loss during the year	(0.1)	–	(91.4)	–
Receivables written off during the year as uncollectible	–	0.1	–	–
Unused amount reversed	–	0.1	–	–
At 31 December	(0.1)	–	(91.4)	–

Trade receivables are written off where there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with the Group, and a failure to make contractual payments for a period of greater than 120 days past due.

Impairment losses on trade receivables and receivables from subsidiary undertakings are presented within operating profit. Subsequent recoveries of amounts previously written off are credited against the same line item.

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. The only financial liability outstanding for periods greater than one year in 2018 is a proportion of the contingent royalty consideration relating to sales of Duaklir[®] and Tudorza[®] made in 2020 and onwards. Financial liabilities outstanding for periods greater than one year in 2017 included non-contingent consideration, contingent royalty consideration and R&D contribution payable to AstraZeneca. The amounts disclosed in the table are the contracted cash flows discounted to present value where such impact is material:

	Less than	Over	Less than	Over
	1 year 2018 £m	1 year 2018 £m	1 year 2017 £m	1 year 2017 £m
At 31 December				
Non-contingent consideration	80.3	–	–	68.7
Contingent consideration	15.4	46.2	–	33.6
Trade and other payables	28.7	–	30.8	20.4
Total	124.4	46.2	30.8	122.7

As at 31 December 2018, the Group is in a net current liability position. This is mainly due to the \$125 million consideration payable to AstraZeneca. Payment of this amount will be addressed by a loan provided by AstraZeneca.

Derivative financial instruments and hedging

There were no derivatives at 31 December 2018 or 31 December 2017.

3. Operating segments

The chief operating decision-maker (the Chief Executive Officer) 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 2018 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); and
- US AZ collaboration relates to the US collaboration agreement with AstraZeneca regarding the commercialisation of Tudorza[®] and Duaklir[®].

The allergy and respiratory operating segments have been classified as discontinued operations. Information about these discontinued segments is provided in note 10.

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

The table below presents information regarding the Group's operating segments for the years ended 31 December 2018 and 2017. 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

Year ended 31 December 2018	NIOX [®] £m	US AZ collaboration £m	Unallocated £m	Total £m
Revenue (from external customers by country, based on the destination of the customer)				
US	9.4	20.9	–	30.3
EU	8.4	–	–	8.4
Asia Pacific	9.5	–	–	9.5
Rest of world	0.1	–	–	0.1
Total segment revenue	27.4	20.9	–	48.3
Research and development	(3.2)	(1.0)	(6.6)	(10.8)
Sales and marketing	(32.3)	(22.1)	–	(54.4)
Administrative expenses	–	–	(11.4)	(11.4)
Operating loss from continuing operations	(17.0)	(2.2)	(18.0)	(37.2)
Depreciation, amortisation & impairment included in the expenditure above	(3.8)	–	(0.6)	(4.4)
Year ended 31 December 2017	NIOX[®]	US AZ collaboration	Unallocated	Total
Restated¹	£m	£m	£m	£m
Revenue (from external customers by country, based on the destination of the customer)				
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
Total segment revenue	27.3	19.0	–	46.3
Research and development	(4.4)	(45.1)	(8.9)	(58.4)
Sales and marketing	(32.6)	(16.8)	(0.1)	(49.5)
Administrative expenses	–	–	(10.6)	(10.6)
Other	(10.0)	–	–	(10.0)
Operating loss from continuing operations	(19.7)	(42.9)	(19.6)	(82.2)
Depreciation, amortisation & impairment included in the expenditure above	(4.2)	–	(0.7)	(4.9)

¹ Restated to show the results of the respiratory business in discontinued operations, see note 10 for further details.

Notes to the financial statements continued

Assets by segment

As at 31 December 2018	NIOX® £m	US AZ collaboration £m	Unallocated £m	Total £m
Cash, cash equivalents and short-term deposits	7.1	4.9	28.7	40.7
Property, plant and equipment	–	0.5	–	0.5
Goodwill	5.2	4.1	–	9.3
Intangible assets	50.7	170.7	–	221.4
Deferred tax assets	8.2	10.9	–	19.1
Investment in joint venture	–	0.1	–	0.1
Non-current tax assets	–	3.0	–	3.0
Inventories	4.2	–	–	4.2
Trade and other receivables	6.1	2.0	–	8.1
Current tax assets	–	1.0	–	1.0
Total assets	81.5	197.2	28.7	307.4

As at 31 December 2017 Restated ¹	NIOX® £m	US AZ collaboration £m	Unallocated £m	Total £m
Cash, cash equivalents and short-term deposits	3.7	55.8	–	59.5
Property, plant and equipment	–	1.4	–	1.4
Goodwill	5.4	0.2	4.4	10.0
Intangible assets	74.9	124.8	–	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
Total assets	84.0	314.0	4.4	402.4

¹ Restated to show the results of the respiratory business in discontinued operations, see note 10 for further details.

4. Revenue from contracts with customers

The Group derives the following types of revenue:

	2018 £m	2017 £m
Sale of goods	27.0	27.2
Rendering of services	21.3	19.0
Licence and milestone revenue	–	0.1
Total revenue from contracts with customers	48.3	46.3

All revenue is recognised at a point in time, rather than over time.

5. Employees and directors

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

By activity	Group		Company	
	2018 Number	2017 Number	2018 Number	2017 Number
Office and management	43	42	8	7
Sales and marketing	285	256	–	–
Research and development	39	68	–	–
Total average headcount	367	366	8	7

The average number of administration staff employed by the Group during the year, including Executive and Non-Executive Directors, was 2 (2017: 2).

Employee benefit costs	Group		Company	
	2018 £m	2017 £m	2018 £m	2017 £m
Wages and salaries	39.1	39.6	1.5	1.4
Social security costs	5.7	3.2	0.2	0.2
Other pension costs	1.5	1.5	–	0.1
Share options expense	2.7	2.5	–	–
Total employee benefit costs	49.0	46.8	1.7	1.7

The Group contributes to defined contribution pension schemes for its Executive Directors and employees. Contributions of £0.1 million (included in other payables) were payable to the funds at the year end (2017: £0.1 million).

The details of directors of the Group who received emoluments from the Group during the year are shown in the Remuneration Committee report.

Key management personnel

The average number of key management personnel employed by the Group during the year including directors (Executive and Non-Executive) was 13 (2017: 13).

Key management personnel during the year included directors (Executive and Non-Executive), Senior VP of Commercial US, Senior VP of General Counsel and Chief Compliance Officer, Senior VP of Human Resources and Senior VP of Commercial EU & RoW. The compensation paid or payable to key management is set out below.

	2018 £m	2017 £m
Short-term employee benefits (including bonus)	3.7	3.0
Post-employment benefits	0.1	0.2
Share based payment	1.0	0.8
Total	4.8	4.0

6. Other gains and losses

	2018 £m	2017 £m
Net foreign exchange gain/(loss)	1.9	(1.1)
Change in fair value of contingent Duaklir® royalty consideration	(1.1)	3.2
Change in fair value of deferred consideration	5.4	–
Foreign exchange (loss)/gain on non-contingent consideration	(4.4)	5.4
Foreign exchange (loss)/gain on contingent royalty consideration	(2.5)	2.9
Foreign exchange loss on exercise of Tudorza® option	(2.7)	–
Foreign exchange loss on contingent consideration	(0.3)	–
Total other gains and losses	(3.7)	10.4

A £5.4 million gain on change in fair value of the deferred non-contingent consideration between date of the initial business combination and Tudorza® option exercise has been recognised. This gain has arisen due to the unwinding of the discount on the consideration payable between initial recognition on 12 April 2017 and 23 October 2018, being the date that Circassia Limited had the substantive rights to exercise the Tudorza® option. See note 35.

7. Finance income and costs

	2018 £m	2017 £m
Finance costs:		
Bank charges and interest payable	(0.1)	(0.1)
Non-contingent consideration: unwinding of discount	(7.2)	(2.7)
Contingent royalty consideration: unwinding of discount	(3.5)	–
Non-current trade payables: unwinding of discount	(1.2)	–
Total finance costs	(12.0)	(2.8)
Finance income:		
Bank interest receivable	0.3	0.4
Total finance income	0.3	0.4

8. Operating expenses by nature

Operating loss is stated after charging the following:

	2018 £m	2017 £m
Employee benefit costs (note 5)	49.0	46.8
Externally contracted research and development ¹	1.6	52.7
Marketing costs	10.7	10.0
Legal and professional fees including patent costs	7.5	3.6
Depreciation ²	0.6	0.8
Amortisation ²	3.8	4.1
Impairment of goodwill and other intangible assets	75.0	37.0
Operating lease payments	0.8	0.8

¹ 2017 includes AZ R&D contribution of £45.1 million, see note 11.

² 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 its associates

During the year the Group obtained the following services from the Group's auditors and its associates:

	2018 £m	2017 £m
Fees payable to the Group's auditors and its associates for the audit of the Parent Company and consolidated financial statements	0.2	0.2
Fees payable to the Group's auditors and its associates for other services:		
– The audit of the Company's subsidiaries	0.1	0.1
– Other assurance services ¹	–	0.2
Total	0.3	0.5

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

10. Discontinued operations

During 2017 it was announced that the Group would no longer continue development of the allergy programmes. Subsequently during 2018, it was announced that the Group would cease investment in the in-house respiratory pipeline. As such, the allergy and respiratory programme costs and the associated research and development tax credit are classified as discontinued operations in the consolidated statement of comprehensive income to comply with IFRS 5 requirements.

	Notes	2018 £m	2017 Restated ¹ £m
Loss for the year			
Expenditure		(3.7)	(8.7)
Goodwill and intangible assets impairment		(75.0)	(37.0)
Share of loss of joint venture	18	(0.1)	(0.2)
Loss before tax		(78.8)	(45.9)
Taxation	12	8.3	7.3
Loss from discontinued operations		(70.5)	(38.6)
		2018	2017
Cash flow		£m	Restated¹ £m
Net cash outflow from operating activities		(0.3)	(4.7)
Net decrease in cash from discontinued operations		(0.3)	(4.7)

¹ Restated to show the results of the respiratory business as discontinued. See note 10 for details.

The disposal groups constituting discontinued operations are all held at fair value less cost to sell.

11. Non-underlying items

Management primarily manage the business and measure performance based on the results of “underlying operations”. Significant irregularly occurring and exceptional items are excluded from the underlying measures. The following non-underlying items have been recognised in the income statement for the period:

	Notes	2018 £m	2017 Restated ¹ £m
Charged to research and development costs			
AZ R&D contribution		–	(45.1)
		–	(45.1)
Charged to sales and marketing costs			
Restructuring costs		(2.9)	–
		(2.9)	–
(Charged)/credited to administrative expenses			
AIM transfer costs		(0.3)	–
Restructuring costs		–	0.1
		(0.3)	0.1
(Charged)/credited to other gains and losses			
Foreign exchange movement on non-contingent consideration	35	(4.4)	5.4
Change in fair value of deferred consideration	35	5.4	–
Foreign exchange movement on contingent consideration	35	(0.3)	–
Change in fair value of contingent Duaklir [®] royalty consideration	35	(1.1)	3.2
Foreign exchange movement on exercise of Tudorza [®] option exercise	35	(2.7)	–
Foreign exchange movement on contingent royalty consideration	35	(2.5)	2.9
		(5.6)	11.5
Charged to finance costs			
Contingent royalty consideration: unwinding of discount	35	(7.1)	–
Contingent consideration: unwinding of discount	35	(0.1)	–
Non-contingent consideration: unwinding of discount	35	(3.5)	(2.7)
Non-current trade payables: unwinding of discount	35	(1.2)	–
		(11.9)	(2.7)
Loss before tax			
		(20.7)	(36.2)
Credited to taxation		–	10.2
Loss from continuing operations			
Loss from discontinued operations	10	(70.5)	(38.6)
Total loss			
		(91.2)	(64.6)

¹ Restated to show the results of the respiratory business as discontinued. See note 10 for details.

AstraZeneca R&D contribution

2017 includes a R&D contribution of £45.1 million for Tudorza® and Duaklir® product development.

Restructuring costs

Restructuring costs comprise cost optimisation initiatives including severance payments, compensation for loss of office, property and other contract termination costs. Restructuring in 2018 relates to the resizing of the US field force, and as such is allocated to sales and marketing. Restructuring in 2017 related to property costs in relation to the closure of the Solna office in Sweden, and therefore allocated to administrative expenses.

AIM transfer costs

AIM transfer costs comprise professional fees in relation to the transfer of Circassia Pharmaceuticals plc shares from the Main Market to AIM.

Non-contingent consideration

The £4.4 million (2017: £5.4 million) foreign exchange movement on non-contingent consideration relates to the impact of the strengthening dollar on translation of the \$100 million and \$5 million deferred non-contingent consideration payable to AstraZeneca. The consideration was measured by discounting the liability with £3.5 million (2017: £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 consideration

Contingent consideration relates to the \$20 million payable to AstraZeneca on approval of Duaklir®. The consideration was measured by discounting the liability with £0.1 million (2017: £nil) increase in the liability due to the passage of time (unwinding of discount) recognised as a finance cost in the year. The £0.3 million (2017: £nil) foreign exchange movement on non-contingent consideration relates to the impact of the strengthening dollar.

Contingent royalty consideration

Contingent royalty consideration relates to the amount of royalties payable to AstraZeneca on the future Tudorza® and Duaklir® sales. The liability was remeasured to fair value at the year end with the resulting £1.1 million (2017: £3.2 million credit) charge recorded in other gains and losses in the income statement. The £2.5 million (2017: £2.9 million) foreign exchange movement relates to the impact of the strengthening dollar on translation of the contingent royalty consideration.

Taxation

The R&D tax credit of £10.2 million for the year ended 31 December 2017 relates to the above R&D contribution to AstraZeneca.

Loss from discontinued operations

The costs relating to the discontinued allergy and respiratory operations 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 2018 and 2017 represents the credit receivable by the Group for the year and adjustments to prior years. The 2018 amounts have not yet been agreed with the relevant tax authorities.

	2018	2017
	£m	Restated ¹ £m
Current tax		
United Kingdom corporation tax research and development credit	(1.0)	(13.8)
Adjustments in respect of prior year	–	(0.2)
Total current tax	(1.0)	(14.0)
Deferred tax		
Decrease/(increase) in deferred tax assets	(3.5)	0.6
(Decrease)/increase in deferred tax liabilities	(13.9)	(7.0)
Adjustments in respect of prior year	0.9	(0.6)
Total deferred tax	(16.5)	(7.0)
Total tax	(17.5)	(21.0)
Tax is attributable to:		
Loss on continuing operations	(9.2)	(13.7)
Loss on discontinued operations	(8.3)	(7.3)
	(17.5)	(21.0)

The tax credit for the year is lower (2017: lower) than the standard rate of corporation tax in the UK of 19.00% (2017: 19.25%). The differences are explained below:

	2018	2017
	£m	Restated ¹ £m
Loss from continuing operations before tax	(55.8)	(74.2)
Loss from discontinued operation before tax	(78.8)	(45.9)
Loss before tax	(134.6)	(120.1)
Loss on ordinary activities before tax multiplied by the standard rate of corporation tax in the UK of 19.00% (2017: 19.25%)	(25.6)	(23.1)
Expenses not deductible for tax purposes (permanent differences)	–	0.5
Employee share options	0.3	–
Research & development relief uplift	(0.4)	(5.8)
Adjustments in respect of prior year	0.9	(0.8)
Tax losses for which no deferred income tax asset was recognised	7.3	8.2
Tax credit for the year	(17.5)	(21.0)

¹ Restated to show the results of the respiratory business as discontinued. See note 10 for details.

At 31 December 2018, the Group has tax losses to be carried forward of approximately £341.3 million (2017: 354.7 million). These can be utilised against future taxable profits. At 31 December 2018, Circassia Limited had tax losses to be carried forward of approximately £148.1 million (2017: £131.2 million). The utilisation of these losses will be restricted to 50% of profits generated in the United Kingdom.

At 31 December 2018, the Group has tax assets arising from tax credits in the United Kingdom for certain research and development expenditure of £4.0 million (2017: £13.8 million). Of this £3.0 million (2017: £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% (2017: 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. As net losses were recorded in both 2018 and 2017, the dilutive potential shares are anti-dilutive and therefore excluded from the earnings per share calculation.

For the year ended 31 December 2018	Continuing operations			Discontinued operations	Total
	Underlying operations	Non-underlying operations	Total		
Loss attributable to ordinary equity owners of the Parent Company (£m)	(25.9)	(20.7)	(46.6)	(70.5)	(117.1)
Weighted average number of ordinary shares in issue (Number)	344,347,267	344,347,267	344,347,267	344,347,267	344,347,267
Loss per share	(0.08)	(0.06)	(0.14)	(0.20)	(0.34)

For the year ended 31 December 2017 Restated ¹	Continuing operations			Discontinued operations	Total
	Underlying operations	Non-underlying operations	Total		
Loss attributable to ordinary equity owners of the Parent Company (£m)	(34.5)	(26.0)	(60.5)	(38.6)	(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
Loss per share	(0.11)	(0.08)	(0.19)	(0.12)	(0.31)

¹ Restated to show the results of the respiratory business as discontinued. See note 10 for details.

14. Property, plant and equipment

Group	Leasehold improvements £m	Fixtures and fittings £m	Plant and equipment £m	Total property, plant and equipment £m
At 1 January 2017				
Cost	0.6	0.3	1.7	2.6
Accumulated depreciation	(0.4)	(0.1)	(0.7)	(1.2)
Net book amount	0.2	0.2	1.0	1.4
Year ended 31 December 2017				
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)
Exchange differences	–	–	–	–
Closing net book amount	0.3	0.3	0.8	1.4
At 31 December 2017				
Cost	0.8	0.5	2.1	3.4
Accumulated depreciation	(0.5)	(0.2)	(1.3)	(2.0)
Net book amount	0.3	0.3	0.8	1.4
Year ended 31 December 2018				
Opening net book amount	0.3	0.3	0.8	1.4
Additions	–	0.1	–	0.1
Depreciation	(0.1)	(0.1)	(0.4)	(0.6)
Disposals	–	–	(0.4)	(0.4)
Closing net book amount	0.2	0.3	–	0.5
At 31 December 2018				
Cost	0.8	0.6	1.7	3.1
Accumulated depreciation	(0.6)	(0.3)	(1.7)	(2.6)
Net book amount	0.2	0.3	–	0.5

15. Goodwill

	2018 £m	2017 £m
At 1 January		
Cost	84.5	84.2
Accumulated impairment	(74.5)	(74.5)
Net book amount	10.0	9.7
Year ended 31 December		
Opening net book amount	10.0	9.7
Acquisition of business (note 35)	3.9	0.2
Impairment	(4.4)	-
Exchange differences	(0.1)	0.1
Closing net book amount	9.3	10.0
At 31 December		
Cost	88.2	84.5
Accumulated impairment	(78.9)	(74.5)
Net book amount	9.3	10.0

During 2018, Circassia Limited exercised its option to acquire the full US commercial rights over Tudorza® resulting in goodwill of £3.9 million being recognised.

In 2018, following the decision to cease investment in the in-house respiratory portfolio, the respiratory portfolio value was written off in full resulting in an impairment charge for the respiratory CGU of £75.0 million, of which £4.4 million related to goodwill.

The carrying value of goodwill is allocated to the following CGUs:

Cash generating unit	2018 £m	2017 £m
NIOX®	5.2	5.4
Respiratory	-	4.4
AstraZeneca collaboration	4.1	0.2
	9.3	10.0

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 value in use for the NIOX® CGU was calculated over a ten year period using a discount factor of 12.5% (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 17.0% (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:

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
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 2018 – 1% 2017 – 1%
Discount rate	Discount rates based on weighted average cost of capital for the CGU, adjusted where appropriate. 2018 – 12.5% 2017 – 10.0%

AstraZeneca collaboration CGU

Valuation basis	Value in use
Anticipated launch dates	2019
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
Advertising and promotion investment	Based on management forecasts of advertising and promotion required in the United States
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 2018 – (5%) 2017 – 1%
Discount rate	Discount rates based on weighted average cost of capital for the CGU, adjusted where appropriate. 2018 – 17.0% 2017 – 11.5%

Period of projected cash flows of 10 years is in line with management's forecasts. This is deemed to be the most appropriate period to assess cash flows due to the time taken to reach peak sales.

In each case the valuations of 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.

Impact of possible changes in key assumptions

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.

16. Intangible assets

Group	IPR&D £m	CMP £m	Customer relationships £m	Technology £m	Other £m	Total intangible assets £m
At 1 January 2017						
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)
Net book amount	88.8	–	31.4	46.9	–	167.1
Year ended 31 December 2017:						
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
Closing net book amount	124.8	–	29.8	45.1	–	199.7
At 31 December 2017						
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)
Net book amount	124.8	–	29.8	45.1	–	199.7
Year ended 31 December 2018:						
Opening net book amount	124.8	–	29.8	45.1	–	199.7
Additions	–	97.4	–	–	0.3	97.7
Amortisation charge	–	–	(1.8)	(2.0)	–	(3.8)
Impairment charge	(51.7)	–	–	(18.9)	–	(70.6)
Exchange differences	–	–	(0.8)	(0.8)	–	(1.6)
Closing net book amount	73.1	97.4	27.2	23.4	0.3	221.4
At 31 December 2018						
Cost	161.9	97.4	34.6	50.3	1.9	346.1
Accumulated amortisation and impairment	(88.8)	–	(7.4)	(26.9)	(1.6)	(124.7)
Net book amount	73.1	97.4	27.2	23.4	0.3	221.4

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. An impairment test is based on the value in use of the intangible assets. Key assumptions and sensitivities used in the impairment review at a CGU level are disclosed in note 15.

An impairment charge of £70.6 million has been recognised in research and development in the income statement in relation to product candidates in the respiratory portfolio following the inability to find an out-licensing partner.

In-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.

Currently Marketed Product (CMP)

CMP comprises the Tudorza[®] product, which is currently marketed in the United States. This has a useful economic life of 13 years, based on the cumulative present value of the positive excess earnings.

The CMP 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. CMP 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

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. Current year additions relate to the development costs of the new ERP software. Amortisation will be charged once the software has been fully developed and is operational.

17. Investments in subsidiaries

Company	2018 £m	2017 £m
Investments in subsidiaries at 1 January	273.5	262.0
Additional investment in Prosonix Limited	–	9.0
Equity settled instruments granted to employees of subsidiaries	2.7	2.5
Investment in Circassia Beijing	1.7	–
Provision against investments	(210.3)	–
Investments in subsidiaries at 31 December	67.6	273.5

Investments in subsidiaries are recorded at cost, which is the fair value of the consideration paid.

The Group tests annually whether investments in subsidiaries have suffered any impairment and tests more frequently when events or circumstances indicate that the current carrying value may not be recoverable. An impairment test is based on the value in use of the subsidiaries. Key assumptions and sensitivities used in the impairment review are disclosed in note 15.

A credit loss provision of £210.3 million has been recognised due to the cessation of investment in the respiratory portfolio.

Changes in the value in use of the subsidiaries might result in a significantly higher or lower fair value of investments. 10% higher or lower value in use would result in £35.4 million lower or higher fair value of investments.

The capital contribution relating to share based payment is for 5,103,400 (2017: 4,141,200) 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.

The Group had the following subsidiaries at 31 December 2018:

Name	Registered address	Nature of business	Proportion of ordinary shares held
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	Dormant	100%
Circassia (Beijing) Medical Device Co. Limited	Room 1109 Jing Guang Center Office Building, No 1 Chao Yang Men Wai Avenue, Hu Jia Lou, Chao Yang District, Beijing, 100020, P.R. China	Sale of devices for management of asthma	100%

All subsidiary undertakings are included in the consolidation. The proportion of the voting rights in the subsidiary undertakings held directly by the Parent Company does not differ from the proportion of ordinary shares held. The Parent Company does not have any shareholdings in the preference shares of subsidiary undertakings included in the Group.

18. Investment in joint venture

	2018 £m	2017 £m
At 1 January	0.5	0.9
Share of loss	(0.1)	(0.2)
Distributions to owners	(0.3)	(0.2)
At 31 December	0.1	0.5

The joint venture listed below has share capital consisting solely of ordinary shares, which is held directly by the Group.

Nature of investment in joint venture 2018 and 2017:

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.

Adiga Life Sciences 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 overleaf is the summarised financial information for Adiga which is accounted for using the equity method.

Summarised statement of financial position at 31 December

	2018 £m	2017 £m
Current assets		
Trade and other receivables	0.1	0.8
Cash	0.1	0.2
	0.2	1.0
Net assets	0.2	1.0

Summarised statement of comprehensive income for the year ended 31 December

	2018 £m	2017 £m
Revenue	–	0.1
Research and development costs	–	(1.0)
Administrative expense	(0.2)	(0.1)
Loss from operation	(0.2)	(1.0)
Income tax	–	0.6
Post tax loss from operation	(0.2)	(0.4)

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 Pharmaceuticals plc. As the allergy programmes are no longer being continued, the results of the joint venture for the year ended 31 December 2018 and 2017 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	2018 £m	2017 £m
Opening net assets 1 January	1.0	1.8
Loss for the year	(0.2)	(0.4)
Dividends paid	(0.6)	(0.4)
Closing net assets	0.2	1.0
Interest in joint venture @ 50%	0.1	0.5
Carrying value	0.1	0.5

19. Inventories

	2018 £m	2017 £m
Finished goods	4.2	5.0

Inventories recognised as an expense during the year ended 31 December 2018 amounted to £7.5 million (2017: £8.5 million). These were included in 'Cost of sales'.

Write-down of inventories to net realisable value amounted to £0.5 million (2017: £0.9 million). These were recognised as an expense during the year and included in 'Cost of sales'. There has been no reversal of any write down in the year ended 31 December 2018.

20. Trade and other receivables

	Group		Company	
	2018 £m	2017 £m	2018 £m	2017 £m
Trade receivables	3.7	3.7	–	–
Prepayments and accrued income	3.9	6.0	–	–
Other receivables	0.5	9.2	0.9	0.7
Receivables from subsidiary undertakings	–	–	281.7	327.5
Total trade and other receivables	8.1	18.9	282.6	328.2

Included within trade receivables is £0.4 million (2017: £0.7 million) of invoices that were more than 30 days 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 operations and studies and future profitability of subsidiary undertakings. As at 31 December 2018, an expected credit loss of £91.4 million (2017: £nil) was recognised against receivables from subsidiary undertakings.

The carrying amounts of the Group and Company receivables, excluding prepayments and recoverable taxes, are denominated in the following currencies:

	Group		Company	
	2018 £m	2017 £m	2018 £m	2017 £m
British pound sterling	0.7	0.2	181.7	263.4
United States dollar	3.7	7.0	100.9	64.8
Swedish krona	0.1	0.1	–	–
Euro	1.8	1.6	–	–
	6.3	8.9	282.6	328.2

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

	Group		Company	
	2018 £m	2017 £m	2018 £m	2017 £m
Short-term bank deposit, with original maturity:				
More than 3 months	–	15.0	–	15.0
Total short-term bank deposits	–	15.0	–	15.0
Cash and cash equivalents:				
Cash at bank and in hand	40.7	44.5	0.1	0.3
Total cash and cash equivalents	40.7	44.5	0.1	0.3

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	
	2018 £m	2017 £m	2018 £m	2017 £m
AA	0.6	0.3	–	–
AA-	31.4	19.3	0.1	0.3
A+	–	20.1	–	–
A	7.1	19.8	–	15.0
BBB	1.6	–	–	–
	40.7	59.5	0.1	15.3

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

	Group		Company	
	2018 £m	2017 £m	2018 £m	2017 £m
British pound sterling	23.2	39.6	0.1	15.3
United States dollar	13.0	16.6	–	–
Canadian dollar	–	0.2	–	–
Euro	4.0	2.6	–	–
Swedish krona	0.5	0.5	–	–
	40.7	59.5	0.1	15.3

22. Trade and other payables

	Group		Company	
	2018 £m	2017 £m	2018 £m	2017 £m
Payable within one year				
Trade payables	19.1	22.7	0.1	0.1
Social security and other taxes	0.3	0.3	–	–
Accruals	7.6	6.7	0.5	0.2
Other payables	1.7	1.1	–	–
Payables to subsidiary undertakings	–	–	5.5	3.7
Total trade and other payables	28.7	30.8	6.1	4.0
Payable after one year				
Trade payables	–	20.4	–	–
Total non-current trade payables	–	20.4	–	–

Non-current trade payables in 2017 related to an R&D contribution payable to AZ on 31 December 2019. As at 31 December 2018 the amount is due within 1 year therefore the balance has been reclassified as current trade payables.

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:

Assets	2018 £m	2017 £m
Cash and cash equivalents	40.7	44.5
Short-term bank deposits	–	15.0
Trade and other receivables	8.1	8.9
Financial assets held at amortised cost (2017: Loans and receivables)	48.8	68.4

Liabilities	2018 £m	2017 £m
Trade and other payables – current	28.7	29.9
Trade payables – non-current	–	20.4
Non-contingent consideration – current	80.3	–
Non-contingent consideration – non-current	–	68.7
Contingent consideration – current	15.4	–
Contingent consideration – non-current	46.2	33.6
Financial liabilities held at amortised cost	170.6	152.6

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

Assets	2018 £m	2017 £m
Cash and cash equivalents	0.1	0.3
Short-term bank deposits	–	15.0
Other receivables	0.9	0.7
Receivable from subsidiary undertaking	281.7	327.5
Financial assets held at amortised cost (2017: Loans and receivables)	282.7	343.5

Liabilities	2018 £m	2017 £m
Trade and other payables – current	0.6	0.3
Payables to subsidiary undertakings	5.5	3.7
Financial liabilities held at amortised cost	6.1	4.0

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 IFRS 9 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 2018 or 31 December 2017.

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
As at 1 January 2017	31.9	(16.6)	15.3
(Credit)/charge to the income statement	(7.8)	0.9	(6.9)
As at 31 December 2017	24.1	(15.7)	8.4
As at 1 January 2018	24.1	(15.7)	8.4
Credit to the income statement	(13.2)	(3.4)	(16.6)
As at 31 December 2018	10.9	(19.1)	(8.2)

The £3.4 million credit to the income statement in relation to tax losses consists of a £8.2 million credit relating to the recognition of a deferred tax asset for expected future profits generated by Circassia AB, and a £4.8 million charge relating to the derecognition of a deferred tax asset held by Prosonix Limited due to no future taxable profits expected to be generated.

	2018 £m	2017 £m
Deferred tax liabilities	10.9	24.1
Deferred tax assets	(19.1)	(15.7)
Total deferred tax position	(8.2)	8.4

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

	2018 £m	2017 £m
Losses	58.0	60.3
Total unrecognised deferred tax asset	58.0	60.3

25. Ordinary shares

Authorised, called up and fully paid	2018 £m	2017 £m
357,286,434 (2017: 333,466,262) ordinary shares of 0.08p each	0.3	0.3

On 18 July 2018, Circassia Pharmaceuticals plc issued 23,725,800 ordinary shares with a value of £20.4 million to AstraZeneca such that AstraZeneca's holding increased from 14.2% to 19.9%. Costs of £0.1 million related to the deal which are offset against the share premium reserve.

Movements in ordinary shares

	Number of shares	Par value £m
As at 1 January 2018	333,466,262	0.3
Share issue to AZ	23,725,800	–
Employee share scheme issues	94,372	–
As at 31 December 2018	357,286,434	0.3

26. Share based payments

Share options

Options have been awarded under the Circassia PSP Share Option Scheme (“the PSP Scheme”) and the Circassia Unapproved Share Option Scheme (“the Unapproved Scheme”).

The share options outstanding can be summarised as follows:

	2018 Number of ordinary shares (‘000)	2017 Number of ordinary shares (‘000)
PSP Scheme ¹	10,671	8,855
Unapproved Scheme ²	187	187
	10,858	9,042

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.

¹ 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.

² 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:

	2018 Number (‘000)	2018 Weighted average exercise price (£)	2017 Number (‘000)	2017 Weighted average exercise price (£)
Outstanding at 1 January	9,042	0.05	7,661	0.06
Granted	5,103	0.0008	4,141	0.0008
Expired	–	n/a	–	n/a
Forfeited/lapsed	(3,129)	0.0007	(1,879)	0.0003
Exercised	(158)	0.0005	(881)	0.0008
Outstanding at 31 December	10,858	0.04	9,042	0.05
Vested and exercisable at 31 December	762	0.59	535	0.84

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

Scheme	Grant year	Expiry year	Exercise price (£)	2018 Number (‘000)	2017 Number (‘000)
PSP 2014	2014	2024	0	284	348
PSP 2015	2015	2025	0.0008	291	1,925
PSP 2016	2016	2026	0.0008	2,510	2,760
PSP 2017	2017	2027	0.0008	3,029	3,822
PSP 2018	2018	2028	0.0008	4,557	–
Unapproved	2013 – 2014	2023 – 2024	2.416	187	187
Total				10,858	9,042

The weighted average remaining contractual life of share options outstanding at the end of the year was 8.4 years (2017: 8.4 years).

Options exercised in 2018 resulted in 158,044 (2017: 880,532) shares being issued at a weighted average price of £0.0005 (2017: £0.0008) each. The related weighted average share price at the time of exercise was £0.74 (2017: £0.88) per share.

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 Unapproved Scheme options granted during the year (2017: nil), all options granted in previous years were valued using the Black Scholes model.

Black Scholes

There were no options granted during the year (2017: 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:

	2018 £m	2017 £m
Exercise price	£0.0008	£0.0008
Share price	£0.90	£0.96
Expected volatility	35%	30%
Expected life	3 years	3 years
Expected dividends	0%	0%
Risk free interest rate	0.89%	0.1%

The Monte Carlo Simulation model has been used to value the portion of the awards which have a market performance vesting condition (Total Shareholder Return (TSR)). The model incorporates a discount factor reflecting this performance condition into the fair value of this portion of the award.

The weighted average fair value of options granted during the year determined using the Monte Carlo Simulation model at the grant date was £0.90 per option (2017: £0.75).

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 2018 and 31 December 2017.

Deferred shares

During the year the Group awarded nil (2017: nil) deferred shares to Executive Directors as part of a deferred bonus for 2018. 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.

27. Share premium

Group and Company	2018 £m	2017 £m
At 1 January	602.2	563.8
Issue of new shares	20.4	40.0
Expenses relating to share issue	(0.1)	(1.6)
At 31 December	622.5	602.2

28. (Accumulated losses)/retained earnings

	Group		Company	
	2018 £m	2017 £m	2018 £m	2017 £m
At 1 January	(394.9)	(295.8)	1.9	0.4
(Loss)/profit for the year	(117.1)	(99.1)	(291.8)	1.5
At 31 December	(512.0)	(394.9)	(289.9)	1.9

29. Other reserves

Group	Share option reserve £m	Translation reserve £m	Treasury shares reserve £m	Transactions with non-controlling interests £m	Total other reserves £m
At 1 January 2017	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
At 31 December 2017	8.9	15.1	(0.7)	(6.1)	17.2
Employee share option scheme	2.7	–	–	–	2.7
Currency translation differences	–	(4.8)	–	–	(4.8)
At 31 December 2018	11.6	10.3	(0.7)	(6.1)	15.1

Company	Share option reserve £m	Total other reserves £m
At 1 January 2017	6.1	6.1
Employee share option scheme	2.5	2.5
At 31 December 2017	8.6	8.6
Employee share option scheme	2.7	2.7
At 31 December 2018	11.3	11.3

30. Cash used in operations

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

	Group		Company	
	2018 £m	2017 Restated ¹ £m	2018 £m	2017 £m
(Loss)/profit from continuing operations before tax	(55.8)	(74.2)	(291.8)	1.5
Loss from discontinued operation before tax	(78.8)	(45.9)	–	–
Loss before tax	(134.6)	(120.1)	(291.8)	1.5
Adjustment for:				
Interest income	(0.3)	(0.4)	(0.2)	(0.3)
Interest expense	12.0	2.8	(4.6)	1.5
Depreciation (note 8)	0.6	0.8	–	–
Amortisation (note 8)	3.8	4.1	–	–
Goodwill impairment charge (note 15)	4.4	–	–	–
Intangible assets impairment charge (note 16)	70.6	37.0	–	–
Profit on sale of fixed assets	(0.1)	–	–	–
Impairment of investments (note 17)	–	–	210.3	–
Share of joint venture loss (note 18)	0.1	0.2	–	–
Fair value gain on contingent royalty consideration	1.1	(3.2)	–	–
Change in fair value of deferred consideration	(5.4)	–	–	–
Share based payment charge (note 5)	2.7	2.5	–	–
Foreign exchange on non-operating cash flows	6.7	(8.5)	6.2	(3.5)
Changes in working capital:				
Decrease/(increase) in trade and other receivables	10.9	(11.4)	(0.1)	1.2
Increase/(decrease) in credit loss provision	0.1	(0.2)	91.4	–
Increase in inventories	(0.1)	–	–	–
(Decrease)/increase in trade and other payables	(23.8)	30.0	0.5	–
Cash (used in)/generated from operations	(51.3)	(66.4)	11.7	0.4

¹ Restated to show the results of the respiratory business as discontinued. See note 10 for details.

In the statement of cash flows, proceeds from sale of property, plant and equipment comprise:

	2018 £m	2017 £m
Net book amount (note 14)	0.4	–
Profit on disposal of property, plant and equipment	0.1	–
Proceeds from disposal of property, plant and equipment	0.5	–

31. Contingent liabilities

There were no contingent liabilities at 31 December 2018 or at 31 December 2017.

During 2017, the Group received a notification about an arbitration claim raised for up to \$4.0 million for the non-performance of certain obligations of the contract against one of the subsidiary companies. On 4 October 2018, a settlement of \$2.5 million was agreed. As at 31 December 2018, \$1.5 million remains unpaid and is recognised within accruals.

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:

	2018 £m	2017 £m
Due within one year	1.2	0.8
Due between one and five years	1.4	1.8
Over five years	1.1	0.5

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 £1.3 million (2017: £1.5 million).

33. Commitments

As per the signed Tudorza[®] transition services agreement, on the date that the Tudorza[®] NDA and sNDA are transferred to Circassia Limited, Circassia Limited has the commitment to purchase from AstraZeneca any remaining Tudorza[®] inventory and replenishment stock, up to a maximum of one batch. The maximum payable is \$1.4 million.

There were no capital commitments as at 31 December 2017.

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 2018 are as follows: Invesco Asset Management (24.1% of total voting rights); Woodford Investment Management (23.8% of total voting rights); AstraZeneca PLC (19.9% of total voting rights); OppenheimerFunds Inc (7.9% of total voting rights); Imperial Innovations Businesses LLP (7.4% of total voting rights); Neptune Investment Management (6.1% of total voting rights).

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

Related party	2018 Purchases £'000	2017 Purchases £'000	2018 Payables £'000	2017 Payables £'000
Adiga Life Sciences (Joint venture)	–	330	–	–
Touchstone Innovations ¹	–	46	–	–

¹ 'Purchases' include compensation paid or payable in respect of services provided by Russell Cummings as Non-Executive Director of the Company.

Company

The following transactions with subsidiaries occurred in the year:

Related party	2018 £m	2017 £m
Rendering of services to Circassia Limited ¹	1.2	1.2
Settlement of liabilities on behalf of the subsidiaries	(2.5)	(2.8)
Net transfer of funds to subsidiaries	89.2	69.8
Deed of assignment transfer	–	42.1
	87.9	110.3

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

	2018 £m	2017 £m
Balances due from subsidiary companies	281.7	327.5
Balances due to subsidiary companies	(5.5)	(3.7)

The amounts due are unsecured and have no fixed date of repayment. Interest is charged at a rate of LIBOR + 4%.

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 2018 (2017: £nil).

No shares were purchased by the Trust during the year ended 31 December 2018 (2017: 373,299). As at 31 December 2018 a cash balance of £4,733 (2017: £4,733) was held by the Trust.

35. Business combinations

Duaklir®

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

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) took place in 2018, with approval granted on 29 March 2019. Circassia Pharmaceuticals plc 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 third-parties 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 17.0% (2017: 20.5%).

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 was 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

The net sales report was received from AstraZeneca on 23 October 2018 and the net sales for the 12 month period to 30 September 2018 exceeded the minimum sales requirement. The threshold was met and therefore Circassia Limited had the ability to exercise the option. On this date, Circassia Limited had substantive rights to exercise the option, and therefore this is the date that Circassia Pharmaceuticals plc had control over the Tudorza® business.

Circassia Limited exercised the option on 11 December 2018. Based on the net sales achieved, further consideration of \$25 million is payable to AstraZeneca within 30 days of Duaklir® approval. Of the maximum \$25 million payable, \$20 million is contingent on the approval of Duaklir®. Under the terms of the agreement, the completion date was 31 December 2018, at which point the licence will transfer to Circassia Limited.

The future royalty payments to third-parties on Tudorza® 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 Tudorza® 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 19.0%.

	2018 £m	2017 £m
Consideration		
Ordinary share capital 47,355,417 shares at £0.0008	–	–
Share premium	40.0	40.0
Deferred non-contingent consideration	77.9	71.4
Contingent Duaklir® royalty consideration	39.7	39.7
Deferred contingent consideration	14.2	–
Contingent Tudorza® royalty consideration	2.7	–
	174.5	151.1
Recognised amounts of identifiable assets acquired		
Duaklir® IPR&D	33.3	33.3
Duaklir® royalty IPR&D	39.7	39.7
Tudorza® CMP	94.7	–
Tudorza® royalty CMP	2.7	–
Total identifiable net assets	170.4	73.0
AZ collaboration goodwill (Duaklir®)	0.2	0.2
AZ collaboration goodwill (Tudorza®)	3.9	–
Prepayment for Tudorza® business combination	–	77.9
	174.5	151.1

The value of the contingent and non-contingent consideration payable on exercise of Tudorza® was calculated by discounting the liability using a pre-tax discount rate of 5.4%.

	2018 £m	2017 £m
Deferred non-contingent consideration		
At 1 January	68.7	71.4
Additional non-contingent consideration payable on exercise of Tudorza®	3.7	–
Unwinding of discount	3.5	2.7
Foreign exchange movement	4.4	(5.4)
At 31 December	80.3	68.7
Deferred contingent consideration		
At 1 January	–	–
Consideration payable on exercise of Tudorza®	14.2	–
Unwinding of discount	0.1	–
Foreign exchange movement	0.3	–
At 31 December	14.6	–
Contingent Duaklir® royalty consideration		
At 1 January	33.6	39.7
Unwinding of discount	7.0	–
Change in fair value	1.1	(3.2)
Foreign exchange movement	2.4	(2.9)
At 31 December	44.1	33.6
Contingent Tudorza® royalty consideration		
At 1 January	–	–
Consideration payable on exercise of Tudorza®	2.7	–
Unwinding of discount	0.1	–
Foreign exchange movement	0.1	–
At 31 December	2.9	–

Duaklir® and Tudorza® royalties payable within 1 year amount to £0.0 million and £0.8 million respectively (2017: £nil and £nil).

Until the Tudorza® option completion date, the Group promoted 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 Pharmaceuticals Inc. In 2018 revenue recognised for rendering this service was £20.9 million (2017: £19.0 million).

A £5.4 million gain on change in fair value of the deferred non-contingent consideration between date of the initial business combination and Tudorza® option exercise is included in 'Other (losses)/gains' in the income statement. This gain has arisen due to the unwinding of the discount on the consideration payable between initial recognition on 12 April 2017 and 23 October 2018, being the date that Circassia Limited had the substantive rights to exercise the option. This is offset by a £2.7 million loss due to fluctuations in foreign exchange. See note 6.

Changes in fair value and foreign exchange movements relating to contingent Duaklir® and Tudorza® royalty consideration are included in 'Other (losses)/gains' in the income statement. See note 6.

Changes in future Duaklir® and Tudorza® sales might result in a significantly higher or lower fair value of contingent 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 £4.4 million lower or higher fair value of the liability. 10% higher or lower Tudorza® sales would result in £0.3 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® and Tudorza® 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:

Duaklir®

Valuation model	Discounted cash flow
Anticipated launch dates	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	17 years
Discount rate	2018: 17.0% 2017: 20.5%

Tudorza®

Valuation model	Discounted cash flow
Anticipated launch dates	Product already launched with Circassia Pharmaceuticals plc full ownership from 1 January 2019
Sales value, volume and growth rates	Estimates of sales value, volume and growth rates are internal forecasts based on previous product performance and market research commissioned by the Company
Period of specified projected cash flows	7 years
Discount rate	2018: 19.0%

On 1 September 2017, a deed of assignment was signed between Circassia Pharmaceuticals plc and Circassia Limited and Circassia Limited was assigned all rights, powers, interests and benefits of the agreement. Under the terms of the agreement, Circassia Limited had the option to secure the remaining commercial rights and economic benefits of Tudorza® based on the sales performance of Tudorza® in the preceding 12 month period.

36. Events occurring after the reporting date

On 24 January 2019, Circassia Pharmaceuticals plc announced that Circassia Limited had entered into a definitive agreement with AIT Therapeutics Inc. (“AIT”) to acquire the exclusive commercialisation rights from to its ventilator compatible nitric oxide product, AirNOvent, in the United States and China.

Under the terms of the agreement, the consideration is structured as follows:

- Circassia Pharmaceuticals plc issued 12,300,971 ordinary shares with a value of \$7.35 million to AIT;
- Circassia Pharmaceuticals plc issued 5,271,844 ordinary shares with a value of \$3.15 million to AIT following the successful completion of a pre-submission meeting with FDA;
- Circassia Limited will pay AIT \$12.6 million upon the sooner of the product’s US launch in PPHN or 90 days post FDA approval;
- Circassia Limited will pay AIT \$8.4 million upon label expansion in a related indication in the US;
- Circassia Limited will pay AIT \$1.05 million on launch in China.

Financial calendar

- Annual General Meeting:
7 June 2019
- Interim results for the six months
ending 30 June 2019:
Q3 2019

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

This is not a recommendation to buy or sell shares. The price of shares can go down as well as up, and you are not guaranteed to get back the amount that you originally invested.

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Forward-looking statements

This Annual Report and Accounts contains certain projections and other forward-looking statements with respect to the financial condition, results of operations, businesses and prospects of Circassia. The use of terms such as “may”, “will”, “should”, “expect”, “anticipate”, “project”, “estimate”, “intend”, “continue”, “target” or “believe” and similar expressions (or the negatives thereof) are generally intended to identify forward-looking statements. These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors that could cause actual results or developments to differ materially from those expressed or implied by these forward-looking statements. Any of the assumptions underlying these forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in the forward-looking statements may not actually be achieved. Nothing contained in this Annual Report and Accounts 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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