

Transforming our business

Circassia Group plc

(formerly Circassia Pharmaceuticals plc)
Annual Report and Accounts 2019

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Circassia in brief

Circassia is a leading medical device business focused on respiratory disease. The Company sells its market-leading NIOX[®] asthma management products directly to specialists in the United States, United Kingdom, China, Germany and Italy, and in a wide range of other countries through its network of distribution partners. Circassia also has the US and Chinese commercial rights to the late-stage ventilator-compatible nitric oxide product LungFit[™] PH. For more information please visit www.circassia.com.

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Strategic report

Executive Chairman's statement

The Company looks beyond this period of disruption with great optimism.

Good progress was made during 2019, increasing sales, controlling underlying costs and reducing net cash outflow. Notably, NIOX® maintained its impressive growth with sales increasing in all its direct markets and across its partner territories. Whilst revenues have been impacted during the recent pandemic, the potential for the underlying NIOX® business remains highly encouraging.

While NIOX® continued to advance, progress in the Company's COPD (chronic obstructive pulmonary disease) portfolio was more nuanced. Tudorza® revenues increased significantly during 2019, reflecting the move to report full in-market sales as well as increased pricing and lower rebates in the second half. However, prescription numbers declined and Duaklir®'s launch proved challenging in a field dominated by major pharmaceutical groups. Consequently, the COPD business continued to make major losses, making the significant debt owed to AstraZeneca in relation to these two products unsustainable. As a result, on 27 May 2020 the Company transferred the products back to AstraZeneca and set off the debt in its entirety.

With this transformational transaction now complete, Circassia is well placed to become a self-sustaining, cash generative business once the effects of the COVID-19 pandemic pass over. During the ongoing pandemic, the Company's focus is firmly on maintaining its world-leading NIOX® business, serving its customers around the world as they support their patients with respiratory diseases. As restrictions lift, Circassia intends to return NIOX® to growth as quickly as possible, and with a strong underlying business and robust debt-free balance sheet the Company looks beyond the current period of disruption with great optimism.

To ensure access to liquidity during this period of disruption, the Company recently concluded an equity financing facility with two of its principal shareholders to allow it to access up to £5 million over the period to 30 November 2020 at a price of 24.6p per share. This provides the Company with access to additional funding should this be required in the coming months.

Ian Johnson
Executive Chairman

16 June 2020

Strategic report

Operational highlights

NIOX[®]

Continued strong revenue growth with sales increasing 27% to £34.6 million (2018 CER¹: £27.3 million)

Strong growth in all direct markets

Post-period update

COVID-19 impact has been significant, but varied by market

Q1 2020 sales excluding China decreased 4% (CER, reflecting 3 weeks of lockdown in most direct markets in March)

China sales fell 66% in Q1 (CER) following two months of lockdown

April and May revenues below 50% of prior year as a result of COVID-19 impact

Some early signs of recovery in several markets although revenues remain well below 2019 level

Alternative performance measures have been used within the strategic report to aid comparisons between financial years. A reconciliation between these and the statutory figures is presented on pages 144 to 145.

¹ Constant exchange rates (CER) for 2019 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 Excludes depreciation and amortisation

³ Includes cash, cash equivalents and short-term deposits

* LungFit[™] PH is not an approved name and may not be the final commercial name

COPD portfolio

Tudorza[®]

Net in-market sales totalled £27.0 million vs 2018 collaboration revenues of £21.5 million (CER)

H2 2019 revenue growth driven by price increase and rebate reductions

Modest fall in prescriptions with decline greater during H2 2019

Duaklir[®]

NDA approved H1 2019 with launch Q4 2019

Challenging launch in market dominated by 'big pharma' competitors

Post-period portfolio update

Strategic review determined COPD business unsustainable

Transformational agreement with AstraZeneca to return products and set off related debt of \$149.9 million

Revenue levels largely unaffected by COVID-19

LungFit[™] PH* (formerly AirNOvent)

US and China commercial rights acquired to late-stage nitric oxide product from BeyondAir (formerly AIT)

Notice received alleging termination and breach of agreement refuted in strongest terms

Post-period update

BeyondAir anticipates US filing Q2 2020

Legal team continues to defend rights under agreement

Strategic report

Financial highlights

Key performance indicators £m	2019 underlying continuing operations	2018 underlying continuing operations	2019 total	2018 total
Revenue	£62.4m	£48.3m	£62.4m	£48.3m
R&D costs ²	(£6.4m)	(£8.6m)	(£96.8m)	(£87.2m)
G&A costs ²	(£11.9m)	(£11.1m)	(£13.0m)	(£11.5m)
S&M costs ²	(£55.7m)	(£52.5m)	(£55.7m)	(£55.4m)
EBITDA	(£27.8m)	(£32.8m)	(£119.3m)	(£114.7m)
Loss for the year	(£39.0m)	(£25.9m)	(£48.3m)	(£117.1m)
Net cash outflow	(£13.7m)	(£18.8m)	(£13.7m)	(£18.8m)
Cash ³ at year end	£27.0m	£40.7m	£27.0m	£40.7m

+27%

NIOX® sales increased 27%
to £34.6 million

(2018 CER¹: £27.3 million)

£62.4m

Revenues increased by
£14.1 million to £62.4 million

(2018: £48.3 million)

£27.0m

Cash³ at year end was
£27.0 million

(2018: £40.7 million)

£13.7m

Net cash outflow reduced
to £13.7 million

(2018: £18.8 million)

Strategic report

Operating review

Strategic overview

During 2019, the Company increased revenues and reduced its net cash outflow compared with the prior year. Notably, the NIOX[®] business continued its upward trajectory with growth in all of its direct markets, while a number of new distribution partners, approvals and launches extended its global reach.

The Company also achieved growth in its COPD business. This reflects the move to record Tudorza[®]'s full in-market sales versus collaboration revenues the prior year, as well as a price increase and rebate reductions in the second half. However, this progress was offset by a challenging launch for Duaklir[®], ongoing operating losses across the COPD portfolio and significant debt owed to AstraZeneca relating to the products. Consequently, the Board conducted a strategic review of the COPD business, which concluded it was unsustainable under all reasonable scenarios. As a result, the Company entered discussions with AstraZeneca and reached agreement to return the products and set off the associated debt in its entirety.

This transformational transaction completed on 27 May 2020, leaving the Company in a strong position with a robust, debt-free balance sheet, market-leading global NIOX[®] products and a clear strategy to grow the business. With a renewed focus on NIOX[®], the Company intends to expand its footprint geographically, enhance its customer offering to drive product utilisation and place greater emphasis on the use of NIOX[®] by clinical research organisations and in other alternative channels. By pursuing this focused strategy, the Company looks forward to transforming into a high-growth, cash-generative, profitable business.

The Company increased revenues and significantly reduced its net cash outflow compared with the prior year.

With a renewed focus on NIOX[®], the Company intends to expand its footprint geographically, enhance its customer offering to drive product utilisation and place greater emphasis on the use of NIOX[®] by clinical research organisations and in other alternative channels.

NIOX[®] asthma management products

NIOX[®] is a simple-to-use point-of-care system used around the world to help improve asthma diagnosis and management. NIOX[®] directly measures the nitric oxide exhaled in patients' breath (fractional exhaled nitric oxide or FeNO), which is an important biomarker of the major underlying cause of asthma, type 2 airway inflammation. Circassia commercialises NIOX[®] through the sale of the core FeNO measurement device, which then generates high margin recurring revenues for sensors and consumables on a per test basis. NIOX[®] is sold directly by Circassia's commercial teams in the United States, China, UK and Germany. In addition, Circassia sells NIOX[®] in nearly 50 additional countries around the world through its international network of distribution partners.

NIOX[®] represents a significant commercial opportunity for Circassia, with the global respiratory diagnostics market valued at \$4.4 billion in 2018 and with an estimated compound annual growth rate (CAGR) of 6.6%. NIOX[®] is the leader in the FeNO testing market and revenues continued to grow, achieving a CAGR of 14% between 2016 and 2019. The Company intends to consolidate this leading position through geographical expansion, improved customer and technical services ensuring customers can maximise throughput and an increased focus on uptake in clinical studies and other alternative channels.

NIOX[®] directly measures the nitric oxide exhaled in patients' breath (fractional exhaled nitric oxide or FeNO), which is an important biomarker of the major underlying cause of asthma, type 2 airway inflammation.

\$4.4bn

NIOX[®] represents a significant commercial opportunity for Circassia, with the global respiratory diagnostics market valued at \$4.4 billion in 2018 and with an estimated compound annual growth rate (CAGR) of 6.6%.

Strategic report

Operating review, continued

Increasing sales

During 2019, NIOX® sales enjoyed continued strong growth. Global revenues of £34.6 million were 27% higher than 2018 at constant exchange rates (CER), reflecting increases in each of the Company's key markets. The Company's revenues in China grew 136% year on year benefitting from the very significant investment in direct resources. In the US, NIOX® sales ended the year 14% ahead of the previous year, and the UK and German markets were 23% and 5% higher respectively (CER). The Company's partner markets also performed well, with revenues increasing by 21% compared with the prior year (CER). Overall clinical sales for use by healthcare professionals were 31% higher in 2019 (CER), while less predictable research sales for use in clinical studies were down modestly (5% at CER).

The performance of the NIOX® business in 2019 indicates that the business is one which is capable of delivering very attractive growth rates and, whilst it is currently being significantly impacted by the reduction in routine testing of asthma patients as a result of COVID-19, the Board has considerable optimism in the underlying growth opportunities over the medium term and beyond.

Post-period performance

In the first five months of 2020 NIOX® revenues were impacted in nearly all markets during the COVID-19 outbreak, although the extent varied by territory and timing of local restrictions. Global revenues declined 34% compared with the same period in 2019, largely driven by falls of 69% in China and 62% in research sales. Revenues in the US and UK slowed, decreasing 36% and 21% respectively. The impact was lesser in Germany and partner markets, where sales were only 11% and 7% lower than the same period in 2019. In April and May 2020, revenues recovered modestly in a number of countries as restrictions were gradually lifted, but remained well below the same period in 2019 at both a global and local level. While it remains highly challenging to predict revenue trajectory, early signs of recovery in certain markets offer some signs of encouragement.

£34.6m

During 2019, NIOX® sales enjoyed continued strong growth

Global revenues of £34.6 million were 27% higher than 2018 at constant exchange rates (CER), reflecting increases in each of the Company's key markets.

As a result of the coronavirus-related downturn, the Company anticipates that the NIOX® business will burn cash for a period before becoming both profitable and cash generative in the medium term.

On 2 June 2020, the Company announced that it had concluded an equity financing facility with two of its principal shareholders to allow it to access up to £5 million until 30 November 2020 at a price of 24.6p per share. This provides the Company with access to additional funding should this be required in the coming months.

Market expansion

Throughout 2019, Circassia maintained its focus on increasing market penetration in its direct sales territories. In the United States, payor coverage reached approximately 80% of insured lives, providing nearly 235 million Americans with access to NIOX®, and the Company was awarded a group purchasing agreement by leading healthcare improvement company, Premier Inc.

In China, the team maintained its focus on market access. During the year, reimbursement coverage for FeNO testing continued to grow and now covers 16 provinces. In the UK the Company continued its 'Asthma Masterclass' programme to drive wider adoption in primary care. Circassia has also rolled out a new European promotional campaign featuring representative materials, website optimisation and syndicated social media content.

In addition to the market access activities in the Company's direct sales territories, Circassia continued to expand its global reach. NIOX® received a number of new approvals, including recently in Brazil, and the Company added new distribution partners in several markets, such as Canada, Saudi Arabia and Chile. With launches in additional territories, Circassia's network of partners covers nearly 50 countries. In addition to expanding its international footprint, the Company continued its programme of support for partners' NIOX® promotion. This included the Company's annual partner meeting, which was held at the European Respiratory Society conference, and at the end of 2019 Circassia launched a new portal to provide easy access to marketing, training, medical and regulatory resources.

In addition to the market access activities in the Company's direct sales territories, Circassia continued to expand its global reach. NIOX® received a number of new approvals, including recently in Brazil, and the Company added new distribution partners in several markets, such as Canada, Saudi Arabia and Chile.

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Circassia's network of partners covers nearly 50 countries

In addition to expanding its international footprint, the Company continued its programme of support for partners' NIOX® promotion.

Strategic report

Operating review, continued

NIOX® innovation

In 2019, NIOX® received a number of awards in recognition of its contribution to healthcare. In the United States, the country's largest healthcare performance improvement company, Vizient Inc., presented Circassia with an Innovative Technology Supplier of the Year award for 2018, while in the UK the Association for Respiratory Technology & Physiology recognised the Company as a manufacturer of the year.

Circassia is building on its position as the market leader, and at the 2019 European Respiratory Society International Congress the Company launched the NIOX VERO® PLUS. This upgrade provides customers with major enhancements, with a significantly larger screen and intuitive new graphical interface, while retaining the core NIOX VERO® FeNO technology. Customer feedback at the launch was highly positive, and with the European CE marking completed the Company plans to roll out the upgrade in Europe initially.

United States COPD portfolio

Tudorza® (aclidinium bromide), a long-acting muscarinic antagonist (LAMA), and Duaklir® (aclidinium bromide / formoterol fumarate), a LAMA / LABA combination (long-acting muscarinic antagonist / long-acting beta agonist), are both approved in the United States for the maintenance treatment of COPD. Throughout 2019 Circassia held the US commercial rights to the products under its 2017 agreement with AstraZeneca.

In the United States, the country's largest healthcare performance improvement company, Vizient Inc., presented Circassia with an Innovative Technology Supplier of the Year award for 2018.

The UK the Association for Respiratory Technology & Physiology recognised Circassia as a manufacturer of the year.

Tudorza®

At the end of 2018, Circassia exercised its option for the full US rights to Tudorza® and consequently recorded the product's total in-market sales throughout 2019. During the first half of the year the Company launched a dedicated COPD sales force, and at the end of June Tudorza®'s licence transferred to Circassia providing the opportunity to introduce new distribution, pricing and patient access strategies. Additionally, in H1 2019 the Food and Drug Administration (FDA) approved the expansion of Tudorza®'s label to include COPD exacerbation reduction data and data demonstrating cardiovascular safety in patients with cardiovascular disease / risk factors.

Tudorza® sales

During 2019, Tudorza® net in-market revenues totalled £27.0 million, compared with the £21.5 million recorded in 2018 (CER) under the Company's previous product collaboration with AstraZeneca. This significant increase reflects the difference in revenue reporting (collaboration revenue versus in-market sales), as well as an increase in the wholesale acquisition cost, reduction in rebates and move away from unfavourable contracts during the second half of the year. With the introduction of these measures, H2 2019 net revenues increased by 90% compared with H1 2019. However, despite this revenue growth prescriptions declined modestly during the year, with an acceleration in the last six months.

Duaklir®

In the first half of 2019, the FDA approved Duaklir® for sale in the United States. Its label includes exacerbation reduction data and a 24-hour profile demonstrating FEV1 improvement providing the product with a number of competitive advantages.

Throughout 2019 Circassia held the US commercial rights to the products under its 2017 agreement with AstraZeneca.

During 2019, Tudorza® net in-market revenues totalled £27.0 million, compared with the £21.5 million recorded in 2018 (CER) under the Company's previous product collaboration with AstraZeneca.

Strategic report

Operating review, continued

At the end of October 2019, the Company launched Duaklir® at the American College of Chest Physicians' CHEST Annual Meeting 2019 in New Orleans. With complementary positioning alongside Tudorza®, Circassia leveraged its newly introduced COPD business model and dedicated team to commercialise Duaklir® across the country.

Since its launch, Duaklir® prescriptions have struggled to gain traction in a market dominated by major multi-national pharmaceutical companies. As a result, revenues remain below expectations, with 2019 sales following the product's launch in October totalling £0.8 million.

Post-period update

Following the launch of Duaklir® the Company conducted a wide-ranging strategic review of its US COPD business. This concluded that despite the increase in Tudorza® revenues the portfolio continued to incur significant operating losses. Given these ongoing losses the Company would likely need to raise additional funding to support the business, with no certainty on what terms this would be available, if at all. The strategic review also considered a range of alternative courses, including greatly reducing the size and scale of the COPD business, but under all reasonable scenarios it remained highly unlikely Circassia would be able to refinance the loan owed to AstraZeneca, which with accrued interest totalled approximately \$150.9 million on the date of completion.

As a result, in April 2020 Circassia and AstraZeneca agreed to terminate the companies' 2017 development and commercialisation agreement relating to the products. Upon termination AstraZeneca acquired the US commercial rights to Tudorza® and Duaklir®, with the consideration equal to and set off against the entire loan and accrued interest owed by Circassia.

At the end of October 2019, the Company launched Duaklir® at the American College of Chest Physicians' CHEST Annual Meeting 2019 in New Orleans.

In April 2020 Circassia and AstraZeneca agreed to terminate the companies' 2017 development and commercialisation agreement relating to the products.

The transaction completed on 27 May 2020. Under the product acquisition agreement, Circassia will continue to sell Tudorza® and Duaklir® with the support of AstraZeneca until the end of March 2021, ensuring patient supply is uninterrupted. At the end of this run-off period the products will transfer to AstraZeneca.

This agreement will transform Circassia's business. Under the transfer arrangements agreed with AstraZeneca, Circassia anticipates that the COPD business will be cash positive during the run-off period, which will significantly reduce the Company's cash burn and allow it to focus its resources on expanding its world-leading NIOX® business. The transaction accelerates the Company's transition towards becoming a cash-generative, self-sustaining business.

LungFit™ PH (previously AirNOvent)

In January 2019, Circassia acquired the US and Chinese commercial rights to AirNOvent (now LungFit™ PH) from AIT Therapeutics Inc. (now BeyondAir Inc.). LungFit™ PH is a late-stage ventilator-compatible system that uses an electric voltage to produce nitric oxide from the nitrogen and oxygen in air. Inhaled nitric oxide is approved in the United States for use in the treatment of hypoxic respiratory failure associated with persistent pulmonary hypertension of the newborn (PPHN). PPHN is potentially fatal and its management can be complex, involving a number of treatments including the use of oxygen and inhaled nitric oxide.

Under the transfer arrangements agreed with AstraZeneca, Circassia anticipates that the COPD business will be cash positive during the run-off period, which will significantly reduce the Company's cash burn and allow it to focus its resources on expanding its world-leading NIOX® business.

Strategic report

Operating review, continued

Agreement status

Under the terms of the companies' agreement, Circassia issued BeyondAir \$10.5 million in new ordinary shares as consideration for upfront and milestone payments. Additional milestones, which are payable in cash or shares, include a payment of \$12.6 million on FDA approval in the treatment of hypoxic respiratory failure associated with PPHN, and a further \$1.05 million on the product's launch in China. Royalties will also be payable on gross profits from product sales.

Under the terms of the agreement, BeyondAir is responsible for the product's development, manufacture and US regulatory filing, and it currently anticipates submitting an application for Premarket Approval (PMA) in Q2 2020 for use in the treatment of PPHN. Circassia is responsible for the product's commercialisation following approval.

At the end of 2019, BeyondAir issued a notice stating that it had terminated the companies' agreement for material breach. Circassia strongly disputes and intends to challenge BeyondAir's allegations and its purported termination. The Company has retained counsel and intends to take steps to enforce its rights under the agreement.

Corporate progress

During the latter part of 2019, and the first months of 2020, Circassia has focused on building a self-sustaining business. It has made good progress, culminating in the recent transaction with AstraZeneca to transfer the Company's loss-making COPD business and focus its resources on its market-leading NIOX® products. The Company has also significantly strengthened its Board, transferred trading in its shares to AIM in February 2019 and changed its name to better reflect its business in May 2020.

During the latter part of 2019, and the first months of 2020, Circassia has focused on building a self-sustaining business.

Board changes

With the completion of the Company's transition into a commercially-focused business, the Board has evolved significantly to drive the next step in Circassia's development. During 2019, the Company's Senior Vice President of R&D, Rod Hafner, stepped down as an Executive Director following 11 years in the role. At the same time, the Company appointed Jonathan Emms as Chief Operating Officer to further strengthen its commercial expertise and oversee its operational and commercial strategy. Prior to joining Circassia, Jonathan was Chief Commercial Officer for Pfizer's Internal Medicines organisation and gained significant respiratory experience at GSK where he held a number of positions. Earlier in the year, Russ Cummings retired as a Non-Executive Director after 12 years in the role.

At the end of 2019, Circassia announced the retirement of CEO and Co-Founder, Steve Harris, after 13 years leading the Company, and of Chairman Dr Francesco Granata who had previously informed the Board of his intention to retire. Concurrently, Circassia appointed a highly-experienced life science company director, Ian Johnson, as Executive Chairman. He is currently Non-Executive Chairman of Redcentric PLC and a Non-Executive Director of Ergomed PLC. He was previously Executive Chairman of Bioquell PLC and Non-Executive Chairman of Quantum Pharma PLC, Cyprotex PLC and Celsis Group Ltd, following a number of years as CEO of Biotrace International PLC.

The Company's executive team was joined by new Chief Financial Officer Michael Roller in January 2020 following the previous CFO, Julien Cotta, stepping down from the role. Michael is a highly experienced Finance Director and life science company Director and was previously Group Finance Director of Bioquell PLC and Corin Group PLC.

With the completion of the Company's transition into a commercially-focused business, the Board has evolved significantly to drive the next step in Circassia's development.

Strategic report

Operating review, continued

At the start of March 2020, the Board was further strengthened with the addition of Garry Watts as Senior Independent Director and Non-Executive Director. Garry is an experienced Chairman and Director, is currently Non-Executive Chairman of Spire Healthcare Group PLC and was Chairman of BTG PLC until its sale to Boston Scientific in 2019.

The Board wishes to thank all of the previous directors for their significant contributions to the development of the Company over many years and welcomes the new team to Circassia.

The newly constituted Board brings significant commercial, corporate and financial expertise to the Company as Circassia drives towards self-sustainability, building shareholder value and a profitable cash-generative business.

Additionally, the Board wishes to thank the wider Circassia team for their hard work and considerable efforts during 2019 and in this ongoing time of significant change in the business and more broadly with the challenge of the ongoing coronavirus pandemic. Following the end of this period of disruption, the Board looks forward to greater stability when the Circassia team can continue its focus on building an exciting high-growth business.

Company name change

Following the agreement in April 2020 to transfer Tudorza® and Duaklir® to AstraZeneca, the Company sought shareholder approval to change its name to Circassia Group plc. This change reflects the transformation in the Company's business and its exclusive focus on its world-leading NIOX® products rather than pharmaceutical products. On 30 April 2020, shareholders granted permission and the name change has been formally adopted by the Company.

The newly constituted Board brings significant commercial, corporate and financial expertise to the Company as Circassia drives towards self-sustainability, building shareholder value and a profitable cash-generative business.



Following the agreement in April 2020 to transfer Tudorza® and Duaklir® to AstraZeneca, the Company sought shareholder approval to change its name to Circassia Group plc.

Summary and outlook

During 2019, Circassia continued to make progress, particularly in its core global NIOX® business where sales grew across all its key markets. While progress in the US COPD business was more nuanced, Tudorza® revenues increased following the introduction of targeted new strategies and the move away from the previous collaboration arrangement to full commercial control. However, this growth was tempered by a challenging launch for Duaklir®, ongoing losses across the COPD portfolio and significant debt relating to the products. As a result, the recent agreement to transfer the products back to AstraZeneca will immediately transform the Company and its prospects.

This transaction leaves Circassia debt-free with a robust balance sheet and provides the opportunity to focus its resources exclusively on growing its market-leading NIOX® business. With a strong commercial team and distribution partners in nearly 50 further countries, Circassia is well placed to pursue its goal of building a cash-generative, profitable business.

During the remainder of the year, the Company intends to build on this position, supporting its customers, controlling underlying costs and driving down corporate expenditure to further protect its balance sheet. While it remains challenging to predict short-term business performance during the coronavirus pandemic, early signs of recovery offer some encouragement and beyond this period of disruption the Company anticipates a return to strong revenue growth in the medium to long-term, creating value for customers, patients, employees and shareholders alike.

During 2019, Circassia continued to make progress, particularly in its core global NIOX® business where sales grew across all its key markets.

With a strong commercial team and distribution partners in nearly 50 further countries, Circassia is well placed to pursue its goal of building a cash-generative, profitable business.

Strategic report

Our stakeholders

Companies Act 2006 section 172(1) statement

Circassia believes that the success of the Group depends on positive engagement with its stakeholders. Reflecting this importance, the Board carefully considers the interests of its various stakeholder groups in its decision making. Through effective engagement, the Group aims to understand its stakeholders, allowing the Board to include issues that are important to each group in its discussions.

This approach to stakeholder engagement allows Circassia to continue supplying its important healthcare products to its patients and partners, providing high quality employment for colleagues, working effectively with suppliers, respecting the environment and local communities, maintaining high standards of professional conduct and building a sustainable, high value business for shareholders.

The following table sets out Circassia's main stakeholders, the areas of its business relating to each and the Group's engagement on the important issues. While the table provides a comprehensive overview, a number of the areas covered and the progress during the year, are explored in more detail in this Annual Report and Accounts, in particular in the Strategic Report and Corporate Governance sections.

Stakeholders

Patients, healthcare professionals and payors

Circassia provides innovative products to help healthcare professionals around the world improve patients' health. The success of the business is only possible by continuing to meet the high standards expected by these important customers.

Partners

In markets where Circassia has no direct presence its success relies on partners who provide its products to local healthcare professionals.

Employees

Circassia's worldwide team of employees drives the Group's business forward. These colleagues provide the broad range of expertise required to build a successful business.

Suppliers

Circassia outsources a number of important functions to a range of suppliers. In particular, the Group's products are manufactured and distributed by third-parties.

Local communities and environment

As a responsible business Circassia recognises the importance of local communities and the global environment to its success.

Shareholders

The support of the Company's shareholders is an important factor in building a strong, sustainable business. Shareholders also play a key role in monitoring and safeguarding Circassia's corporate governance.

Key factors	Engagement	2019 progress
– Effective products – High quality products – Safe products – Customer experience and support – Provide value	Circassia's products meet stringent regulatory requirements to ensure their safety and efficacy. The Group has dedicated teams of regulatory and quality experts supporting its product supply and provides a customer support service in the markets where it sells directly. Circassia prices its products to reflect the value they provide.	– Record product sales – Regulatory approvals and launches in several markets – Product upgrade launched to improve user experience
– Partnership approach – Promotional support – Robust product supply	Circassia works with an international network of partners to sell its products. Through its dedicated partner team the Group provides a range of promotional materials and commercial support, including an annual partnership meeting and holds regular updates to resolve any issues.	– New partners welcomed in several countries – Launch of new partner portal providing access to promotional materials and support – Annual partner meeting
– Opportunity to make a difference – Open communication – Development and progression – Flexible working – Diversity and inclusion	Circassia's employees are crucial to the ongoing provision of its important healthcare products and the whole team helps make a difference to patients' lives. The Group holds regular update meetings across the organisation and provides ongoing news updates. Circassia supports ongoing development of employees with annual plans and individual targets. The Group operates local flexible working and has a clear diversity and equality policy ensuring recruitment and progression is based on merit alone.	– Series of townhall update meetings for all employees – Local focus groups for employee feedback – Training on Code of Conduct and related policies, including diversity and equality – Annual development plans and flexible working policies implemented
– Long-term partnerships – Collaborative approach – Fair terms of business	The Group has a number of long-term collaborations with third-parties for the supply of its products. Circassia's supply chain team holds regular meetings with suppliers to ensure close working and treats its partners with respect and fairness.	– Dedicated supply chain team in place – Ongoing meetings with suppliers
– Quality employer – Contribution to science base – Minimal environmental impact	Circassia provides high quality, well remunerated employment in each of its local markets. The Group adheres to high standards of professional conduct and enforces a strict code of conduct. Circassia contributes to science in its area of expertise, providing healthcare training in a number of countries, and supporting clinical research through the provision of its products. As a business focused on commercialisation, the Group has a limited environmental impact, which it endeavours to minimise through a number of initiatives such as local recycling and home working policies.	– Broad range of quality employment – Expansion of Asthma Masterclass training for health workers – Recycling maintained across organisation
– Strategy and business model – Financial progress – Clear communication	Circassia meets with shareholders throughout the year to outline its strategy and business plans and provides the market with regular updates on its commercial and financial progress, including via its interim and annual reports. The Executive Chairman is available to meet shareholders and its Annual General Meeting provides all members with the opportunity to meet senior management.	– Series of investor meetings – Annual shareholder meeting – Publication of business updates

Strategic report

Strategy and business model

Strategy and objectives

Circassia's strategy has three components:

1. Market novel life sciences products directly in key markets and through partners elsewhere.
2. Pursue opportunities to build a portfolio of products where possible.
3. Deliver products to the market in support of strategic objectives 1 and 2.

The Group continues to pursue its objectives. It sells its NIOX[®] products directly in the US, China, UK and Germany, and has launched a modest sales presence in Italy. Circassia's products are also commercialised in nearly 50 additional countries by its network of partners.

The Group continues to consider business development opportunities where there is a strategic fit with its capabilities and a realistic prospect of success. Circassia also maintains a focus on innovation and launched its NIOX VERO[®] PLUS upgrade in the second half of 2019.

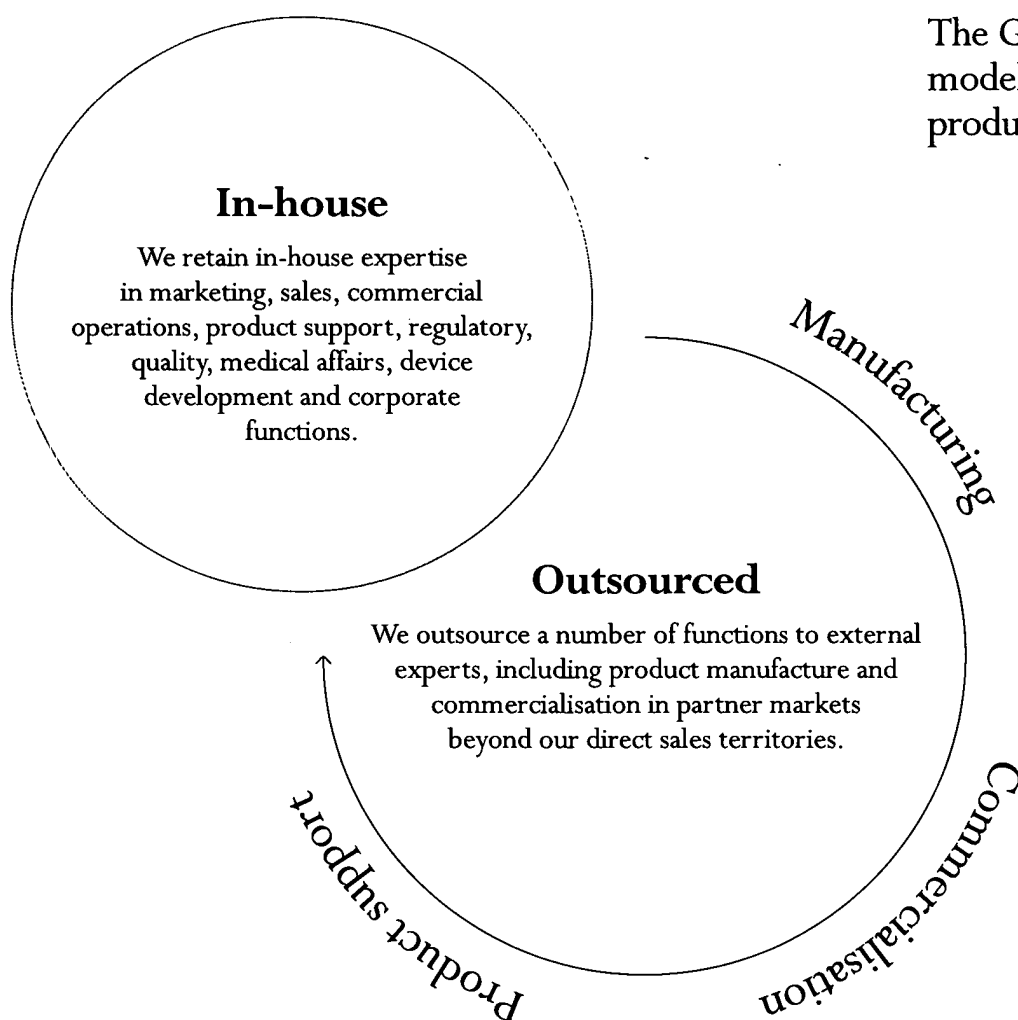
Business model

The Group's business model focuses resources on product commercialisation. Consequently, Circassia retains in-house expertise in marketing, sales, commercial operations, product support, regulatory, quality, medical affairs, device development and corporate functions. The Group outsources other areas of its business, including product manufacture and commercialisation in partner markets beyond its direct sales territories.

The Group continues to pursue its objectives. It sells its NIOX[®] products directly in the US, China, UK and Germany.

Circassia also maintains a focus on innovation and launched its NIOX VERO[®] PLUS upgrade in the second half of 2019.

The Group's business model focuses resources on product commercialisation.



Strategic report

Financial review

On 27 May 2020, the Group handed back the rights to its COPD products to AstraZeneca. The COPD business is presented below as a continuing activity of the Group as it did not meet the criteria at the balance sheet date to be classified as a discontinued operation. In 2020, it will be presented as a discontinued operation and the Group will report as continuing activities both the results of its NIOX[®] business and, separately, its corporate costs.

The table opposite sets out the Group's results for the year ended 31 December 2019, separated into continuing and discontinued operations. Continuing operations are further divided into underlying and non-underlying operations. Continuing underlying operations include revenues from sales of Tudorza[®], Duaklir[®] and NIOX[®], as well as the costs of the underlying business.

Non-underlying operations include irregular and non-recurring expenditure, such as those relating to the reorganisation of the Board and Senior Management Team 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.

In the coming year, the Group will be simplified in order to achieve its objective of becoming a profitable and cash generative business.

	2019					2018				
	Underlying operations £m	Non-underlying operations £m	Total continuing £m	Dis-continued operations ¹ £m	Total £m	Underlying operations £m	Non-underlying operations £m	Total continuing £m	Dis-continued operations ¹ £m	Total £m
Revenue	62.4	—	62.4	—	62.4	48.3	—	48.3	—	48.3
Cost of sales	(16.2)	—	(16.2)	—	(16.2)	(8.9)	—	(8.9)	—	(8.9)
Gross profit	46.2	—	46.2	—	46.2	39.4	—	39.4	—	39.4
Gross margin	74%	—	74%	—	74%	82%	—	82%	—	82%
Research and development	(19.1)	(90.4)	(109.5)	—	(109.5)	(10.8)	—	(10.8)	(78.6)	(89.4)
Sales and marketing	(57.5)	—	(57.5)	—	(57.5)	(54.4)	(2.9)	(57.3)	—	(57.3)
Administrative expenditure	(12.6)	(1.1)	(13.7)	—	(13.7)	(11.4)	(0.3)	(11.7)	(0.1)	(11.8)
EBITDA	(27.8)	(91.5)	(119.3)	—	(119.3)	(32.8)	(3.2)	(36.0)	(78.7)	(114.7)
Operating loss	(43.0)	(91.5)	(134.5)	—	(134.5)	(37.2)	(3.2)	(40.4)	(78.7)	(119.1)
Other gains and (losses)	(3.5)	97.5	94.0	—	94.0	1.9	(5.6)	(3.7)	(0.1)	(3.8)
Finance costs	(3.5)	(15.3)	(18.8)	—	(18.8)	(0.1)	(11.9)	(12.0)	—	(12.0)
Finance income	0.2	—	0.2	—	0.2	0.3	—	0.3	—	0.3
Loss before tax	(49.8)	(9.3)	(59.1)	—	(59.1)	(35.1)	(20.7)	(55.8)	(78.8)	(134.6)
Taxation	10.8	—	10.8	—	10.8	9.2	—	9.2	8.3	17.5
Loss for the financial year	(39.0)	(9.3)	(48.3)	—	(48.3)	(25.9)	(20.7)	(46.6)	(70.5)	(117.1)
Cash²	27.0					40.7				

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

² Includes cash, cash equivalents and short-term deposits.

Strategic report

Financial review, continued

Revenue

Circassia's revenues of £62.4 million (2018: £48.3 million) include NIOX[®] sales of £34.6 million (2018: £27.4 million), Tudorza[®] revenues of £27.0 million (2018: £20.9 million) and Duaklir[®] revenues of £0.8 million (2018: £nil).

NIOX[®] revenues include sales for use in clinical practice of £30.5 million (2018: £23.4 million), sales for use in pharmaceutical company research of £3.6 million (2018: £3.7 million) and other revenues such as freight of £0.5 million (2018: £0.3 million).

Gross profit

Gross margin decreased from 82% to 74%. This was mainly due to taking commercial control of sales of Tudorza[®] from 1 January 2019. During 2018, contribution of revenues from AstraZeneca had a 100% gross margin due to the agreement structure, whereas in 2019, a gross margin of 74% was achieved. Gross profit on NIOX[®] sales was £25.5 million (2018: £18.5 million), with a gross margin of 74% (2018: 68%). This increase is due to the impact of higher margin direct sales in China and the weakening of sterling against the dollar.

Sales and marketing

Sales and marketing costs increased to £57.5 million (2018: £57.3 million). This was mainly as a result of significant expansion of commercial operations in China and higher marketing expenditure following the acquisition of the Tudorza[®] licence on 1 January 2019, and the launch of Duaklir[®] in October 2019. This is offset by the previous year's restructuring of the US field force into dedicated NIOX[®] and COPD teams. Sales and marketing costs of £2.9 million included in non-underlying continuing operations in 2018 represents the reorganisation cost of the US field force.

↑ **29.2%**

Revenues

During 2019 revenues continued to grow, increasing 29% to £62.4 million.

↑ **17.5%**

Gross profit

During 2019 gross profit increased from £39.4 million in 2018 to £46.2 million.

74%

Gross margin on NIOX[®]

Gross margin on NIOX[®] increased from 68% in 2018 to 74%.

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 increased to £19.1 million (2018: £10.8 million) due to amortisation charged on COPD intangible assets, offset by significantly lower headcount.

Research and development costs of £90.4 million included in non-underlying continuing operations relates to an impairment charge for the Tudorza[®], Duaklir[®] and LungFit[™] PH licences.

Discontinued operations in 2018 included costs relating to the in-house respiratory pipeline of £78.6 million, most of which related to an impairment charge of the associated intangible assets. The impairment costs had no impact on cash.

Administrative expenditure

Underlying administrative expenditure, which includes overheads relating to corporate functions, centrally managed support functions and corporate costs, increased to £12.6 million (2018: £11.4 million). This was mainly due to the higher senior management headcount for part of the year, and higher one-off legal and professional fees.

Administrative expenses of £1.1 million included in non-underlying continuing operations represents the reorganisation cost of the Board and other members of senior management in 2019, and in 2018, the costs associated with the transfer of the Company's shares to AIM.

Gross margin on NIOX[®] increased from 68% to 74%. This was mainly due to the impact of higher margin direct sales in China and the weakening of sterling against the dollar.

Strategic report

Financial review, continued

Other gains and (losses)

Other gains increased to £94.0 million (2018: £3.8 million loss). This was mainly due to the change in fair value of contingent royalty consideration payable to AstraZeneca for future sales of Duaklir® and Tudorza®, and to Beyond Air for future sales of LungFit™ PH.

Net finance costs

Net finance costs were £18.6 million (2018: £11.7 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 balance sheet. The discounted amount reflects the time value of money. Also included is £2.6 million (2018: £ nil) of interest charged on the loan from AstraZeneca.

Taxation

Taxation for the year was a credit of £10.8 million (2018: £17.5 million). Included in underlying continuing operations is an R&D tax credit of £0.1 million (2018: £1.0 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 £10.7 million (2018: £8.2 million) which has arisen on an increase in recognised carried-forward tax losses in the Group.

The taxation credit relating to discontinued operations in the previous financial year of £8.3 million was mainly due to a reduction in the deferred tax liability following the impairment of intangible assets in the respiratory pipeline.

£94.0m

Other gains

Other gains increased to £93.5 million from £3.8 million loss in 2018.

Other gains increased to £94.0 million from a loss of 3.8 million in 2018. This was mainly due to the change in fair value of contingent royalty consideration payable to AstraZeneca for future sales of Duaklir® and Tudorza®, and to Beyond Air for future sales of LungFit™ PH.

Loss after tax and loss per share

Basic loss per share for the period was 13p (2018: 34p loss) reflecting a loss of £48.3 million (2018: £117.1 million), with the decrease mainly due to a higher impairment of intangible assets in the previous financial year. Loss per share for continuing operations stayed constant at 13p (2018: 14p loss) reflecting a loss for the financial period of £39.0 million (2018: £25.9 million loss).

Statement of financial position

The Group's net assets at 31 December 2019 were £84.8 million (2018: £125.9 million). The decrease was mainly due to impairment of the COPD intangible assets and associated goodwill, combined with a lower cash balance and higher trade and other payables.

Current liabilities at the end of the period were £41.3 million (31 December 2018: £124.4 million). The decrease was mainly due to settlement of deferred non-contingent consideration to AstraZeneca. This was offset by the issue of a five year loan, which is classified as a non-current liability. On 27 May 2020, the Tudorza® and Duaklir® licences were handed back to AstraZeneca and the loan was set off in its entirety.

Total tax assets at 31 December 2019 were £0.2 million (31 December 2018: £4.0 million), representing the R&D tax credit due from HM Revenue and Customs. An R&D tax credit of £3.9 million was received in October 2019.

Strategic report

Financial review, continued

Cash flow

The Group's cash position, including cash equivalents, decreased from £40.7 million at 31 December 2018 to £27.0 million at 31 December 2019.

Cash used in operations decreased to £28.9 million (2018: £51.3 million), reflecting higher revenues and a net decrease in the overall cost base of the business.

Other significant cashflows included purchases of intangible assets of £10.0 million (2018: £0.3 million), receipt of an R&D tax credit of £3.9 million (2018: £10.9 million) and proceeds from the issue of share capital of £8.0 million (2018: £20.4 million).

Outlook

In the coming year, the Group will be simplified in order to achieve its objective of becoming a profitable and cash generative business. The NIOX® business will form the Group's continuing activities and has good growth potential in the medium term, although 2020 results will be affected by the impact of the COVID-19 pandemic. The Group plans to remain focused on cost control and anticipates a significant reduction in the core cost base during the coming year.

Michael Roller
Chief Financial Officer

16 June 2020

The NIOX® business will form the Group's continuing activities and has good growth potential in the medium term, although 2020 results will be affected by the impact of the COVID-19 pandemic.

Strategic report

Corporate social responsibility

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

People

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

Values

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

Passion

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

Recognition

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

Integrity

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

Attracting, motivating and retaining a highly skilled workforce is key to the Group's long-term success.

Strategic report

Corporate social responsibility, continued

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 2019.

Member	Male	Female	Total	% Male	% Female
plc Board including Non-Executive Directors	4	2	6	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	8	2	10	80%	20%
All other employees	183	147	330	55%	45%
Total	198	152	350	57%	43%

The Group does not have formal diversity quotas but recognises that a diverse employee profile is of significant benefit.

Employee welfare and involvement

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

Employment, training, career development and promotion of disabled persons

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

The Group appoints, trains, develops and promotes employees on the basis of merit alone.

Strategic report

Corporate social responsibility, continued

Health and safety

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

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

Ethical and social policies

The Group is a pharmaceutical and medical devices group and accordingly operates in a highly regulated ethical framework. It complies fully with these laws and regulations. The Group 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.

The Group continuously monitors its health and safety policy and practices to ensure they are robust, appropriate, and reflect changes in best practice.

Human rights

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

Product development

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

Environment

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

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.

Strategic report

Corporate social responsibility, continued

Greenhouse gas emission

This section of the Annual Report and Accounts 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 2019 are higher than those in 2018 due to being in the Beijing office in China for a full year (lease entered at the beginning of October 2018). The Group's emissions are largely a function of the heating and lighting of leased office premises.

	2019	2018
CO ₂ equivalent emissions – scope 2 (tonnes)	250	194
Intensity ratio (kg/m ² of office space)	50	40

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

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

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

250t

CO₂ equivalent emissions

Emissions for 2019 are higher than those in 2018 due to being in the Beijing office in China for a full year (lease entered at the beginning of October 2018). The Group's emissions are largely a function of the heating and lighting of leased office premises.

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.

As part of the Group's 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.

Strategic report

Risks and risk management

The management of risks is a key responsibility of the Board of Directors. 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 Group 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 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 on the following pages, 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 Group 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.

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.

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, Italy 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.

Strategic report

Risks and risk management, continued

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 continues to apply significant resources to sales of the NIOX[®] device. In the United States there is a dedicated commercial team, including sales representatives, selling NIOX[®]. The products are also sold directly by the Group's teams in China, the United Kingdom, Italy and Germany who manage local commercialisation activities. Partner markets, where products are sold through distributors, are managed by an experienced Senior Director of Partner Management.

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.

Mitigating activities

The Group has an internal Compliance function, which is managed by the Chief Compliance Officer together with dedicated Compliance resources in the United States and China. The Chief Compliance Officer has 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.

Strategic report

Risks and risk management, continued

The Group relies on partners, such as 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.

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 Duaklir[®] and will continue to do so until the licences are transferred back to AstraZeneca.

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.

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 relies upon its collaborations with PHC Corporation for the development of the NIOX[®] device and upon IT Dr. Gambert GmbH for the development of the sensors contained in the NIOX[®] devices.

Mitigating activities

The development collaboration with PHC Corporation is managed by steering committees which include representatives from the Group.

Strategic report

Risks and risk management, continued

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 licenses certain intellectual property rights from third parties. 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.

Strategic report

Risks and risk management, continued

Financial operations

The Group has incurred significant losses since the inception of its various businesses. However it anticipates that it should become profit making once the Tudorza® and Duaklir® licences are transferred back to AstraZeneca and the effects of COVID-19 on the short term trading of the NIOX® business have ceased.

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.

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 may be made when it is considered necessary to do so in order to mitigate specific foreign exchange risks.

Brexit

There continues to be political and economic uncertainties following the United Kingdom leaving the European Union (EU) on 31 January 2020. 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 Germany (Circassia AG), Italy (Circassia srl), and Sweden (Circassia AB), where the Group's NIOX[®] inventory for the EU and other markets outside the United States is held, so the Group will still have a presence in the EU even after Brexit comes into effect. In the event of extreme disruption, product could be shipped to the UK from the US warehouse to mitigate EU-UK border issues.

Corporate governance

Board of Directors

Ian Johnson

Executive Chairman

Ian Johnson joined Circassia as Executive Chairman on 5 December 2019. Ian has spent his business career in life science and was founder and CEO of Biotrace International PLC, which was a listed company until its sale to 3M in December 2006. Most recently Ian was Executive Chairman of Bioquell PLC, which was acquired by Ecolab Inc. in January 2019. Prior to this Ian was non-executive Chairman of Quantum Pharma PLC, Cyprotex PLC and Celsis Group Ltd. He has also served on the boards of various other public and private companies including the AIM traded companies, Evans Analytical Group, MyCelx Technologies Corporation and AOI Medical Inc. Ian studied at Cardiff University obtaining a BSc and MSc in Microbiology. He is a chartered biologist, and a fellow of the Royal Society of Biology and the Institute of Directors.

Michael Roller

Chief Financial Officer

Michael Roller joined Circassia as Chief Financial Officer on 9 January 2020. Michael is a highly experienced Finance Director and life sciences company Director. He was previously Group Finance Director of Bioquell PLC, Corin Group PLC and Genus PLC and is currently a Non-Executive Director of Filtronic PLC. In addition, Michael has held a number of senior finance roles in a broad range of public and private companies. Michael completed his training at KPMG and is a Chartered Accountant and member of the ICAEW. He graduated from Merton College, Oxford with a BA in History.

Jonathan Emms

Chief Operating Officer

Jonathan Emms joined Circassia as Chief Commercial Officer on 2 September 2019. Jonathan brings significant senior-level experience of the global pharmaceutical industry to Circassia. Prior to joining the Company, he was Chief Commercial Officer for Pfizer's Internal Medicines organisation, where he led commercial activities across the company's global operations. Previously, he held a number of senior positions at Pfizer, including Head of Marketing for its Global Established Pharmaceutical Business and Head of Marketing for Specialty Care, Europe, and oversaw the UK launch of Spiriva® under the company's co-promotion agreement with Boehringer Ingelheim. He was also Country Manager in the UK, Pfizer's largest affiliate outside the United States, where he had responsibility for manufacturing, research and commercial operations and during his tenure was elected President of the Association of the British Pharmaceutical Industry (ABPI). Prior to his time at Pfizer, Jonathan held several roles of increasing responsibility at GSK, where he gained significant respiratory experience, including leading the UK launch of Serevent® in COPD. He holds a BSc in Materials Technology from Coventry University, UK.

Garry Watts

Senior Independent Director and
Non-Executive Director

Garry Watts joined Circassia as a Non-Executive Director and its Senior Independent Director on 2 March 2020. Garry brings to the Company extensive Board-level experience gained in the healthcare sector. He is currently Non-Executive Chairman of Spire Healthcare Group plc and was until recently Non-Executive Chairman at BTG plc prior to its sale to Boston Scientific. He was previously CEO of SSL International plc, Finance Director at Medeva plc and a Director at Celltech Group plc. In addition to his executive roles, Garry was a Non-Executive Director at Protherics plc and a Non-Executive member of the Board of the UK Medicines and Healthcare Regulatory Agency for over 15 years, for which he was awarded an MBE. Garry is a chartered accountant and former partner at KPMG and is a member of the ICAEW.

Jo LeCouilliard

Non-Executive Director

Jo LeCouilliard was appointed to the Board as an Independent Non-Executive Director on 8 February 2018. She has 25 years' healthcare management experience gained in Europe, the US and Asia. Much of her career has been in pharmaceuticals at GlaxoSmithKline where, amongst other roles, she headed the US vaccines business and Asia Pacific Pharmaceuticals business and led a program to modernise the commercial model. She was previously Chief Operating Officer at the BMI group of private hospitals in the UK. She was a non-executive director at Frimley Park NHS Foundation Trust in the UK and at the Duke NUS Medical School in Singapore. Jo is currently a Non-Executive Director at the UK listed companies Alliance Pharma plc, Cello Health plc and at the Italian listed pharmaceutical company, Recordati S.p.a. Jo is a graduate of Cambridge University and a Chartered Accountant.

Sharon Curran

Non-Executive Director

Sharon Curran was appointed to the Board as an Independent Non-Executive Director on 8 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.

Corporate governance

Corporate governance report

Dear shareholders,

On behalf of the Board, I am pleased to present Circassia's Corporate governance report for the year ended 31 December 2019.

I am delighted to join Circassia at this important time in the Company's development. I believe Circassia has great potential and I look forward to working with the whole team to achieve this ambition.

There have been several developments to the Board during the year. Most notably, our CEO and Co-Founder, Steve Harris, retired following 13 years of leading the business. Subsequently, in January 2020, Julien Cotta stepped down from his role of CFO and Executive Director and has been succeeded by Michael Roller. I would like to thank our outgoing Chairman, Dr Francesco Granata, and Steve Harris, for the strong leadership they have provided over many years, and Julien Cotta for his significant contribution to the Company over many years.

Our long-serving Non-Executive Director, Russell Cummings, decided not to stand for re-election, and Ms Lota Zoth and Dr Heribert Staudinger retired from the Board following the transfer to AIM. In addition, Dr Rod Hafner also stepped down from the Board. We are very grateful to Russell and Rod for their significant contributions over the years and we extend our thanks to Lota and Heribert for the excellent support and guidance they have provided.

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.

Maintaining good communication with our shareholders is extremely important to us. During the year the Executive Directors have held a number of meetings with investors and current shareholders and presented at several conferences which were attended by existing and potential shareholders.

Ian Johnson
Executive Chairman

16 June 2020

Corporate Governance Statement

Statement of Compliance with the Quoted Companies Alliance (QCA) Corporate Governance Code (the 'Code')

Circassia Group plc adopts compliance with the QCA Corporate Governance Code and confirms that the Group is fully compliant. This report follows the structure of these guidelines and explains how we have applied the guidance.

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

The Group's values are stated within the Corporate social responsibility report on page 27 and the Group's strategy and business model are explained in detail in the Strategic report on pages 18 to 19.

2) Seek to understand and meet shareholder needs and expectations

Dialogue with shareholders

I, the Executive Chairman (previously Steven Harris, Chief Executive Officer), am responsible for the day to day management of the Group and for implementing the strategy which has been reviewed and approved by the Board. I am 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 Executive 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 Executive Chairman (previously Chief Executive Officer) and the Chief Financial Officer give annual and bi-annual presentations to institutional investors and analysts. 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.

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.

Corporate governance

Corporate governance report, continued

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 27.

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 34.

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 is 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 currently comprises the Executive Chairman, two Executive Directors, one Senior Independent Director, and two Non-Executive Directors. The biographies of the current members of the Board are set out on pages 44 to 45 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 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.

The Non-Executive Directors are expected to devote such time as is necessary for the proper performance of their duties. The Executive Directors are full time employees of the Company.

Chairman

I, the Executive Chairman, am 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 is evaluated each year; and
- there is effective communication with shareholders, brokers, and analysts.

I am also responsible for the day to day management of the Group and for implementing the strategy which has been reviewed and approved by the Board.

The Executive Chairman (previously Chairman) and the Non-Executive Directors met in the absence of the Executive Directors at the end of each Board meeting which occurred in 2019.

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, there are three Non-Executive Directors (including the Senior Independent Director), all of whom are deemed to be independent.

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.

Corporate governance

Corporate governance report, continued

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 2019.

	Committee Memberships	Independent status	Board	Nomination Committee	Audit and Risk Committee	Remuneration Committee
Executive Directors						
Steven Harris ³	n/a	n/a	5 (5)	2 (2) ¹	3 (3) ¹	2 (2) ¹
Julien Cotta	n/a	n/a	5 (5)	2 (2) ²	3 (3) ²	2 (2) ²
Jonathan Emms ⁴	n/a	n/a	3 (3)	—	—	—
Rod Hafner ⁵	n/a	n/a	2 (2)	—	—	—
Ian Johnson ⁶	n/a	n/a	1 (1)	—	—	—
Non-Executive Directors						
Francesco Granata ⁷	N(Chair)	Yes	4 (4)	1 (1)	—	1 (1) ¹
Russell Cummings ⁸	—	No	2 (2)	—	1 (1) ¹	2 (2) ¹
Lota Zoth ⁹	A, R(Chair)	Yes	0 (0)	—	0 (0)	0 (0)
Jo LeCouilliard	N(Chair) ¹⁰ , A(Chair), R	Yes	5 (5)	2 (2)	3 (3)	2 (2)
Heribert Staudinger ¹¹	N	Yes	0 (0)	0 (0)	—	—
Sharon Curran	N ¹² , A ¹³ , R(Chair) ¹⁴	Yes	5 (5)	1 (1)	3 (3)	2 (2)

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 2019 when the director was in office.

- 1 By invitation.
- 2 In the capacity of Secretary to the Committee.
- 3 Until 31 December 2019, when he retired from the Board.
- 4 From 2 September 2019, when he was appointed as Chief Operating Officer.
- 5 Until 2 September 2019, when he retired from the Board.
- 6 From 5 December 2019, when he was appointed as Executive Chairman of the Board.
- 7 Until 5 December 2019, when he stepped down as Chairman of the Board.
- 8 Until 7 June 2019, when he retired from the Board (not having put himself forward for re-election at the AGM).
- 9 Until 4 February 2019, when she retired from the Board following the transfer to AIM.
- 10 From 5 December 2019, when she was promoted to Chair of the Nomination Committee.
- 11 Until 4 February 2019, when he retired from the Board following the transfer to AIM.
- 12 From 5 December 2019, when she was appointed as a member of the Nomination Committee.
- 13 From 4 February 2019, when she was appointed as a member of the Audit and Risk Committee.
- 14 From 4 February 2019, when she was promoted from member to Chair of the Remuneration 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. 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 44 to 45 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.

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 27.

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 the Company Secretary role being undertaken by someone other than an Executive Director, and the composition of the Board being a majority of Non-Executive Directors. The QCA code requires a minimum of two independent Non-Executive Directors. The current Board composition is made up of three independent Non-Executive Directors, including Garry Watts, the newly appointed Senior Independent Director. This composition is deemed effective for the current strategy and direction of the company, and therefore there are currently no plans to further increase the number of Non-Executive Directors. Plans are in place to separate the roles of Company Secretary and CFO at the appropriate time.

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.

Corporate governance

Corporate governance report, continued

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 2019 until 4 February 2019 the Committee comprised Dr Francesco Granata (Chairman and Chair of the Committee); Dr Heribert Staudinger, and Ms Jo LeCouilliard. All members are considered to be independent.

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

On 5 December 2019, Dr Francesco Granata retired from the Board, and Ms Jo LeCouilliard was promoted to Chair of the Nomination Committee. Subsequently, Ms Sharon Curran was appointed as member of the Nomination Committee.

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 Non-Executive Directors, all of whom should be independent.

For the period from 1 January 2019 until 4 February 2019, the Committee members were: Ms Lota Zoth (Chair of the Committee) and Ms Jo LeCouilliard. All members are considered to be independent.

On 4 February 2019, Ms Lota Zoth retired from the Board following the transfer to AIM, and Ms Sharon Curran was appointed as Chair of the Remuneration Committee.

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 2019 until 4 February 2019, the Committee members were: Jo LeCouilliard (Chair of the Committee); and Ms Lota Zoth. All members are considered to be independent.

On 4 February 2019, Ms Lota Zoth retired from the Board following the transfer to AIM, and Ms Sharon Curran was appointed as a member of the Audit and Risk Committee.

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 Executive Chairman (previously 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 Executive Chairman (previously 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.

Corporate governance

Audit and Risk Committee report

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 2019.

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 LeCoulliard
Chair of the Audit and Risk Committee

16 June 2020

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® and launching Duaklir®, the Group also promotes two approved medicines 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 appointed	Meetings attended (held)
L S Zoth (resigned 4 February 2019)	27 February 2015	0 (0)
J LeCouilliard (Chair of the Committee)	30 May 2018	3 (3)
S Curran	30 May 2018	3 (3)

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

Upon joining the Board on 2 March 2020, Garry Watts became a member of the Audit and Risk Committee.

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 44 to 45 of this report.

Ms Jo LeCouilliard, Chair of the Audit and Risk Committee, is a Chartered Accountant and a member of the ICAEW. She has recent and relevant experience which enables her to understand the risks facing the business, be able to challenge the financial position and performance of the Company and make recommendations to the board.

The Company Secretary acts as the Secretary to the Committee. The Executive Chairman (previously the Chief Executive Officer) attends Committee meetings at the invitation of the Chair. The Committee meets 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	Review of the interim and full year results. Consideration of whether the Annual Report is fair, balanced and understandable. Review of the external auditors' report for the full year results. Review of significant accounting judgements and estimates (see overleaf). Review of anticipated changes in accounting standards and their impact. Review of the going concern basis of preparation of the financial statements.
External auditor	Review of the external auditors' independence. Review of the auditors' compliance with ethical and professional guidance on audit partner rotation. Assessment of the effectiveness of the audit process. Recommendation regarding reappointment of the auditors.
Risk management and internal control	Review of risk, risk management systems, internal controls and the whistleblowing policy. Review of compliance activities.
Governance	Review of the Committee's terms of reference.

Financial reporting

During the year to 31 December 2019 and up to the date of this report, the Committee reviewed the interim report and accounts for the period ended 30 June 2019 and the preliminary announcement and Annual Report and Accounts for the year ended 31 December 2019.

Significant accounting matters

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

- Measurement of Tudorza[®] revenue deductions
- Measurement of Duaklir[®] contingent royalty consideration
- Assessment of the possible impairment of goodwill and intangible assets
- Assessment of the possible impairment of investments in subsidiaries and intercompany receivables
- Going concern and the impact of COVID-19

Measurement of Tudorza[®] revenue deductions

Since commencing invoicing of Tudorza[®] sales on 1 July 2019, Circassia must estimate the rebates and chargebacks that are expected to be paid and also a refund liability for the amount of consideration received for which the entity does not expect to be entitled. The liability relating to these revenue deductions is re-estimated at the end of each period with gains/losses recognised through the statement of comprehensive income. The value of the rebate accrual is calculated by taking into account specific contract provisions, coupled with expected performance. The value of the refund liability is calculated based on historical information. A liability of £12.9 million was recognised on the statement of financial position as at 31 December 2019.

Measurement of Duaklir® contingent royalty consideration

As part of the collaboration agreement entered into in April 2017 between Circassia and AstraZeneca, Circassia is liable to 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 were initially classified as additional consideration and 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.

During 2019, the sales performance of Duaklir® was well below internal forecasts and as such management concluded that future sales of Duaklir® were expected to remain low in the short-term and therefore as at 31 December 2019, the royalty liability has been remeasured to £nil resulting in a £51.4 million credit in 'other gains and losses'. This sales underperformance led to the decision to hand the licences back to AstraZeneca, with the agreement completed and the licences handed back on 27 May 2020.

Assessment of the possible impairment of goodwill and intangible assets

In line with IAS 36 Impairment of Assets, the carrying value of each cash generating unit (CGU) including the allocated goodwill was tested for impairment. Impairment assessments were performed on each CGU (NIOX®, COPD and LungFit™ PH) and at an individual intangible asset level.

On 19 December 2019, BeyondAir announced it is terminating the agreement for the commercial licence of LungFit™ PH. The Company disputes and intends to challenge BeyondAir's actions. At this time, however, the Company has concluded that impairment is required to the LungFit™ PH CGU intangible assets of £44.0 million. See note 17 for further details.

During 2019, the sales performance of Tudorza® and Duaklir® was well below internal forecasts and as such management concluded that impairment was required to the COPD CGU. This resulted in an impairment of £4.1 million to goodwill and £42.1 million to intangible assets. This sales underperformance led to the decision to hand the licences back to AstraZeneca, with the agreement completed and the licences handed back on 27 May 2020. See notes 16 and 17 for further details.

Assessment of the possible impairment of investments in subsidiaries and intercompany receivables

In line with IAS 36 Impairment of Assets, the carrying value of each investment held by Circassia Group plc in its subsidiaries was tested for impairment. Management concluded that further impairment was required to the investments held in Circassia Limited and Circassia Pharmaceuticals Inc. This is related to the impairment of the COPD CGU as discussed above. This resulted in an impairment of £12.5 million. See note 17 for further details.

In line with IFRS 9, the carrying value of intercompany receivable balances owed to Circassia Group plc by its subsidiaries was assessed measuring expected credit losses by using a range of probability weighted scenarios for the recoverability of the balances. Management concluded that a further provision was required to the intercompany receivable balances with Circassia Limited and Circassia Pharmaceuticals Inc. This resulted in an additional provision of £256.4 million being recognised. See notes 2 and 21 for further details.

Going concern the impact of COVID-19

In assessing the appropriateness of the going concern assumption, the Board has considered the availability of funding alongside the possible cash requirements of the Group and Company, taking into account the unprecedented circumstances caused by COVID-19.

The Board has prepared cash flow forecasts for a period of 18 months from the date of approval of these financial statements. This base case scenario includes the benefits of actions already taken by management to mitigate the trading downsides brought about by COVID-19, for example, restrictions on travel, limiting new hires and reducing discretionary spend as well as utilising the equity facility agreed with significant shareholders. This base case assumes that sales of NIOX® will gradually build back towards pre-COVID-19 levels of trade (94% of the value of budgeted sales) by December 2020. Under this base case scenario, the Group is expected to continue to have sufficient resources beyond 12 months from the approval of the financial statements.

Corporate governance

Audit and Risk Committee report, continued

The most extreme downside scenario modelled the impact of no recovery from current levels of NIOX® sales up until December 2020, rising to around 76% of pre-COVID-19 sales in December 2021 and remaining at this level for the foreseeable future. In addition, this assumes a gradual reduction of current Tudorza® revenue down to a reduction to 80% of current levels by the end of 2020, when it is expected that the run off period for this activity will cease. These reductions in revenue would be offset by significant mitigating cost reductions and cash protection actions, within the control of the Board, commencing in September 2020 (for example significant salary cuts for Board members, non-payment of discretionary bonuses and the reduction in size of certain central functions by the end of 2020). In this scenario the Group remains cash positive beyond 12 months from the approval of the financial statements.

After due consideration, the directors have concluded that there is a reasonable expectation that the Group has adequate resources to continue in operational existence for at least 12 months from the date of this report.

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 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 2019 or up to the date of this report.

At the end of the audit for the year ended 31 December 2019, the Committee formally evaluated the performance of PricewaterhouseCoopers LLP (PwC) who had been reappointed as auditors following a tender carried out in 2016 for the audit of the 2017 financial year.

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's 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. During the year, the Group paid £1,356 to PwC in respect of non-audit services for an accounting research tool subscription.

In summary, the Committee confirms that the Group has received an independent audit service in the year to 31 December 2019 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. Miles Saunders, the current audit partner, was appointed for the year ending 31 December 2019 and is not due for rotation until after the completion of the audit for the year ending 31 December 2023.

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 2019 as part of the process of evaluating Board effectiveness. The findings of the evaluation were debated by the Board and a list of actions agreed.

Jo LeCouilliard
Chair of the Audit and Risk Committee

16 June 2020

Corporate governance

Nomination Committee report

Dear shareholders,

On behalf of the Board, I am pleased to present Circassia's Nomination Committee report for the year ended 31 December 2019. 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.

There has been a significant change to the composition of the Board during the period. Two of our Non-Executive Directors, Dr Heribert Staudinger and Ms Lota Zoth, retired from the Board in February following the transfer to AIM. Subsequently, Mr Russell Cummings decided not to stand for re-election at the AGM. In September, Dr Rod Hafner stepped down from the Board and the Board appointed a new COO, Jonathan Emms.

Following Dr Francesco Granata and Steve Harris announcing their intentions to retire from the Board, Ian Johnson was appointed as Executive Chairman effective from 5 December 2019. Subsequently, in January 2020, Julien Cotta stepped down from his role of CFO and Executive Director and has been succeeded by Michael Roller. Following these changes, which saw the Board reduce to 5 members, the Nomination Committee recommended the appointment of Garry Watts as Senior Independent Director. Garry joined the Board in March 2020 and became a member of the Audit and Risk Committee and the Remuneration Committee. He will replace me as Chair of the Nomination Committee with effect from 17 June 2020.

Further details of the Nomination Committee's activities are set out below.

Jo LeCouilliard
Chair of the Nomination Committee

16 June 2020

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 until 5 December 2019)	21 February 2014	1 (1)
Ms Jo LeCouilliard (Chair of the Committee from 5 December 2019)	30 May 2018	2 (2)
Dr Heribert Staudinger (resigned 4 February 2019)	30 May 2018	0 (0)
Ms Sharon Curran	5 December 2019	2 (2)

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

On 5 December 2019, Dr Francesco Granata retired from the Board, and Ms Jo LeCouilliard was promoted to Chair of the Nomination Committee. Subsequently, Ms Sharon Curran was appointed as a member of the Nomination Committee.

Upon joining the Board on 2 March 2020, Garry Watts became a member of the Nomination Committee. He will take over the position of Chair of the Nomination Committee effective from 17 June 2020.

The Company Secretary acts as Secretary to the Committee.

The Executive Chairman (previously 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.

Corporate governance

Nomination Committee report, continued

Primary responsibilities

In accordance with its terms of reference, the Nomination Committee's primary responsibilities include:

- leading the process for Board appointments and making recommendations to the Board;
- regularly reviewing the Board structure, size and composition (including skills, knowledge, independence, experience and diversity), recommending any necessary changes;
- considering plans for orderly succession for appointments to the Board and to senior management to maintain an appropriate balance of skills and experience within the Company and to ensure progressive refreshing of the Board;
- keeping under review the leadership needs of the Group, both executive and non-executive, to ensure the organisation competes efficiently in the marketplace; and
- being responsible for identifying and nominating, for the approval of the Board, candidates to fill Board vacancies as and when they arise.

Committee activities during the year

The principal activities during the year were:

- Executive Chairman appointment: The Nomination Committee carried out a recruitment process to identify suitable candidates to succeed Dr Francesco Granata as Chairman and Steve Harris as CEO. Recruitment searches were carried out based on criteria agreed by the Nomination Committee. All directors met with the final candidate. Following its deliberations, the Nomination Committee recommended to the Board to appoint Ian Johnson as Executive Chairman.
- Reviewing Board composition: The Nomination Committee had met during the period to discuss the Board's size and composition in relation to the various Board appointments noted above. Following its deliberations, the Nomination Committee recommended to the Board to appoint Garry Watts as Senior Independent Director and Non-Executive Director and he joined the Board in March 2020.
- Performance evaluation: The Committee's effectiveness was reviewed as part of the Board's performance evaluation process which was carried out during the final quarter of the year under review. This evaluation concluded that the Committee was continuing to function effectively.
- Chief Operating Officer appointment: The Nomination Committee carried out a recruitment process to identify suitable candidates for the position of Chief Operating Officer based on criteria agreed by the Nomination Committee. All directors met with the final candidate. Following its deliberations, the Nomination Committee recommended to the Board to appoint Jonathan Emms as Chief Operating Officer commencing 2 September 2019.
- Chief Financial Officer appointment: The Nomination Committee carried out a recruitment process to identify suitable candidates to succeed Julien Cotta as Chief Financial Officer based on criteria agreed by the Nomination Committee. All directors met with the final candidate. Following its deliberations, the Nomination Committee recommended to the Board to appoint Michael Roller as Chief Financial Officer commencing 9 January 2020.

Corporate governance

Remuneration Committee report

Dear shareholders,

On behalf of the Board, I am pleased to present Circassia's Remuneration Committee report for the year ended 31 December 2019. This report complies with the regime set out in the Quoted Company Alliance Code ('the Code') and will be presented for the consideration and approval of Shareholders at the Annual General Meeting on 26 June 2020.

Accordingly, it consists of three parts:

- (i) an annual statement which summarises the remuneration policy and explains the business context in which the Committee's main decisions were taken;
- (ii) the annual report on remuneration which sets out details of and the rationale for the remuneration provided to the Group's directors during the 2019 financial year; and
- (iii) the Directors' remuneration policy.

The annual report on remuneration is subject to an advisory vote at the AGM.

Annual statement

Remuneration policy

The remuneration policy, which was approved by Shareholders at the 2019 AGM, aims to reward Executive Directors for performance, and for delivery of shareholder value judged against transparent and demanding criteria. It is consistent with Circassia's current vision, strategy, risk appetite, culture and philosophy. As part of this policy a significant proportion of potential remuneration is linked to the achievement of corporate objectives.

Share incentive arrangements have been in effect since 2014 and are intended to closely align the interests of the Executive Directors with those of Shareholders.

Recent developments and Remuneration Committee decisions

Appointment of COO

Jonathan Emms joined the Board as COO in September 2019 and on 17 October 2019 received an award under the Performance Share Plan having a vesting period of 3 years and an additional holding period of 2 years, other than for the sale of shares to satisfy any tax liability created on exercise. The value of the award was equal to his salary in line with the remuneration policy. An additional award for the same value was made on 1 May 2020, further details of which can be found overleaf. The COO is also eligible to participate in an annual bonus. 50% of any award will be deferred into shares for three years and will be subject to forfeiture in certain circumstances.

Appointment of Executive Chairman and other management changes

As discussed in the Chairman's Statement, Ian Johnson joined the Board as Executive Chairman on 5 December 2019 and Michael Roller replaced Julien Cotta as CFO after the financial year end in January 2020.

The Board decided that these management changes were necessary in the long-term interests of the Company and its stakeholders. The remuneration packages agreed with Messrs Johnson and Roller are exceptions to the Company's approved policy. Their packages were determined by the Remuneration Committee in consultation with and support from, principal shareholders in the Group and have subsequently been approved by shareholder vote at an Extraordinary General Meeting held on 30 April 2020.

Corporate governance

Remuneration Committee report, continued

Both Messrs Roller and Johnson are incentivised through a significant option grant which will pay out only if the Company's share price trebles from its average level in the 10 days immediately preceding the appointment of Ian Johnson. On 19 December 2019, Ian Johnson was granted a nil-cost share option, which will vest on the third anniversary of the date of grant and is exercisable until the tenth anniversary of that date. Vesting is subject to either the Company's share price reaching 62.4p, equating to three times the average closing price for an ordinary share for the 10 dealing days immediately preceding the grant date, for at least 30 consecutive dealing days or a liquidity event occurring above this level. On his appointment, after the year-end, Michael Roller was granted a nil-cost share option on similar terms.

The base salaries of Messrs Johnson and Roller are significantly lower at £300,000 and £220,000, respectively than the salaries of their predecessors and, unlike other Executive Directors, they are not eligible for an annual bonus. Both Messrs Johnson and Roller receive an expenses allowance of £10,000 per annum.

Details of the share option grants made to Ian Johnson, Michael Roller and to other Executive Directors are set out in the annual report on remuneration on page 68.

Statement of consideration of shareholder views

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

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

Shareholder approval

The annual report on remuneration will be the subject of an advisory vote at the AGM on 23 July 2020.

Sharon Curran
Chair of the Remuneration Committee

16 June 2020

Annual report on remuneration

This section describes the remuneration outcomes for the Executive Directors for the year ended 31 December 2019 in accordance with the remuneration policy applicable to that year. The Company's future remuneration policy is described in the following section of this report, entitled Directors' remuneration policy.

Members of the Remuneration Committee

The names of the members of the Remuneration 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)
Ms Lota Zoth (resigned 4 February 2019)	27 February 2015	0 (0)
Ms Sharon Curran ¹	30 May 2018	2 (2)
Ms Jo LeCouilliard	30 May 2018	2 (2)

¹ Ms Sharon Curran replaced Ms Lota Zoth as Chair of the Remuneration Committee on 4 February 2019 when Ms Lota Zoth resigned from the Board.

Upon joining the Board on 2 March 2020, Garry Watts became a member of the Remuneration Committee.

All members are considered to be independent and therefore the Committee complied with the requirements of the QCA Code that all members of the Remuneration Committee are to be Independent Non-Executive Directors.

Single total figure of remuneration for each director (audited)

The table below shows the remuneration for each person who has served as a director of Circassia Group plc at any time during the year:

For the year ended 31 December 2019:

	Salary and fees £'000	Pension £'000	Benefits £'000	Annual bonus £'000	LTIP/PSP ¹ £'000	Payments for loss of office ² £'000	Total £'000
Executive Directors							
Ian Johnson	12	—	—	—	—	—	12
Steven Harris	420	49	2	105	15	432	1,023
Julien Cotta	281	22	2	69	8	392	774
Rod Hafner ³	167	23	1	73	8	96	368
Jonathan Emms	103	5	1	—	—	—	109
Non-Executive Directors							
Francesco Granata	138	—	—	—	—	37	175
Russell Cummings	26	—	—	—	—	—	26
Lota Zoth	6	—	—	—	—	—	6
Jo LeCouilliard	70	—	—	—	—	—	70
Sharon Curran	58	—	—	—	—	—	58
Heribert Staudinger	4	—	—	—	—	—	4
Total	1,285	99	6	247	31	957	2,625

Corporate governance

Remuneration Committee report, continued

For the year ended 31 December 2018:

	Salary and fees £'000	Pension £'000	Benefits £'000	Annual 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 LeCouilliard	55	—	—	—	—	55
Sharon Curran	49	—	—	—	—	49
Heribert Staudinger	46	—	—	—	—	46
Total	1,445	146	6	412	33	2,042

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

² Payments for loss of office is the total amount of compensation for loss of office paid to or receivable by the person, and Any other payments paid to or receivable by the person in connection with the termination of qualifying services

³ Remuneration has been pro-rated to 2 September 2019, being the date he stepped down from the Board

Annual bonus for the year to 31 December 2019

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.

For the year ended 31 December 2019, bonuses up to a maximum of 100% of base salary for Executive Directors could be earned, with 100% only payable for over-performance. Steve Harris, Julien Cotta and Jonathan Emms' bonuses are based on performance against corporate objectives.

The bonus achievement for Steve Harris, Julien Cotta and Jonathan Emms is as follows:

	Weighting	Bonus pay-out achievable			Bonus achieved %
		Threshold (£m)	On target (£m)	Over-performance (£m)	
Corporate objectives		25%	50%	100%	
Objective 1: Sales	50%	64.1	71.2	78.3	0.0%
Objective 2: Cash	25%	16.1	17.9	19.6	25.0%
Objective 3: EBITDA	25%	(22.7)	(20.6)	(18.5)	0.0%
					25.0%

The total bonus pay-out percentage awarded to both Steve, Julien and Jonathan is 25.0%. Jonathan Emms' bonus has been pro-rated as he joined Circassia part way through the performance year.

Rod Hafner's bonus was allocated 50% to corporate objectives, 25% to team objectives, and 25% to individual objectives. The bonus achievement for corporate objectives is as above.

Team objectives Bonus pay-out achievable			Bonus achieved %
Threshold	On target	Over-performance	
Approval of Tudorza® sNDA with MACE data added to label	Approval of Tudorza® sNDA with exacerbations data added to label	Approval of Tudorza® sNDA with exacerbations and hospitalisations data added to label	33.3%
Approval of Duaklir® NDA	Approval of Duaklir® NDA with exacerbations data added to label	Approval of Duaklir® NDA with exacerbations data added to label and no boxed warning	33.3%
a) NIOX VERO® Re-registration in China submitted	a) and b) commercially sensitive NIOX® objective	a), b), and Functional layout of VERO 2.0 with in house firmware complete, ready for industrialisation	33.3%
			100.0%

Individual objectives Bonus pay-out achievable			Bonus achieved %
Threshold	On target	Over-performance	
Complete one licensing or M&A transaction with base case NPV <\$100M (excluding AirNOvent)	Complete one licensing or M&A transaction with base case NPV >\$100M (excluding AirNOvent)	Complete one licensing or M&A transaction which brings additional revenues into the business in 2019	0.0%
			0.0%

The total bonus pay-out percentage achieved by Rod Hafner is 37.5%.

Ian Johnson will not be eligible to participate in the annual bonus scheme for 2020 and did not participate in the annual bonus scheme for 2019.

Deferred share bonus awards are mandatory, with 50% of bonuses paid in cash and 50% in shares, which are deferred for two years. The only exception to this is for Executive Directors who have served notice, in which case bonuses will be paid in cash.

Corporate governance

Remuneration Committee report, continued

Share options awarded to directors during the financial year (audited)

Executive Director	Type of award	Share price at date of grant	Number of shares over which award was granted	% of shares granted that vest at threshold performance	Face value of shares over which award originally granted £'000
Ian Johnson	Nil cost option	£0.19	4,322,767	0.00%	£900
Steven Harris	Nominal cost option	£0.19	803,200	25.00%	£153
Julien Cotta	Nominal cost option	£0.19	518,728	25.00%	£99
Rod Hafner	Nominal cost option	£0.19	562,674	25.00%	£107
Jonathan Emms	Nominal cost option	£0.17	1,630,435	25.00%	£277

Ian Johnson's share options will vest on the third anniversary of the date of grant and are exercisable until the tenth anniversary of the date of grant. Vesting is subject to either the share price reaching 62.4p, equating to three times the average closing price for an ordinary share for the 10 dealing days immediately preceding the grant date, for at least 30 consecutive dealing days or a liquidity event occurring above this level.

All other share options vest 3 years from date of grant and are subject to an additional two-year holding period.

On 1 May 2020, Messrs Roller, Johnson and Emms were granted 4,000,000, 1,677,233 and 1,128,966 options respectively over new ordinary shares in the Company under the Performance Share Plan.

The options will vest on the third anniversary of the date of grant and are exercisable until the tenth anniversary of the date of grant. Vesting is subject to either the price of an ordinary share reaching 62.4p for at least 30 consecutive dealing days or a liquidity event occurring above this level.

Deferred bonus share awards made during the year

During the year, the following awards were made under the Circassia Group plc Deferred Share Bonus Plan (the DSBP) to the Executive Directors in respect of the deferred portion of their 2018 bonus.

Executive Director	Type of award	Share price at date of grant	Number of shares over which award was granted	Face value of shares over which award originally granted £'000
Steven Harris	Deferred bonus	£0.40	104,896	£42
Julien Cotta	Deferred bonus	£0.40	156,206	£62
Rod Hafner	Deferred bonus	£0.40	151,604	£61

All deferred bonus shares are held for three years from date of grant. Awards made under the deferred share bonus plan from 2020 onwards will be held for two years from date of grant.

Gain on exercise of share options

No directors exercised share options in the financial years ended 31 December 2019 and 2018.

Payments to past directors (audited)

There were no payments during the financial year to past directors.

Payments for loss of office (audited)

The Remuneration Committee's approach when exercising its discretion under the policy is to be mindful of the particular circumstance of the departure and the contribution the individual made to the Group.

Dr Francesco Granata

Dr Francesco Granata stepped down as Chairman of the Company on 4 December 2019 and was paid £36,806 in lieu of notice until his termination date of 3 March 2020.

Steve Harris

Steve Harris stepped down from the Board as Chief Executive Officer on 31 December 2019 and was placed on garden leave until his employment with the company ends on the termination date. The termination date will be at the latest 4 December 2020. If Mr Harris wishes to commence employment or provide services to a new company such that he wishes to curtail his notice period, he can do so provided he gives sufficient notice.

Mr Harris will continue to be paid his normal monthly salary and will receive contractual benefits up to and including the termination date, as defined above. Depending on the agreed termination date, he will receive a maximum of £391,643 in respect of salary, £39,164 in respect of a pension supplement, and £1,655 of taxable benefits. He will receive no additional termination payments.

The Board of Directors has permitted payment of a bonus in respect of 2019. This will not be subject to the 50% deferral rules. No bonus shall be due or payable for the 2020 performance year or thereafter, nor will he be granted any long-term incentive awards.

Corporate governance

Remuneration Committee report, continued.

Portions of Mr Harris's bonuses for the financial years 2014, 2015, 2017 and 2018 were deferred for three years in the form of shares. The deferred bonus shares in respect of 2017 and 2018 were due to vest on 6 February 2021 and 5 February 2022 respectively. These will now vest on the termination date, as defined above, and remain subject to malus and clawback provisions.

Mr Harris is entitled to retain his outstanding long-term incentive awards, and these shall vest on the normal vesting date, subject to the PSP rules. The 2019 award will remain subject to a two-year holding period following the end of the three-year performance period.

Julien Cotta

On 18 December 2019, the Board agreed for Julien Cotta to step down following the appointment of Michael Roller as Chief Financial Officer. Mr Cotta stepped down from the Board as CFO on 9 January 2020 and was placed on garden leave until his employment with the company ends on the termination date. The termination date will be at the latest 9 January 2021. If Mr Cotta wishes to commence employment or provide services to a new company such that he wishes to curtail his notice period, he can do so provided he gives sufficient notice.

Mr Cotta will continue to be paid his normal monthly salary and will receive contractual benefits up to and including the termination date, as defined above. Depending on the agreed termination date, he will receive a maximum of £272,322 in respect of salary, £27,233 in respect of a pension supplement, and £1,999 of taxable benefits. Mr Cotta will also receive an ex-gratia termination payment of £90,000 within 28 days of the termination date.

The Board of Directors has permitted payment of a bonus in respect of 2019. This will not be subject to the 50% deferral rules. No bonus shall be due or payable for the 2020 performance year or thereafter, nor will he be granted any long-term incentive awards.

Portions of Mr Cotta's bonuses for the financial years 2014, 2015, 2017 and 2018 were deferred for three years in the form of shares. The deferred bonus shares in respect of 2017 and 2018 were due to vest on 6 February 2021 and 5 February 2022 respectively. These will now vest on the termination date, as defined above, and remain subject to malus and clawback provisions.

Mr Cotta is entitled to retain his outstanding long-term incentive awards, and these shall vest on the normal vesting date, subject to the PSP rules. The 2019 award will remain subject to a two-year holding period following the end of the three-year performance period.

Rod Hafner

Rod Hafner stepped down from the Board as an Executive Director on 2 September 2019 and remained an employee of Circassia Limited until 17 January 2020 when he was placed on garden leave until his employment ended on 22 April 2020.

Mr Hafner continued to be paid his normal monthly salary and received contractual benefits up to and including the termination date. He received £77,695 in respect of salary, £7,769 in respect of a pension supplement, and £486 of taxable benefits. Mr Hafner also received a statutory termination payment of £10,238.

Portions of Mr Hafner's bonuses for the financial years 2014, 2015, 2017 and 2018 were deferred for three years in the form of shares. The deferred bonus shares in respect of 2017 and 2018 were due to vest on 6 February 2021 and 5 February 2022 respectively. These vested on 22 April 2020 and remain subject to malus and clawback provisions.

Mr Hafner is entitled to retain his outstanding long-term incentive awards, and these shall vest on the normal vesting date, subject to the PSP rules. The 2019 award is not subject to an additional two-year holding period.

PIRC guidance on payment of 2019 bonuses

The only current Executive Director entitled to a bonus in respect of 2019 is Jonathan Emms; he has waived his bonus entitlement in accordance with PIRC guidelines.

The Company had entered into legally binding settlement agreements with Messrs Harris, Cotta and Hafner prior to the date of issuance of the PIRC guidance. These agreements contained provisions for the payment of 2019 bonuses upon the publication of audited results for 2019.

Statement of directors' shareholding and share interests (audited)

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

The value of the shareholding is calculated using the higher of the share price on 31 December 2019 (19p) and the acquisition price of the shares.

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

	Shares beneficially owned as at 31 December 2019	Value of owned shares as a % of salary	Requirement met?
Executive Directors			
I Johnson	—	0%	No
S Harris	6,494,427	266%	Yes
J Cotta	46,875	3%	No
R Hafner	900,544	53%	No
J Emms	300,000	18%	No
Non-Executive Directors			
F Granata	331,854	n/a	n/a

On 9 April 2020, Ian Johnson, Executive Chairman of Circassia purchased 200,000 ordinary shares at a price of 22.85 pence per share, Michael Roller, Chief Financial Officer purchased 200,000 ordinary shares at a price of 22.683 pence per share and Jonathan Emms, Chief Operating Officer of Circassia, purchased 300,000 ordinary shares at a price of 23.2 pence per share.

Following these purchases, Ian Johnson holds 200,000 ordinary shares (0.05% of the issued share capital of the Company), Michael Roller holds 200,000 ordinary shares (0.05% of the issued share capital of the Company) and Jonathan Emms holds 600,000 ordinary shares (0.16% of the issued share capital of the Company).

Corporate governance

Remuneration Committee report, continued

Statement of directors' shareholding and share interests (audited)

Plan	Date of grant	Awards granted, and options held as at 1 January 2019	Awards and options granted, exercised, lapsed, or cancelled during year	Awards and options held at 31 December 2019 and at the date of this report
Executive Directors				
I Johnson				
2019 PSP	19-Dec-19	—	4,322,767	4,322,767
Total		—	4,322,767	4,322,767
S Harris				
2014 PSP	12-Mar-14	52,736	—	52,736
2015 PSP	26-Feb-15	42,889	—	42,889
2016 PSP	19-May-16	212,946	(133,091)	79,855
2017 PSP	17-May-17	425,000	—	425,000
2018 PSP	17-May-18	425,000	—	425,000
2019 PSP	23-Aug-19	—	803,200	803,200
Total		1,158,571	670,109	1,828,680
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	22,408	—	22,408
2016 PSP	19-May-16	111,272	(69,545)	41,727
2017 PSP	17-May-17	250,000	—	250,000
2018 PSP	17-May-18	250,000	—	250,000
2019 PSP	23-Aug-19	—	518,728	518,728
Total		810,466	449,183	1,259,649
R Hafner				
2014 PSP	12-Mar-14	42,998	—	42,998
2015 PSP	26-Feb-15	24,306	—	24,306
2016 PSP	19-May-16	120,703	(75,439)	45,264
2017 PSP	17-May-17	250,000	—	250,000
2018 PSP	17-May-18	250,000	—	250,000
2019 PSP	23-Aug-19	—	562,674	562,674
Total		688,007	487,235	1,175,242
J Emms				
2019 PSP	17-Oct-19	—	1,630,435	1,630,435
Total		—	1,630,435	1,630,435

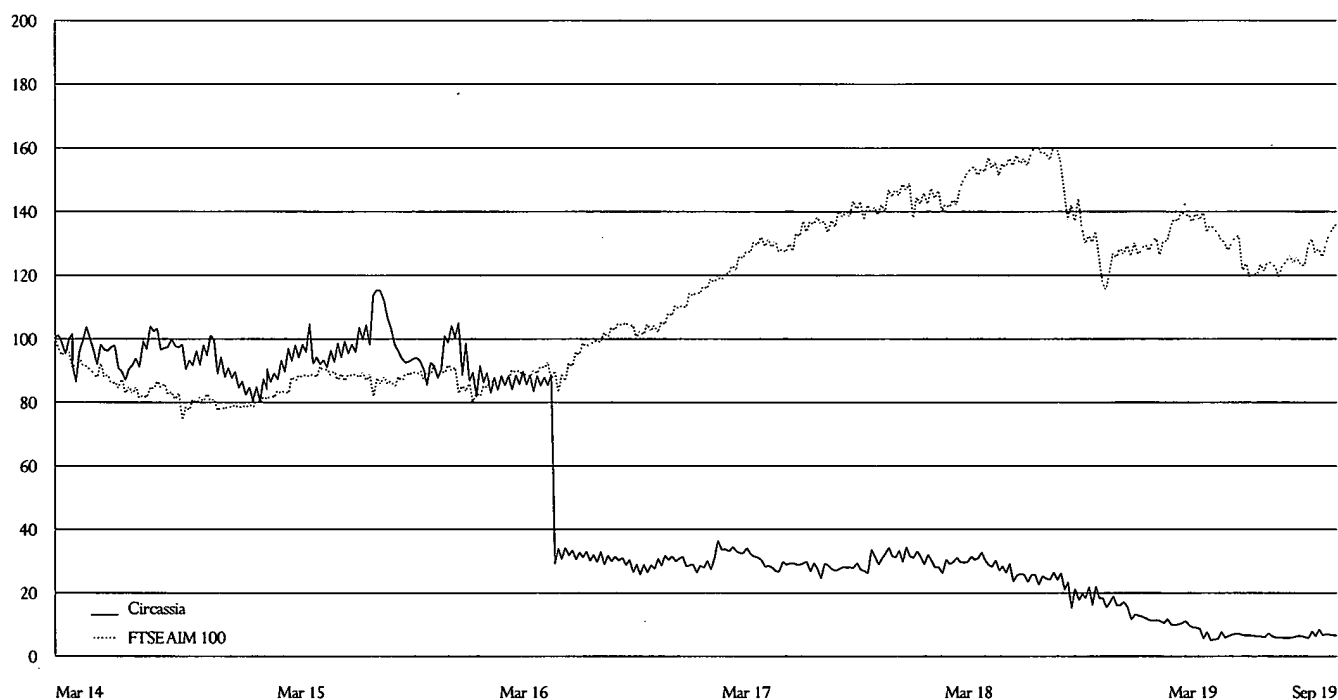
Vesting during year	Vested as at year end	Unvested as at year end	Exercise price (p)	Date from which first exercisable	Expiry date
—	—	4,322,767	nil	19-Dec-22	19-Dec-29
—	—	4,322,767			
—	52,736	—	nil	12-Mar-17	11-Mar-24
—	42,889	—	0.08	26-Feb-18	25-Feb-25
79,855	79,855	—	0.08	19-May-19	18-May-26
—	—	425,000	0.08	17-May-20	16-May-27
—	—	425,000	0.08	17-May-21	16-May-28
—	—	803,200	0.08	23-Aug-22	23-Aug-29
79,855	175,480	1,653,200			
—	149,250	—	242	22-Oct-16	21-Oct-23
—	27,536	—	nil	12-Mar-17	11-Mar-24
—	22,408	—	0.08	26-Feb-18	25-Feb-25
41,727	41,727	—	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
—	—	518,728	0.08	23-Aug-22	23-Aug-29
41,727	240,921	1,018,728			
—	42,998	—	nil	12-Mar-17	11-Mar-24
—	24,306	—	0.08	26-Feb-18	25-Feb-25
45,264	45,264	—	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
—	—	562,674	0.08	23-Aug-22	23-Aug-29
45,264	112,568	1,062,674			
—	—	1,630,435	0.08	17-Oct-22	17-Oct-29
—	—	1,630,435			

Corporate governance

Remuneration Committee report, continued

Performance graph

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 2019 is shown in the graph below:



Chief Executive Officer's remuneration

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

		2019	2018	2017	2016	2015	2014
Ian Johnson	(£'000)	12	—	—	—	—	—
Steven Harris	(£'000)	649	669	825	458	831	1,528
Total remuneration	(£'000)	661	669	825	458	831	1528
Percentage change in total remuneration from the preceding financial year	(%)	(1%)	(19%)	80%	(45%)	(46%)	—
Bonus awarded	(%)	25%	40%	75%	Nil	100%	93%
LTIP vesting	(%)	38%	20%	21%	n/a	n/a	100%

The CEO's salary did not increase between 31 December 2018 and 31 December 2019. This average percentage increase in respect of employees of the Group was 2%.

Relative importance of spend on pay

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

	2019 £m	2018 £m
Overall expenditure on pay	37.9	49.0
Dividend plus share buyback	Nil	Nil

Statement of voting at general meeting

The annual report on remuneration was approved by shareholders at the AGM held on 7 June 2019 with the following votes cast for and against:

Voting results at 2019 AGM	For (%)	Against (%)	Withheld (votes)
To approve the annual report on remuneration	99.99	0.01	2,100

The annual report on remuneration was approved by shareholders at the 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.

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

Directors' remuneration policy

The directors' remuneration policy was approved at the AGM on 7 June 2019 and is expected to remain in force until the AGM in 2022.

Statement of implementation of remuneration policy in the following financial year

Base salary

The Committee considered the base salaries for Executive Directors and agreed there will be no change.

Salary per annum	2020 £	2019 £
Ian Johnson (Executive Chairman)	300,000	300,000
Michael Roller (CFO)	220,000	—
Jonathan Emms (COO)	300,000	300,000

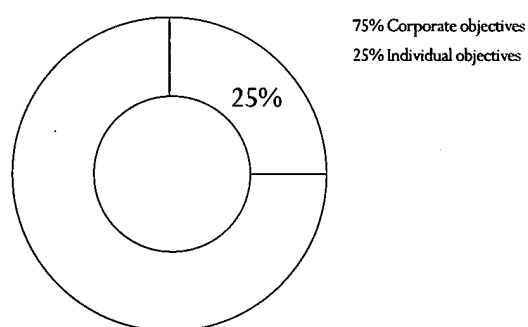
Corporate governance

Remuneration Committee report, continued

Annual bonus

The 2020 annual bonus structure and weighting for the Chief Operating Officer remains unchanged, and is set out below:

2020 Bonus Structure



Neither Ian Johnson nor Michael Roller are eligible to participate in the annual bonus scheme, as discussed on page 64 of this report.

Details of the specific financial targets for the bonuses are not provided as these are commercially sensitive. The achievement against these targets will be disclosed in next financial year's annual report.

Service contracts and letters of appointment

Executive Directors are engaged on rolling service contracts, which provide for 6 months' written notice of termination from either the individual or the Company.

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

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

Illustration of application of remuneration policy

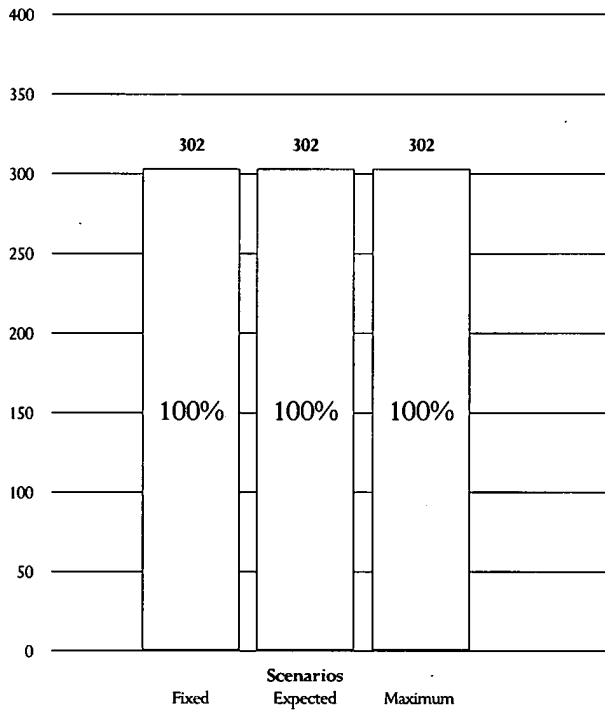
The chart below sets out for illustrative purposes only, what annual remuneration the Company expects the Executive Directors to obtain in the next financial year if performance levels are below threshold, meet expectations or exceed the maximum targets.

The assumptions used in the calculations are set out below:

- Fixed pay: this includes salary, pension and benefits. Base salary effective 1 January 2020 and expected pension contribution has been used. The actual monetary value of benefits received in 2019 have been used.
- Expected: this includes salary, pension, benefits, annual bonus and PSP. This assumes that 50% of the annual bonus maximum will be payable for the COO. The Executive Chairman and CFO are not eligible to participate in the annual bonus scheme. It also assumes that 50% of PSP awards for the COO will vest (this is nil as the first tranche of PSP awarded to the COO vest in 2022), and 0% for the Executive Chairman and CFO.
- Maximum: It is assumed that the maximum annual bonus would be payable and that the awards under the PSP vest in full.
- No share price growth has been assumed.

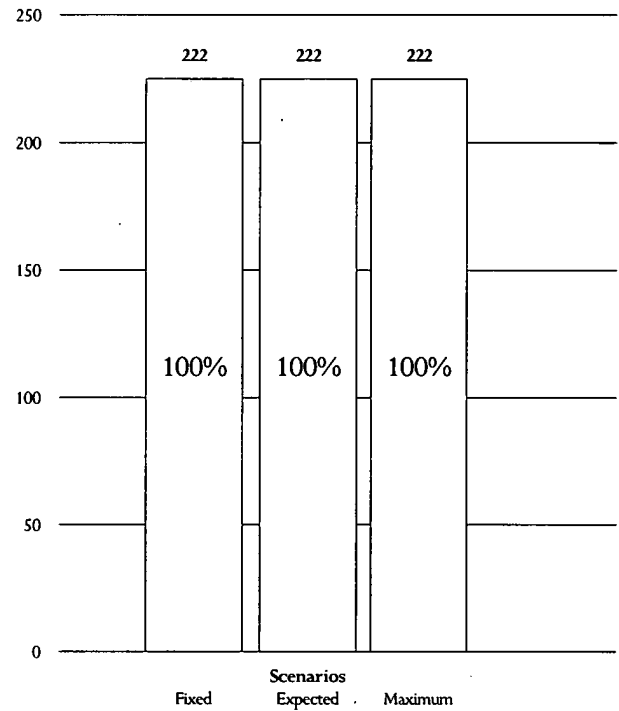
Executive Chairman

£'000



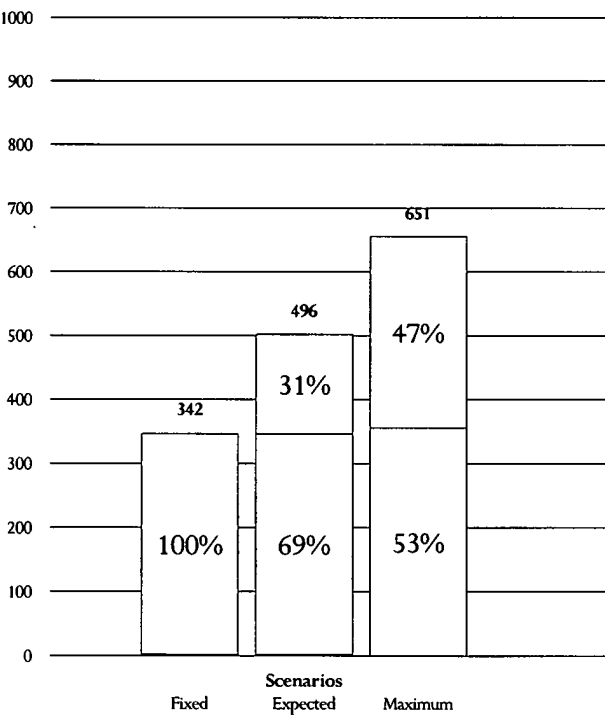
CFO

£'000



COO

£'000



Fixed
Annual bonus
Long-term variable remuneration

Corporate governance

Remuneration Committee report, continued

Statement of consideration of employment conditions elsewhere in the company

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. 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 corporate and individual performance, with Executive Directors bonus weighted more heavily towards corporate objectives.

Approval

This report was approved by the Board on 16 June 2020 and signed on its behalf by:

Sharon Curran

Chair of the Remuneration Committee

16 June 2020

Corporate governance

Directors' report

Directors' report

In accordance with the Companies Act 2006, the directors present their report together with the consolidated financial statements and the Independent auditors' report for the year ended 31 December 2019.

Change of name

With effect from 1 May 2020, the name of the Company was changed from Circassia Pharmaceuticals plc to Circassia Group plc.

Information included in Strategic report

The Company's Strategic report is on pages 01 to 43 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	4 to 15
Research and development	4 to 15
Employee involvement	29
Disclosures concerning greenhouse gas emissions	32
Post balance sheet events (note 37)	141

Corporate governance statement

The information that fulfils the requirements of the Corporate Governance Statement can be found in the Corporate Governance report on pages 46 to 53 and the Strategic report on pages 2 to 19 (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 2019 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 2019 (2018: £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.

Only Ms Jo LeCouilliard and Ms Sharon Curran served throughout the year and up to the date of this report.

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.

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. Furthermore, qualifying third party indemnity was in force during the financial year and at the date this report was approved.

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.

Corporate governance

Directors' report, continued

Share capital and shareholders

Share capital

At 1 January 2019 the Company had 357,286,434 ordinary shares in issue.

The share capital of the Company increased by 12,300,971 ordinary shares on 25 January 2019 and a further 5,271,844 ordinary shares on 4 February 2019 as a result of shares issued to BeyondAir (previously called AIT Therapeutics Inc.) such that BeyondAir's holding increased from nil to 4.69%. The share capital of the Company increased by a further 162,680 as a result of share issues required to satisfy employee share awards and a further 177,405 in return for broker services.

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 27 to the financial statements. The Circassia Pharmaceuticals plc Employee Benefit Trust (the "Trust") abstains from voting on the shares held by it. No shares were acquired by the Trust during the year (2018: 251,377), 6,738 were transferred out (2018: 125,524) and the balance of shares held at 31 December 2019 was therefore 727,138 (2018: 733,876).

Pursuant to the Articles of Association and vote of shareholders at the AGM which took place on 7 June 2019 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 2019 to 31 December 2019 the share price ranged from a high of 55p to a low of 14p. The average price for the period was 20p. The mid-market price of an ordinary share on 31 December 2019 was 19p.

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 2019.

Independent auditors

PricewaterhouseCoopers LLP has been re-appointed as auditor and a resolution to approve this re-appointment will be put to the members at the forthcoming Annual General Meeting.

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

Annual General Meeting

The Annual General Meeting will be held at the offices of Circassia Group plc on 23 July 2020 at 10:00 a.m. Details of the business to be transacted at the forthcoming AGM will be given in a separate circular to shareholders.

By order of the Board

Michael Roller
Company secretary

16 June 2020

Corporate governance

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

Corporate governance

Independent auditors' report to the members of Circassia Group plc

Report on the audit of the financial statements

Opinion

In our opinion:

- Circassia Group 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 2019 and of the Group's loss and the Group's and the Parent Company's cash flows for the year then ended;
- the Group financial statements have been properly prepared in accordance with International Financial Reporting Standards (IFRSs) as issued by the International Accounting Standards Board (IASB);
- the Parent Company financial statements have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards, comprising FRS 101 "Reduced Disclosure Framework", and applicable law); and
- the financial statements 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 2019; 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.

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 entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

Corporate governance

Independent auditors' report to the members of Circassia Group plc, continued

Our audit approach

Overview

- Overall Group materiality: £3.2 million (2018: £3.0 million), based on 5% of average loss before tax from continuing operations for the three years FY17 - FY19.
- Overall Parent Company materiality: £2.9 million (2018: £2.8 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.
- We have explained in more detail the split of work by the group and component teams in "the scope of our audit work" paragraph below.
- Recognition of variable consideration in Tudorza® sales for the period from 1 July 2019 (Group)
- Impairment of goodwill and intangible assets (Group)
- Duaklir® contingent royalty consideration (Group)
- COVID-19 (Group and Parent Company)
- Impairment of investments 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. In particular, we looked at where the directors made subjective judgements, for example in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits we also addressed the risk of management override of internal controls, including evaluating whether there was evidence of bias by the directors that represented a risk of material misstatement due to fraud.

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 Pharmaceuticals Inc (incorporated in the USA), 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 determined a full scope audit was required for Circassia (Beijing) Medical Devices Co. Ltd, based on our professional judgement and undertook the statutory audit of two further reporting units incorporated in the UK, Circassia Group plc and Circassia Limited. Circassia Group 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, Chinese and US component teams.

In addition to the work performed at the in-scope reporting entities, there is 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, share-based payments, current and deferred taxes, contingent royalty consideration, IFRS 9 and 16 adjustments, testing of COPD revenue for the period to 30 June 2019 and central adjustments recorded as part of the consolidation process.

In aggregate our audit procedures gave coverage over 97% 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. 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.

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.

Corporate governance

Independent auditors' report to the members of Circassia Group plc, continued

Key audit matter

How our audit addressed the key audit matter

Recognition of variable consideration in Tudorza® sales for the period from 1 July 2019 (Group)

The Group sells Tudorza® exclusively in the US, these sales are subject to various commercial and government mandated contracts and reimbursement arrangements that include rebates, returns and chargebacks. The most significant payer channels within the rebate accrual are Medicaid, Medicare and co-pay programmes. As described in Note 1, net revenue recognised includes an estimate of gross-to-net sales adjustments which involve significant estimation and judgement. Rebates provided to customers under these arrangements are accounted for as variable consideration, estimated at the time of sale using the expected value method, and recognised as a deduction in revenue, for which unsettled amounts are accrued, referred to by management as rebate accruals. Management has recognised total deductions in revenue in relation to Tudorza® for the period from 1 July 2019 of £25.4 million, including an estimated accrual of £12.9 million. The main causes of significant estimation uncertainty are:

- the utilisation rates (the portion of total sales which will be made into each payer channel), which is influenced by market demand and other factors outside the control of the Group, resulting in significant estimation uncertainty;
- the time lag between the point of sale and the point at which exact rebate amounts are known to the Group (upon receipt of a claim), which can be up to one year. Those payer channels with the longest time lag result in a greater accrued period, and as such a greater level of estimation uncertainty.
- the limited history available to management, given the short period of time following the transition of the product sales through the AstraZeneca channel to the channel run directly by Circassia from 1 July 2019 with different commercial arrangements.

Refer to pages 56 (Audit Committee Report) and page 99 (Critical accounting estimates and judgements).

Our US component audit team have performed the following audit procedures:

- evaluated methodology applied by management in estimating the accrual against industry practice;
- substantively tested a sample of actual rebate claims received and paid to supporting documentation;
- agreed a sample of estimated rebate percentages to contract or government regulations
- agreed a sample of estimated utilisation rates to third-party information
- recalculated the accrual recognised using management's assumptions;
- traced a sample of management's estimate of sales by channel to independent third-party sales data obtained by management
- developed an expectation of the accrual balance for each of the key channels, based on historical claims received adjusted to reflect market changes in the period including an assessment of the time lag between the initial point of sale and the claim receipt. We then used this expectation to consider the appropriateness of management's ending accrual position.

We have supported and directed as appropriate the work performed by our component audit team, including reviewing their working papers and attending key meetings.

Based on the procedures performed we did not identify any material misstatements in the accruals.

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. Management performed their annual impairment review and an impairment trigger was identified relating to the performance of the COPD assets. This resulted in an impairment of £4.1 million to goodwill and £42.1 million to intangible assets. An impairment trigger was also identified for the AIT cash generating unit following the dispute that has arisen with BeyondAir. This resulted in an impairment of £44.0 million of intangible assets. No impairment was recognised in respect of the NIOX® cash generating unit.

Goodwill of £4.8 million and intangible assets of £163.0 million are significant balances to the Group. Judgement is required in the impairment assessment, specifically in forecasting the future results of 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 page 57 (Audit Committee Report), page 100 (Critical accounting estimates and judgements), and pages 122 and 125 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 three cash generating units (CGU's), all of which are active.

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: For the NIOX® CGU, we used our experts to compare the forecast revenues with market expectations, where available. We observed that the management sales forecasts, including the growth rates applied, are close to market expectations. For COPD, we tested historical forecasting accuracy and assessed the appropriateness of assumptions. We identified and corroborated any differences in the historical forecasting accuracy to conclude that forecasting accuracy is appropriate.
- Expenses and overheads: We tested historical forecasting accuracy and assessed the appropriateness of assumptions. 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 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 appropriate.

Corporate governance

Independent auditors' report to the members of Circassia Group plc, continued

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 £56.5 million is a significant balance. In addition, the Parent Company has net intercompany receivables totalling £35.1 million from its subsidiary companies. Management have considered the performance of the COPD assets as a potential impairment trigger as the balances are expected to be repaid from future trading cashflows. Management have recorded impairments of £12.5 million and £256.4 million against the investment in subsidiaries and intercompany receivables balances respectively in the year.

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 the calculation of the impairment of the intercompany receivables and investment in the subsidiary undertakings. Management have considered a range of scenarios in determining the recoverability of the intercompany balance in line with IFRS 9.

Refer to pages 57 (Audit Committee Report), page 100 (Critical accounting estimates and judgements), and pages 125 and 130 in the notes.

The company's investment in subsidiaries and intercompany receivables balances are expected to be repaid from future trading cashflows. The performance of the COPD assets is considered to be a potential impairment trigger. Management have performed an assessment over the recoverability of the asset balances.

After performing this assessment, management have recorded impairments of £12.5 million and £256.4 million against the investment in subsidiaries and intercompany receivables balances respectively in the year.

We have leveraged our testing (as set out in the KAM titled "Impairment of goodwill and intangibles" above) of the 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 on a subsidiary-by-subsidiary basis.

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 £12.5 million to investments in subsidiaries and £256.4 million to intercompany receivables recorded by management are appropriate.

Misstatement of Duaklir® royalty consideration (Group)

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

As part of the terms, Circassia agreed to pay contingent consideration linked to the future sales of Duaklir®.

Management has considered the impact of the performance of Duaklir® and the potential return of the Duaklir® rights to AstraZeneca and has estimated that there will be no further royalty payments due in relation to Duaklir® sales, and the brought forward royalty consideration creditor of £44.1 million has been taken to the profit and loss account in the period.

Refer to page 57 (Audit Committee Report), page 100 (Critical accounting estimates and judgements), and page 133 in the notes.

We have performed the following procedures to address the key audit matter:

- critically assessed and challenged the assumptions inherent in management's assessment;
- tested the terms and conditions of the return of the products to AstraZeneca; and
- tested management forecasts for future sales of Duaklir®.

From the procedures performed, we found that management's analysis is supportable and that the disclosures within the financial statements are appropriate.

COVID-19 (Group and Company)

In December 2019, a novel strain of coronavirus (COVID-19) surfaced in China and has spread globally. The extent of the impact of the virus was not anticipated as at 31 December 2019 and it was not considered a global pandemic until after the year end, when this was declared by the World Health Organisation (WHO). Consequently, the impact of the virus is not considered an adjusting post balance sheet event for the purposes of these financial statements.

As noted in the company's press release dated 9 April 2020, COVID-19 has had an impact on the Group's trading in 2020, and may impact the Group's ability, as well as the ability of the Group's customers and suppliers, to operate in a "business as usual" manner, which could have a material effect on the results of the business, financial condition or results of operations.

The Group has considered the potential impacts on its cash flow and liquidity position by performing various sensitivities and modelling scenarios to ensure that it has sufficient liquidity to continue as a going concern.

The Group has also considered the potential impacts on its required disclosures for this non adjusting event in relation to impairment testing of intangibles, goodwill, deferred tax assets and for the parent investments and intercompany receivables.

Refer to pages 57 and 58 (Audit Committee Report) and pages 98 and 99 (Critical accounting estimates and judgements).

We have performed the following procedures to address the key audit matter:

- held discussions with management to understand, in qualitative terms, the impact of COVID-19 on business operations;
- evaluated management's sensitivities/modelling and challenged the key assumptions contained within the cash flow forecasts;
- assessed the reasonableness/achievability of management's mitigating actions; and
- read management's disclosures in the financial statements.

From the procedures performed, we agree that it is appropriate that the Group prepares the accounts on a going concern basis and consider that the related disclosures within the financial statements 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	£3.2 million (2018: £3.0 million).	£2.9 million (2018: £2.8 million).
How we determined it	5% of average loss before tax from continuing operations for the three years FY17 – FY19.	1% of total assets restricted so as not to exceed 95% of Group materiality.
Rationale for benchmark applied	The business continues to pursue revenue generating activities. We therefore considered loss before tax to be the most appropriate benchmark. To reflect the continued growth in the business and decrease in loss from continuing operations year on year, we determined to change our benchmark this year to take into account the average trading performance of the Group's continuing operations over the past three years. This provides a stable materiality benchmark which takes into account the improved performance of the Group.	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.

Corporate governance

Independent auditors' report to the members of Circassia Group plc, continued

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 £0.5 million and £2.9 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 £157,600 (Group audit) (2018: £149,500) and £157,600 (Parent Company audit) (2018: £149,500) as well as misstatements below those amounts that, in our view, warranted reporting for qualitative reasons.

Conclusions relating to going concern

We have nothing to report in respect of the following matters in relation to which ISAs (UK) require us to report to you where:

- 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.

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.

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, ISAs (UK) require us also to report certain opinions and matters as described below.

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 2019 is consistent with the financial statements and has been prepared in accordance with applicable legal requirements.

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.

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 in respect of the financial statements, 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.

Miles Saunders (Senior Statutory Auditor)
for and on behalf of PricewaterhouseCoopers LLP
Chartered Accountants and Statutory Auditors

Reading
16 June 2020

Consolidated statement of comprehensive income for the year ended 31 December 2019

		2019			2018		
	Notes	Underlying operations £m	Non-underlying items £m	Total £m	Underlying operations £m	Non-underlying items £m	Total £m
Continuing operations							
Revenue from contracts with customers	4	62.4	–	62.4	48.3	–	48.3
Cost of sales		(16.2)	–	(16.2)	(8.9)	–	(8.9)
Gross profit		46.2	–	46.2	39.4	–	39.4
Research and development costs	6	(19.1)	(90.4)	(109.5)	(10.8)	–	(10.8)
Sales and marketing		(57.5)	–	(57.5)	(54.4)	(2.9)	(57.3)
Administrative expenses		(12.6)	(1.1)	(13.7)	(11.4)	(0.3)	(11.7)
Operating loss		(43.0)	(91.5)	(134.5)	(37.2)	(3.2)	(40.4)
Other (losses) and gains – net	7	(3.5)	97.5	94.0	1.9	(5.6)	(3.7)
Finance costs	8	(3.5)	(15.3)	(18.8)	(0.1)	(11.9)	(12.0)
Finance income	8	0.2	–	0.2	0.3	–	0.3
Loss before tax		(49.8)	(9.3)	(59.1)	(35.1)	(20.7)	(55.8)
Taxation	12	10.8	–	10.8	9.2	–	9.2
Loss from continuing operations		(39.0)	(9.3)	(48.3)	(25.9)	(20.7)	(46.6)
Discontinued operations							
Loss from discontinued operations (attributable to owners of Circassia Group plc)	10	–	–	–	–	(70.5)	(70.5)
Loss for the year		(39.0)	(9.3)	(48.3)	(25.9)	(91.2)	(117.1)
Other comprehensive expense							
Items that may be subsequently reclassified to profit or loss							
Exchange differences on translation of foreign operations	31	(1.6)	–	(1.6)	(4.8)	–	(4.8)
Other comprehensive expense for the year, net of tax		(1.6)	–	(1.6)	(4.8)	–	(4.8)
Total comprehensive expense for the year		(40.6)	(9.3)	(49.9)	(30.7)	(91.2)	(121.9)

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

		2019 £	2018 £
Basic and diluted loss per share			
Loss per share from continuing operations	13	(0.13)	(0.14)
Total loss per share	13	(0.13)	(0.34)

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.

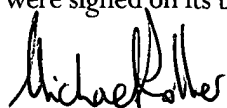
The notes on pages 98 to 143 are an integral part of these financial statements.

Consolidated statement of financial position as at 31 December 2019

	Notes	2019 £m	2018 £m
Assets			
Non-current assets			
Property, plant and equipment	14	0.5	0.5
Right-of-use assets	15	1.9	—
Goodwill	16	4.8	9.3
Intangible assets	17	163.0	221.4
Deferred tax assets	26	28.3	19.1
Investment in joint venture	19	—	0.1
Non-current tax assets	12	—	3.0
		198.5	253.4
Current assets			
Inventories	20	6.5	4.2
Trade and other receivables	21	14.6	8.1
Current tax assets	12	0.2	1.0
Cash and cash equivalents	22	27.0	40.7
		48.3	54.0
Total assets		246.8	307.4
Equity			
Share capital	28	0.3	0.3
Share premium	29	630.4	622.5
Other reserves	30	14.7	15.1
Accumulated losses	31	(560.6)	(512.0)
Total equity		84.8	125.9
Liabilities			
Non-current liabilities			
Borrowings	25	109.9	—
Lease liabilities	15	1.5	—
Deferred tax liabilities	26	9.3	10.9
Contingent consideration	24	—	46.2
		120.7	57.1
Current liabilities			
Trade and other payables	23	39.6	28.7
Lease liabilities	15	0.6	—
Non-contingent consideration	24	—	80.3
Contingent consideration	24	1.1	15.4
		41.3	124.4
Total liabilities		162.0	181.5
Total equity and liabilities		246.8	307.4

The notes on pages 98 to 143 are an integral part of these financial statements.

The financial statements on pages 92 to 143 were authorised for issue by the Board of Directors on 16 June 2020 and were signed on its behalf by



Michael Roller
Chief Financial Officer
Circassia Group plc

Registered number: 05822706

Parent Company statement of financial position as at 31 December 2019

	Notes	2019 £m	2018 £m
Assets			
Non-current assets			
Investments in subsidiaries	18	56.5	67.6
		56.5	67.6
Current assets			
Trade and other receivables	21	35.1	282.6
Cash and cash equivalents	22	0.1	0.1
		35.2	282.7
Total assets		91.7	350.3
Equity attributable to the owners of the Company			
Share capital	28	0.3	0.3
Share premium	29	630.4	622.5
Accumulated losses	30	(558.7)	(289.9)
Other reserves	31	11.8	11.3
Total equity		83.8	344.2
Liabilities			
Current liabilities			
Trade and other payables	23	7.9	6.1
		7.9	6.1
Total equity and liabilities		91.7	350.3

The loss for the Parent Company for the year was £268.8 million (2018: £291.8 million).

The notes on pages 98 to 143 are an integral part of these financial statements.

The financial statements on pages 92 to 143 were authorised for issue by the Board of Directors on 16 June 2020 and were signed on its behalf by



Michael Roller
Chief Financial Officer
Circassia Group plc

Registered number: 05822706

Consolidated and Parent Company statements of cash flows for the year ended 31 December 2019

	Notes	Group		Company	
		2019 £m	2018 £m	2019 £m	2018 £m
Cash flows from operating activities					
Cash (used in)/generated from operations	32	(28.9)	(51.3)	(6.7)	11.7
Interest paid	8	(0.1)	(0.2)	–	–
Tax credit received	12	3.9	10.9	–	–
Net cash (used in)/generated from operating activities		(25.1)	(40.6)	(6.7)	11.7
Cash flows from investing activities					
Payments for property, plant and equipment	14	(0.3)	(0.1)	–	–
Payments for intangible assets	17	(10.0)	(0.3)	–	–
Proceeds from sale of property, plant and equipment	14	–	0.5	–	–
Interest received	8	0.3	0.2	–	–
Dividends from joint venture	19	0.1	0.3	–	–
Grant of loans to subsidiary undertakings	21	–	–	(1.2)	(45.5)
Decrease in short-term bank deposits	22	–	15.0	–	15.0
Net cash (used in)/generated from investing activities		(9.9)	15.6	(1.2)	(30.5)
Cash flows from financing activities					
Proceeds from issue of shares	28	8.0	20.4	8.0	20.4
Share issue transaction costs	28	(0.1)	(0.1)	(0.1)	(0.1)
Proceeds from borrowings	25	14.9	–	–	–
Acquisition of interest in a subsidiary	18	–	–	–	(1.7)
Principal elements of lease payments	15	(0.9)	–	–	–
Net cash generated from financing activities		21.9	20.3	7.9	18.6
Net decrease in cash and cash equivalents		(13.1)	(4.7)	–	(0.2)
Cash and cash equivalents at 1 January	22	40.7	44.5	0.1	0.3
Effects of exchange rate changes on cash and cash equivalents		(0.6)	0.9	–	–
Cash and cash equivalents at 31 December	22	27.0	40.7	0.1	0.1

The notes on pages 98 to 143 are an integral part of these financial statements.

Consolidated statement of changes in equity for the year ended 31 December 2019

	Notes	Share capital £m	Share premium £m	Other reserves ¹ £m	Accumulated losses £m	Total equity £m
At 1 January 2018		0.3	602.2	17.2	(394.9)	224.8
Loss for the year	30	—	—	—	(117.1)	(117.1)
Currency translation differences	31	—	—	(4.8)	—	(4.8)
Total comprehensive expense		—	—	(4.8)	(117.1)	(121.9)
Transactions with owners:						
Issue of ordinary shares	28, 29	—	20.3	—	—	20.3
Employee share option scheme	27	—	—	2.7	—	2.7
At 31 December 2018		0.3	622.5	15.1	(512.0)	125.9
Change in accounting policy	38	—	—	—	(0.3)	(0.3)
Restated at 1 January 2019		0.3	622.5	15.1	(512.3)	125.6
Loss for the year	30	—	—	—	(48.3)	(48.3)
Currency translation differences	31	—	—	(1.6)	—	(1.6)
Total comprehensive expense		—	—	(1.6)	(48.3)	(49.9)
Issue of ordinary shares	28, 29	—	7.9	—	—	7.9
Acquisition of treasury shares	31	—	—	(0.2)	—	(0.2)
Employee share option scheme	27	—	—	1.4	—	1.4
At 31 December 2019		0.3	630.4	14.7	(560.6)	84.8

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

The notes on pages 98 to 143 are an integral part of these financial statements.

Parent Company statement of changes in equity for the year ended 31 December 2019

	Notes	Share capital £m	Share premium £m	Other reserves ¹ £m	Retained earnings/ (Accumulated losses) £m	Total equity £m
At 1 January 2018		0.3	602.2	8.6	1.9	613.0
Loss and total comprehensive expense	30	—	—	—	(291.8)	(291.8)
Transactions with owners:						
Issue of ordinary shares	28, 29	—	20.3	—	—	20.3
Employee share option scheme	27	—	—	2.7	—	2.7
At 31 December 2018		0.3	622.5	11.3	(289.9)	344.2
At 1 January 2019		0.3	622.5	11.3	(289.9)	344.2
Loss and total comprehensive income	28	—	—	—	(268.8)	(268.8)
Transactions with owners:						
Issue of ordinary shares	28, 29	—	7.9	—	—	7.9
Acquisition of own shares	31	—	—	(0.9)	—	(0.9)
Employee share option scheme	27	—	—	1.4	—	1.4
At 31 December 2019		0.3	630.4	11.8	(558.7)	83.8

¹ Other reserves include share option reserve and own shares reserve.

The notes on pages 98 to 143 are an integral part of these financial statements.

Notes to the financial statements

1. Accounting policies and significant judgements

General information

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

Circassia Group 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.

The directors do not recommend the payment of a dividend for the year ended 31 December 2019 (2018: £nil).

Basis of preparation

With effect from 1 May 2020, the name of the Company was changed from Circassia Pharmaceuticals plc to Circassia Group plc. The consolidated financial statements of the Circassia Group plc Group have been prepared in accordance with International Financial Reporting Standards (IFRS) and interpretations issued by the IFRS Interpretations Committee (IFRS IC) applicable to companies reporting under IFRS. The financial statements comply with IFRS as issued by the International Accounting Standards Board (IASB). 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 2019 and 2018 are audited. Statutory accounts of the Company in respect of the financial year ended 31 December 2019 were approved by the Board of Directors on 16 June 2020 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 2019 under section 479A of Companies Act 2006. Circassia Group 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

In assessing the appropriateness of the going concern assumption, the Board has considered the availability of funding alongside the possible cash requirements of the Group and Company, taking into account the unprecedented circumstances caused by COVID-19.

The Board has prepared cash flow forecasts for a period of 18 months from the date of approval of these financial statements. This base case scenario includes the benefits of actions already taken by management to mitigate the trading downsides brought about by COVID-19, for example, restrictions on travel, limiting new hires and reducing discretionary spend as well as utilising the equity facility agreed with significant shareholders. This base case assumes that sales of NIOX® will gradually build back towards pre-COVID-19 levels of trade (94% of the value of budgeted sales) by December 2020. Under this base case scenario, the Group is expected to continue to have sufficient resources beyond 12 months from the approval of the financial statements.

The most extreme downside scenario modelled the impact of no recovery from current levels of NIOX® sales up until December 2020, rising to around 76% of pre-COVID-19 sales in December 2021 and remaining at this level for the foreseeable future. In addition, this assumes a gradual reduction of current Tudorza® revenue down to a reduction to 80% of current levels by the end of 2020, when it is expected that the run off period for this activity will cease. These reductions in revenue would be offset by significant mitigating cost reductions and cash protection actions, within the control of the Board, commencing in September 2020 (for example significant salary cuts for Board members, non-payment of discretionary bonuses and the reduction in size of certain central functions by the end of 2020). In this scenario the Group remains cash positive beyond 12 months from the approval of the financial statements.

After due consideration, the directors have concluded that there is a reasonable expectation that the Group has adequate resources to continue in operational existence for at least 12 months from the date of this report.

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 2019:

IFRS 16 – Leases

The Group elected to adopt the new rules retrospectively from 1 January 2019 but has not restated comparatives for the 2018 reporting period, as permitted under the specific transition provisions in the standard. The reclassifications and the adjustments arising from the new leasing rules are therefore recognised in the opening balance sheet on 1 January 2019. This is disclosed in note 38.

New standards and interpretations not yet adopted

Certain new accounting standards and interpretations have been published that are not mandatory for 31 December 2019 reporting periods and have not been early adopted by the Group. These standards are not expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

Critical accounting estimates, 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 turning out to be wrong. Detailed information about each of these estimates and judgements is included in other notes together with information about the basis of calculation for each affected line item in the financial statements.

The areas involving significant estimates or judgements are:

Rebate accruals (estimate)

When invoicing Tudorza® sales, Circassia must estimate the rebates and chargebacks that are expected to be paid. These rebates typically arise from sales contracts with third-party managed care organisations, hospitals, long-term care facilities, group purchasing organisations and various federal or state programmes (Medicaid contracts, supplemental rebates, etc).

Accrual assumptions are calculated on a sales channel basis, taking into account specific contract provisions coupled with expected performance, and are then aggregated into a weighted average rebate accrual rate. Accrual rates are reviewed and adjusted on an as needed basis. There may be further adjustments when actual rebates are invoiced based on utilisation information submitted to us (in the case of contractual rebates) and claims/invoices are received (in the case of regulatory rebates and chargebacks).

As at 31 December 2019, the rebates and chargebacks accrual was £12.9 million (2018: £nil). If rebate claims were to differ by 10% from management's estimates, the rebate and chargebacks accrual would be an estimated £4.7 million (2018: £nil) higher or lower.

Recognition of deferred tax asset for carried-forward tax losses (estimate)

The deferred tax assets include an amount of £18.9 million (2018: £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 Group 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 from the year ended 2017 and is expected to continue generating taxable income from 2020 onwards. The losses can be carried forward indefinitely and have no expiry date. The judgement is how profitable the entity will be in future and therefore how much of the asset can be recognised. If the future profits of Circassia AB were to differ by 10% from management's estimates, the deferred tax asset would be an estimated £1.9 million (2018: £0.9 million) higher or lower.

Notes to the financial statements, continued

Valuation of contingent royalty consideration payable on Duaklir® sales (estimate)

As part of the collaboration agreement entered into in April 2017 between Circassia and AstraZeneca, Circassia is liable to 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 were initially classified as additional consideration and 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.

During 2019, the sales performance of Duaklir® was well below internal forecasts and as such management concluded that future sales of Duaklir® were expected to remain low in the short-term and therefore as at 31 December 2019, the royalty liability has been remeasured to £nil. This sales underperformance led to the decision to hand the licences back to AstraZeneca, with the agreement completed and the licences handed back on 27 May 2020.

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

Valuation model	Discounted cash flow
Anticipated launch date	Reviewed and amended to take into account development, regulatory and marketing risks
Sales value, volume and growth rates	Estimates of sales value, volume and growth rates are internal forecasts based on both internal and external market information and market research commissioned by the Company
Period of specified projected cash flows	16 years
Discount rate	2019: 12.2% 2018: 17.0%

Goodwill and other intangible assets (estimate)

Goodwill and other intangible assets impairment reviews are undertaken annually or more frequently if events or changes in circumstances indicate a potential impairment. Judgements and estimates are made in respect of the carrying value of the cash generating units (CGUs) containing the goodwill taking into account key assumptions (see note 16) about the product candidates. If the Group is unable to successfully commercialise its product candidates and become profitable, this could result in an impairment of the related goodwill and intellectual property rights.

Investments (estimate)

Circassia Group 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 Group plc's aggregate investment in subsidiaries, this could result in an impairment of the investment.

Recoverable amount of intercompany receivables (judgement)

Circassia Group plc has significant intercompany receivables due from subsidiary companies. In line with IFRS 9, the carrying value of intercompany receivable balances owed to Circassia Group plc by its subsidiaries is assessed using the simplified approach to measuring expected credit losses, which uses a lifetime expected loss allowance for all trade receivables. Judgements and estimates are made in respect of the recoverable amount of each subsidiary. If the recoverable amount of a subsidiary is below the carrying value of Circassia Group plc's intercompany receivable, this could result in an impairment of the receivable.

Estimates and judgements are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

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 Group 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.

Segmental reporting

The Group had three continuing operating segments during 2019, NIOX®, COPD (2018: USAZ collaboration) and LungFit™ PH. 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 Chairman, who makes strategic decisions.

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

Non-underlying operations

Management primarily manages the business and measures performance based on the results of “underlying operations”. Non-underlying operations are excluded from the underlying results of the Group and consist of significant irregularly occurring and exceptional items.

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 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 2018 have been reclassified as discontinued operations in the Consolidated statement of comprehensive income in accordance with IFRS 5 requirements. The decision to treat the respiratory business as discontinued was made in April 2018 when the Group announced a decision to cease investment in the in-house respiratory pipeline and to seek an out-license partner.

The COPD CGU was not classified as a discontinued operation in the current financial year as at 31 December 2019 the sale of the Tudorza® and Duaklir® licences to AstraZeneca was not highly probable.

Notes to the financial statements, continued

Financial instruments

The Group's financial instruments comprise cash and cash equivalents, loans, receivables and payables arising directly from operations.

Cash balances are mainly held on short and medium term deposits with quality financial institutions, in line with the Group's policy to minimise the risk of loss. The main risks associated with the Group's financial instruments relate to interest rate risk and foreign currency risk (note 2).

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. The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables.

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 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

Until 31 December 2018, leases in which a significant portion of the risks and rewards of ownership are retained by the lessor were classified as operating leases. Payments made under operating leases (net of any incentives received from the lessor) were charged to the income statement on a straight line basis over the period of the lease.

From 1 January 2019, leases are recognised as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the group.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the fixed and variable lease payments, less any lease incentives receivable.

The lease payments are discounted using the Group's incremental borrowing rate, being the rate that the Group would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security and conditions. To determine the incremental borrowing rate, the Group where possible, uses recent third-party financing received, adjusted to reflect changes in financing conditions since third party financing was received.

Lease payments are allocated between principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Right-of-use assets are measured at cost comprising the following the amount of the initial measurement of lease liability, plus any lease payments made at or before the commencement date less any lease incentives received.

Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

Payments associated with short-term leases of equipment and vehicles and all leases of low-value assets are recognised on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprise IT equipment and small items of office furniture.

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
Software	5 years
CMP	13 years
Customer Relationships	18 years
IPR&D	5 – 17 years
Technology	15 – 20 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.

Notes to the financial statements, continued

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, China 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. Management utilise sales forecasts to calculate the level of inventory required and compare this to current levels of inventory held to assess net realisable value.

Write-downs of inventory generally occur in the ordinary course of business and are recognised in cost of sales. Inventory purchased as sample stock is recognised as sales and marketing costs.

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.

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.

Borrowings

Interest-bearing loans are initially measured at fair value (with direct transaction costs being amortised over the life of the loan) and are subsequently measured at amortised cost using the effective interest rate method at each reporting date. Changes in carrying value are recognised in profit or loss.

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 expense

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.

Notes to the financial statements, continued

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 27. 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 Finnerty model (an at-market put option variant of the Black-Scholes 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 Finnerty 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 from contracts with customers

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. Revenue represents net invoice value including fixed and variable consideration. Variable consideration arises on the sale of goods as a result of discounts and allowances given and accruals for estimated future returns and rebates. Revenue is not recognised until it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur. Income is reported as follows:

Sale of NIOX®

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.

Sale of Tudorza® and Duaklir®

The Group markets and sells Tudorza® and Duaklir® in the United States, where it is indicated for the maintenance treatment of patients with COPD. Revenue is recognised when the goods are delivered to the wholesaler and represents net invoice value less estimated rebates, returns and chargebacks, which are considered to be key estimates. Delivery occurs when the products have been shipped to the specific location, the risks of obsolescence and loss have been transferred to the wholesaler and the wholesaler has accepted the products. When invoicing Tudorza® and Duaklir® sales, customers have a right to return a product within a given period and therefore the Group recognises a refund liability for the amount of consideration received for which the entity does not expect to be entitled.

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) – net'.

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 income 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.

Notes to the financial statements, continued

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 2019, the Company issued 17,572,815 ordinary shares with a value of £8.0 million to BeyondAir. This share issue was non-cash consideration in respect of the acquisition of the LungFit™ PH licence. The Group's capital is comprised of share capital and share premium, which are disclosed in notes 28 and 29 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

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 Executive Chairman, 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, euro and Chinese yuan. 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 United States dollars, 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 2019 is 10% (2018: 10%).

At 31 December 2019, 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 £0.3 million (2018: £0.5 million) lower/higher, as a result of net foreign exchange gains/losses on translation of euro denominated payables, receivables and foreign exchange losses/gains on translation of euro denominated bank balances.

The impact on post tax loss at 31 December 2019 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 £11.0 million (2018: £0.7 million), as a result of net foreign exchange gains/losses on translation of dollar denominated borrowings, payables, receivables and foreign exchange losses/gains on translation of dollar denominated bank balances.

The impact on post tax loss and equity is immaterial for the remaining currencies.

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's main interest expense arises from long-term borrowings with variable rates, which exposes the Group to cash flow interest rate risk. During 2019, the Group's borrowings at variable rates were denominated in United States dollar. The Group had no borrowing in 2018.

Profit or loss is sensitive to higher/lower interest expense from cash and cash equivalents as a result of changes in interest rates.

If variable interest rates had been 10 basis points higher/lower the impact on net loss and accumulated losses in 2019 would have been an increase/decrease of £0.2 million (2018: £0.0 million) due to changes in the amount of interest receivable and interest payable.

Credit risk

Credit risk arises from cash and cash equivalents, contractual cash flows of debt investments carried at amortised cost, deposits with banks and financial institutions, as well as credit exposures to customers, including outstanding receivables.

i) Risk management

The Group's policy generally is to place funds with financial institutions which have a minimum credit rating with Fitch IBCA of A- long term/F1 short-term.

During 2019 the Group placed funds on deposit with 8 banks (2018: 8 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. While cash and cash equivalents are also subject to the impairment requirements of IFRS 9, the identified impairment loss was immaterial.

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables. To measure the expected credit losses, trade receivables 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 2019 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.

Notes to the financial statements, continued

On that basis, the loss allowance as at 31 December 2019 and 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 2019					
Expected loss rate	0.5%	31.9%	20.5%	7.5%	1.2%
Gross trade receivables carrying amount	11.9	0.1	0.1	0.4	12.5
Loss allowance	(0.1)	–	–	–	(0.1)

	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	1.5%	12.5%	10.1%	7.9%	1.6%
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 2019					
Expected loss rate	91%	0%	0%	0%	91%
Gross receivables from subsidiary undertakings carrying amount	382.9	–	–	–	382.9
Loss allowance	(347.8)	–	–	–	(347.8)

	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%	24%
Gross receivables from subsidiary undertakings carrying amount	373.1	–	–	–	373.1
Loss allowance	(91.4)	–	–	–	(91.4)

The closing loss allowance for trade receivables reconciles to the opening loss allowances as follows:

	Group		Company	
	2019 £m	2018 £m	2019 £m	2018 £m
Opening loss allowance as at 1 January	(0.1)	–	(91.4)	–
Increase in loss allowances recognised in profit or loss during the year	–	(0.1)	(256.4)	(91.4)
At 31 December	(0.1)	(0.1)	(347.8)	(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 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 amounts disclosed in the table are the contracted cash flows discounted to present value where such impact is material:

At 31 December	Less than 1 year 2019 £m	Over 1 year 2019 £m	Less than 1 year 2018 £m	Over 1 year 2018 £m
Non-contingent consideration	—	—	80.3	—
Borrowings	—	109.9	—	—
Lease liabilities	0.6	1.5	—	—
Contingent consideration	1.1	—	15.4	46.2
Trade and other payables	39.6	—	28.7	—
Total	41.3	111.4	124.4	46.2

Derivative financial instruments and hedging

There were no derivatives at 31 December 2019 or 31 December 2018.

3. Operating segments

The chief operating decision-maker is the Executive Chairman, (previously the Chief Executive Officer) and 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 2019 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);
- COPD (2018: USAZ collaboration) relates to the Tudorza[®] and Duaklir[®] Pressair[®] products marketed in the United States, where they are indicated for the maintenance treatment of patients with COPD; and
- LungFit[™]PH relates to the portable ventilator-compatible system, the rights to which were purchased from BeyondAir.

The revenues generated in the COPD CGU in the current financial year of £27.8m are derived through sales to one wholesaler and as such is reliant on one major customer.

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.

Notes to the financial statements, continued

The table below presents information regarding the Group's operating segments for the years ended 31 December 2019 and 2018. Only the results for the Group's underlying continuing activities are included in order to aid comparison. Costs shared between the segments are not allocated to individual segments for decision making purposes. These are disclosed under the column headed 'Unallocated'. There was no activity in the LungFit CGU for either financial year presented below.

Segment operating loss

Year ended 31 December 2019	NIOX ^b £m	COPD £m	Unallocated £m	Total £m
Revenue (from external customers by country, based on the destination of the customer)				
US	10.4	27.8	–	38.2
UK	2.0	–	–	2.0
EU	7.4	–	–	7.4
Asia Pacific	14.5	–	–	14.5
Rest of world	0.3	–	–	0.3
Total segment revenue	34.6	27.8	–	62.4
Cost of sales	(9.1)	(7.1)	–	(16.2)
Research and development	(1.9)	(12.2)	(5.0)	(19.1)
Sales and marketing	(24.6)	(32.9)	–	(57.5)
Administrative expenses	–	(0.1)	(12.5)	(12.6)
Operating loss from continuing operations	(1.0)	(24.5)	(17.5)	(43.0)
Depreciation and amortisation included in the expenditure above	(3.7)	(10.7)	(0.8)	(15.2)
Year ended 31 December 2018	NIOX^b £m	COPD £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
UK	1.6	–	–	1.6
EU	6.8	–	–	6.8
Asia Pacific	9.5	–	–	9.5
Rest of world	0.1	–	–	0.1
Total segment revenue	27.4	20.9	–	48.3
Cost of sales	(8.9)	–	–	(8.9)
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 and amortisation included in the expenditure above	(3.8)	–	(0.6)	(4.4)

Assets by segment

Year ended 31 December 2019	NIOX® £m	COPD £m	Unallocated £m	Total £m
Cash and cash equivalents	11.4	15.3	0.3	27.0
Property, plant and equipment	—	0.5	—	0.5
Right-of-use assets	1.3	0.6	—	1.9
Goodwill	4.8	—	—	4.8
Intangible assets	45.3	117.7	—	163.0
Deferred tax assets	18.9	9.4	—	28.3
Inventories	3.5	3.0	—	6.5
Trade and other receivables	6.8	7.8	—	14.6
Current tax assets	0.2	—	—	0.2
Total assets	92.2	154.3	0.3	246.8

Year ended 31 December 2018	NIOX® £m	COPD £m	Unallocated £m	Total £m
Cash and cash equivalents	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

4. Revenue from contracts with customers

The Group derives the following types of revenue:

	2019 £m	2018 £m
Sale of goods	60.7	27.0
Rendering of services	1.6	21.3
Licence and milestone revenue	0.1	—
Total revenue from contracts with customers	62.4	48.3

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

Notes to the financial statements, continued

5. Employees and directors

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

By activity	Group		Company	
	2019 Number	2018 Number	2019 Number	2018 Number
Office and management	46	43	6	8
Sales and marketing	244	285	—	—
Research and development	32	39	—	—
Total average headcount	322	367	6	8

Employee benefit costs	Group		Company	
	2019 £m	2018 £m	2019 £m	2018 £m
Wages and salaries	32.8	39.1	2.2	1.5
Social security costs	4.4	5.7	0.3	0.2
Other pension costs	1.3	1.5	—	—
Share options expense	1.4	2.7	—	—
Total employee benefit costs	39.9	49.0	2.5	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 (2018: £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 on page 65.

Key management personnel

Key management personnel during the year included directors (Executive and Non-Executive), Senior VP of Commercial US, 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.

	2019 £m	2018 £m
Short-term employee benefits (including bonus)	3.2	3.7
Post-employment benefits	1.2	0.1
Share based payment	0.6	1.0
Total	5.0	4.8

Post-employment benefits have increased mainly due to the restructuring of the Board, see the remuneration report for further information.

6. Operating expenses by nature

Operating loss is stated after charging the following:

	Notes	2019 £m	2018 £m
Employee benefit expenses	5	39.9	49.0
Externally contracted research and development		1.9	1.6
Marketing costs		16.8	10.7
Legal and professional fees including patent costs		9.3	7.5
Depreciation charge of property, plant and equipment ¹	14	0.3	0.6
Depreciation charge of right-of-use assets ¹		0.5	—
Amortisation charge of intangible assets ¹	17	14.4	3.8
Impairment of goodwill	16	4.1	4.4
Impairment of intangible assets	17	86.1	70.6

¹ 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'

7. Other gains and (losses) – net

	2019 £m	2018 £m
Net foreign exchange (loss)/gain	(3.5)	1.9
Change in fair value of contingent Duaklir [®] royalty consideration	51.4	(1.1)
Change in fair value of contingent Tudorza [®] royalty consideration	2.2	—
Change in fair value of contingent LungFit [™] PH royalty consideration	23.9	—
Gain on exercise of Tudorza [®] option	—	5.4
Change in fair value of LungFit [™] PH contingent consideration	15.9	—
Foreign exchange gain/(loss) on non-contingent consideration	3.8	(4.4)
Foreign exchange gain/(loss) on contingent royalty consideration	0.3	(2.5)
Foreign exchange loss on exercise of Tudorza [®] option	—	(2.7)
Foreign exchange loss on contingent consideration	—	(0.3)
Total other gains and losses	94.0	(3.7)

On 23 January 2019, Circassia entered into an agreement with BeyondAir to acquire the commercial rights to LungFit[™] PH. In addition to the £8.0 million upfront payments, Circassia owed BeyondAir further consideration of £16.1 million based on certain triggering events. As such, on this date Circassia recognised a contingent liability, and an offsetting intangible asset. As the liability is denominated in United States dollars, this was revalued to £15.9 million.

Following an announcement made by BeyondAir in December 2019 that they are terminating the agreement for the commercial licence of LungFit[™] PH, Circassia remeasured the fair value of the contingent liability resulting in a £15.9 million credit to other gains. On the same date, the intangible asset was impaired resulting in an impairment charge of £16.1 million which is included within 'Research and Development costs'.

Notes to the financial statements, continued

8. Finance costs and income

	2019 £m	2018 £m
Finance costs:		
Bank charges and interest payable	(0.2)	(0.1)
Interest charges for lease liabilities	(0.1)	–
Interest charges for borrowings	(3.2)	–
Non-contingent consideration: unwinding of discount	(3.1)	(7.2)
Contingent royalty consideration: unwinding of discount	(11.6)	(3.5)
Non-current trade payables: unwinding of discount	(0.6)	(1.2)
Total finance costs	(18.8)	(12.0)
Finance income:		
Bank interest receivable	0.2	0.3
Total finance income	0.2	0.3

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:

	2019 £m	2018 £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	0.2	0.1
Total	0.4	0.3

During the year, the Group paid £1,356 (2018: £1,000) to the Group's auditors in respect of non-audit services for an accounting research tool subscription.

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	2019 £m	2018 £m
Loss for the year			
Expenditure		–	(3.7)
Goodwill and intangible assets impairment		–	(75.0)
Share of loss of joint venture	19	–	(0.1)
Loss before tax		–	(78.8)
Taxation	12	–	8.3
Loss from discontinued operations		–	(70.5)

	Notes	2019 £m	2018 £m
Cash flow			
Net cash outflow from operating activities		–	(0.3)
Net decrease in cash from discontinued operations		–	(0.3)

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	2019 £m	2018 £m
Charged to research and development costs			
Impairment		(90.2)	—
Restructuring costs		(0.2)	—
		(90.4)	—
Charged to sales and marketing costs			
Restructuring costs		—	(2.9)
		—	(2.9)
Charged to administrative expenses			
AIM transfer costs		—	(0.3)
Restructuring costs		(1.1)	—
		(1.1)	(0.3)
Credited/(charged) to other gains and losses			
Change in fair value of contingent Duaklir® royalty consideration	7	51.4	(1.1)
Change in fair value of contingent Tudorza® royalty consideration	7	2.2	—
Change in fair value of contingent LungFit™ PH royalty consideration	7	23.9	—
Gain on exercise of Tudorza® option	7	—	5.4
Change in fair value of LungFit™ PH contingent consideration	7	15.9	—
Foreign exchange (loss)/gain on non-contingent consideration	7	3.8	(4.4)
Foreign exchange (loss)/gain on contingent royalty consideration	7	0.3	(2.5)
Foreign exchange (loss)/gain on exercise of Tudorza® option	7	—	(2.7)
Foreign exchange (loss)/gain on contingent consideration	7	—	(0.3)
		97.5	(5.6)
Charged to finance costs			
Non-contingent consideration: unwinding of discount	8	(3.1)	(3.5)
Contingent consideration: unwinding of discount	8	—	(0.1)
Contingent royalty consideration: unwinding of discount	8	(11.6)	(7.1)
Non-current trade payables: unwinding of discount	8	(0.6)	(1.2)
		(15.3)	(11.9)
Loss before tax		(9.3)	(20.7)
Credited to taxation		—	—
Loss from continuing operations		(9.3)	(20.7)
Loss from discontinued operations	10	—	(70.5)
Total loss		(9.3)	(91.2)

Notes to the financial statements, continued

Impairment

On 19 December 2019, an announcement was made by BeyondAir that they are terminating the agreement for the commercial licence of LungFit™ PH and as such management concluded that impairment was required to the LungFit™ PH CGU. This resulted in an impairment of £44.0 million to intangible assets. See note 17 for further details.

During 2019, the sales performance of Tudorza® and Duaklir® was well below internal forecasts and as such management concluded that impairment was required to the COPD CGU. This resulted in an impairment of £4.1 million to goodwill and £42.1 million to intangible assets. This sales underperformance led to the decision to hand the licences back to AstraZeneca, with the agreement completed and the licences handed back on 27 May 2020. See notes 16 and 17 for further details.

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 2019 relates mainly to the restructuring of the Board.

AIM transfer costs

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

Non-contingent consideration

The £3.8 million (2018: £4.4 million) foreign exchange movement on non-contingent consideration relates to the impact of the strengthening dollar on translation of the \$100 million, \$20 million and \$5 million deferred non-contingent consideration payable to AstraZeneca. The consideration was measured by discounting the liability with a £11.6 million (2018: £3.5 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 in the prior year related to the \$20 million payable to AstraZeneca on approval of Duaklir®. This consideration was reclassified as non-contingent on the approval of Duaklir® in March 2019.

Contingent royalty consideration

Contingent royalty consideration relates to the amount of royalties payable to AstraZeneca on the future Tudorza® and Duaklir® sales, and to BeyondAir on the future sales of LungFit™ PH. The Duaklir® liability was remeasured to fair value at the year end with the resulting £51.4 million (2018: £1.1 million charge) credit recorded in other gains and losses in the income statement. The Tudorza® liability was remeasured to fair value at the year end with the resulting £2.2 million (2018: £nil) credit recorded in other gains and losses in the income statement. The LungFit™ PH liability was remeasured to fair value at the year end with the resulting £23.9 million (2018: £nil) credit recorded in other gains and losses in the income statement. The £0.3 million (2018: £2.5 million) foreign exchange movement relates to the impact of the weakening dollar on translation of the contingent royalty consideration.

Change in fair value of LungFit™ PH contingent consideration

In addition to the £8.0 million upfront payments and £19.9 million of contingent royalty payments, Circassia owed BeyondAir further consideration of £16.1 million based on certain triggering events. As such, on this date Circassia recognised a contingent liability, and an offsetting intangible asset. As the liability is denominated in United States dollars, this was revalued to £15.9 million. Following an announcement made by BeyondAir in December 2019 that they are terminating the agreement for the commercial licence of LungFit™ PH, Circassia derecognised the contingent liability resulting in a £15.9 million credit to other gains.

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 2019 and 2018 represents the credit receivable by the Group for the year and adjustments to prior years. The 2019 amounts have not yet been agreed with the relevant tax authorities.

	2019 £m	2018 £m
Current tax		
United Kingdom corporation tax research and development credit	(0.1)	(1.0)
Adjustments in respect of prior year	–	–
Total current tax credit	(0.1)	(1.0)
Deferred tax		
Increase in deferred tax assets	(9.1)	(3.5)
Decrease in deferred tax liabilities	(1.6)	(13.9)
Adjustments in respect of prior year	–	0.9
Total deferred tax credit	(10.7)	(16.5)
Total tax credit	(10.8)	(17.5)
Tax is attributable to:		
Loss on continuing operations	(10.8)	(9.2)
Loss on discontinued operations	–	(8.3)
	(10.8)	(17.5)

The tax credit for the year is lower (2018: lower) than the standard rate of corporation tax in the UK of 19.00% (2018: 19.00%). The differences are explained below:

	2019 £m	2018 £m
Loss from continuing operations before tax	(59.1)	(55.8)
Loss from discontinued operations before tax	–	(78.8)
Loss before tax	(59.1)	(134.6)
Loss on ordinary activities before tax		
multiplied by the standard rate of corporation tax in the UK of 19.00% (2018: 19.00%)	(11.2)	(25.6)
Expenses not deductible for tax purposes (permanent differences):	0.6	–
Temporary timing differences on employee share options	–	0.3
Research and development relief uplift	(0.2)	(0.4)
Adjustments in respect of prior year	–	0.9
Tax losses for which no deferred income tax asset was recognised	–	7.3
Tax credit for the year	(10.8)	(17.5)

At 31 December 2019, the Group has tax losses to be carried forward of approximately £526.3 million (2018: £341.3 million). These can be utilised against future taxable profits. At 31 December 2019, Circassia Limited had tax losses to be carried forward of approximately £158.9 million (2018: £148.1 million). The utilisation of these losses will be restricted to 50% of profits generated in the United Kingdom.

At 31 December 2019, the Group has tax assets arising from tax credits in the United Kingdom for certain research and development expenditure of £0.2 million (2018: £4.0 million). None of this is receivable after more than one year (2018: £3.0 million).

Notes to the financial statements, continued

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 2019 and 2018, the dilutive potential shares are non-dilutive and therefore excluded from the earnings per share calculation.

For the year ended 31 December 2019	Continuing operations			Discontinued operations	Total
	Underlying operations	Non-underlying operations	Total		
Loss attributable to ordinary equity owners of the Parent Company (£m)	(39.0)	(9.3)	(48.3)	–	(48.3)
Weighted average number of ordinary shares in issue (Number)	373,703,488	373,703,488	373,703,488	373,703,488	373,703,488
Loss per share	(0.11)	(0.02)	(0.13)	–	(0.13)

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)

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 2018				
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 charge	(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
Year ended 31 December 2019				
Opening net book amount	0.2	0.3	–	0.5
Additions	0.1	0.2	–	0.3
Depreciation charge	(0.1)	(0.2)	–	(0.3)
Closing net book amount	0.2	0.3	–	0.5
At 31 December 2019				
Cost	0.9	0.8	1.7	3.4
Accumulated depreciation	(0.7)	(0.5)	(1.7)	(2.9)
Net book amount	0.2	0.3	–	0.5

Notes to the financial statements, continued

15. Leases

The balance sheet shows the following amounts relating to leases:

	2019 £m	2018 £m
Right-of-use assets		
Leasehold improvements	1.8	—
Plant and equipment	0.1	—
	1.9	—
Lease liabilities		
Current	(1.3)	—
Non-current	(0.8)	—
	(2.1)	—

Additions to the right-of-use assets during the financial year were £2.4 million (2018: £nil).

The statement of profit or loss shows the following amounts relating to leases:

	Notes	2019 £m	2018 £m
Depreciation charge of right-of-use assets	6	(0.5)	—
Interest expense (included in finance cost)	8	(0.1)	—
Expense relating to leases of low-value assets that are not shown above as short-term leases (included in administrative expenses)		(0.2)	—
		(0.8)	—

The total cash outflow for leases in 2019 was £0.9 million.

16. Goodwill

	2019 £m	2018 £m
At 1 January		
Cost	88.2	84.5
Accumulated impairment	(78.9)	(74.5)
Net book amount	9.3	10.0
Year ended 31 December		
Opening net book amount	9.3	10.0
Acquisition of business	—	3.9
Impairment	(4.1)	(4.4)
Exchange differences	(0.4)	(0.2)
Closing net book amount	4.8	9.3
At 31 December		
Cost	87.8	88.2
Accumulated impairment	(83.0)	(78.9)
Net book amount	4.8	9.3

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. Subsequently 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.

During 2019, the sales performance of Tudorza® and Duaklir® was well below internal forecasts and as such management concluded that impairment was required to the COPD CGU. This resulted in an impairment of £4.1 million to goodwill. This sales underperformance led to the decision to hand the licences back to AstraZeneca, with the agreement completed and the licences handed back on 27 May 2020.

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

Cash generating unit	2019 £m	2018 £m
NIOX®	4.8	5.2
COPD (2018: US AZ Collaboration)	–	4.1
	4.8	9.3

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 post-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 11.5% (being a weighted average cost of capital rate for the CGU). The calculations use post-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 post-tax and reflects specific risks relating to the Group and uncertainties surrounding the cash flow projections. As noted earlier, the value in use calculations include expected revenue growth from historic levels. The impact of COVID-19 is uncertain and has not been included in the impairment assessment this year. The impact will be included in future years, and if sales do not resume growth then this would give rise to an impairment.

The value in use for the COPD (2018: US AZ Collaboration) CGU was calculated using risk-adjusted post-tax cash flow projections, plus disposal proceeds being the forgiveness of the loan.

Notes to the financial statements, continued

The key assumptions used for the valuations of the CGUs are as follows:

NIOX® CGU

Assumption	Approach used to determine values
Valuation basis	Value in use
Sales volume	Based on past performance and management's expectations of market development
Sales price	Based on current industry trends and including long-term inflation forecasts for each territory
Operating costs	Management forecasts these costs based on the current structure of the business, adjusting for inflationary increases but not reflecting any future restructurings or cost-saving measures
Profit margins	Based on past performance and management's expectations for the future
Period of specified projected cash flows	10 years
	Terminal growth rates based on management's estimate of future long-term average growth rate
Long-term growth rate	2019 – 1% 2018 – 1%
	Reflect specific risks relating to the relevant segments and the countries in which they operate
Discount rate	2019 – 11.5% 2018 – 12.5%

COPD (2018: US AZ Collaboration) CGU

Valuation basis	Value in use
Sales proceeds	Based on agreement with AstraZeneca
	Terminal growth rates based on management's estimate of future long-term average growth rate
Terminal growth rate	2019 – (n/a) 2018 – (5%)
	Reflect specific risks relating to the relevant segments and the countries in which they operate
Discount rate	2019 – 12.2% 2018 – 17.0%

Impact of possible changes in key assumptions

Reduction in revenue growth in the NIOX® CGU

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

If sales growth does not resume in future years following the impact of COVID-19 then this would give rise to an impairment.

COPD CGU

The goodwill allocated to the COPD CGU is fully impaired. No changes in the key assumptions mentioned above would result in a change to this.

17. Intangible assets

Group	IPR&D £m	CMP £m	Customer relationships £m	Technology £m	Intellectual property £m	Other £m	Total intangible assets £m
At 1 January 2018							
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
Acquisition of business	–	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
Year ended 31 December 2019:							
Opening net book amount	73.1	97.4	27.2	23.4	–	0.3	221.4
Additions	–	–	–	–	44.0	2.0	46.0
Amortisation charge	(2.1)	(8.6)	(1.8)	(1.9)	–	–	(14.4)
Transfers	(71.0)	(71.0)	–	–	–	–	–
Impairment charge	–	(42.1)	–	–	(44.0)	–	(86.1)
Exchange differences	–	–	(2.1)	(1.8)	–	–	(3.9)
Closing net book amount	–	117.7	23.3	19.7	–	2.3	163.0
At 31 December 2019							
Cost	90.9	168.4	34.6	50.3	44.0	3.9	392.1
Accumulated amortisation and impairment	(90.9)	(50.7)	(11.3)	(30.6)	(44.0)	(1.6)	(229.1)
Net book amount	–	117.7	23.3	19.7	–	2.3	163.0

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 16.

Notes to the financial statements, continued

In-Process Research & Development (IPR&D)

IPR&D comprises 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. When Duaklir® was launched in October 2019, the related assets were transferred from IPR&D assets and into CMP.

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.

The CMP asset was partially impaired to the expected value receivable following the sales underperformance of Tudorza® and Duaklir® which led to the decision to hand the licences back to AstraZeneca. It will be fully disposed of in the 2020 financial year.

Customer relationships

Customer relationships represent the existing customers, as at the date of acquisition that are expected to continue to support the NIOX® 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") in 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. This technology is used by the Group in its NIOX® devices. The valuation of the Technology was based on a pre-determined hypothetical royalty rate attributable to the use of the Technology. The estimated remaining useful life of the Technology was determined as 15 years at acquisition. Amortisation has been calculated on a straight line basis over this period from the date of acquisition.

Intellectual property

Intellectual property comprises the LungFit™ PH licence which was acquired from BeyondAir in the current financial year. The asset was initially valued at £44.0 million, being the fair value of consideration. This includes £8.0 million paid upfront in the form of shares and contingent milestone and royalty payments valued at £36.0 million.

The intellectual property was fully impaired following an announcement made by BeyondAir in December 2019 purporting to terminate the agreement for the commercial licence of LungFit™ PH. The Company intends to challenge this termination.

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.

18. Investments in subsidiaries

Company	2019 £m	2018 £m
Investments in subsidiaries at 1 January	67.6	273.5
Equity settled instruments granted to employees of subsidiaries	1.4	2.7
Investment in Circassia Beijing	–	1.7
Provision against investments	(12.5)	(210.3)
Investments in subsidiaries at 31 December	56.5	67.6

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 16.

A credit loss provision of £12.5 million (2018: £210.3 million) has been recognised due to sales underperformance of Tudorza® and Duaklir® resulting in the handing back of the licences to AstraZeneca, combined with the termination of the agreement for the commercial licence of LungFit™ PH.

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 £22.3 million (2018: £35.4 million) lower or higher fair value of investments.

The capital contribution relating to share based payment is for 9,397,741 (2018: 5,103,400) 0.08p share options and 4,322,767 (2018: nil) nil-cost 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 27.

Notes to the financial statements, continued

The Group had the following subsidiaries at 31 December 2019:

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	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	Sale of asthma management devices 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, Robert Robinson Avenue, 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%
Circassia srl	Viale Andrea Doria 7, 20124 Milano, Italia	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. All investments held by the Parent Company are equal to the holdings of the Group. The Parent Company does not have any shareholdings in the preference shares of subsidiary undertakings included in the Group.

19. Investment in joint venture

	2019 £m	2018 £m
At 1 January	0.1	0.5
Share of loss	–	(0.1)
Distributions to owners	(0.1)	(0.3)
At 31 December	–	0.1

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 2019 and 2018:

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 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 below is the summarised financial information for Adiga which is accounted for using the equity method.

Summarised statement of financial position at 31 December	2019 £m	2018 £m
Current assets		
Trade and other receivables	–	0.1
Cash	–	0.1
	–	0.2
Net assets	–	0.2

Summarised statement of comprehensive income for the year ended 31 December	2019 £m	2018 £m
Revenue	–	–
Research and development costs	–	–
Administrative expense	–	(0.2)
Loss from operation	–	(0.2)
Income tax	–	–
Post tax loss from operation	–	(0.2)

The information above reflects the amounts presented in the financial statements of the joint venture adjusted for differences in accounting policies between the Group and the joint venture (and not Circassia Group plc’s share of those amounts).

Notes to the financial statements, continued

The Adiga Life Sciences joint venture managed clinical research organisations (CROs) in Canada in respect of allergy programmes on behalf of Circassia Group plc. As the allergy programmes are no longer being continued, the results of the joint venture for the year ended 31 December 2019 and 2018 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	2019 £m	2018 £m
Opening net assets 1 January	0.2	1.0
Loss for the year	–	(0.2)
Dividends paid	(0.2)	(0.6)
Closing net assets	–	0.2
Interest in joint venture @ 50%	–	0.1
Carrying value	–	0.1

20. Inventories

	2019 £m	2018 £m
Finished goods	6.5	4.2

Inventories recognised as an expense during the year ended 31 December 2019 amounted to £13.9 million (2018: £7.5 million). These were included in cost of sales.

Write-downs of inventories to net realisable value amounted to £2.3 million (2018: £0.5 million). These were recognised as an expense during the year and included in cost of sales. The increase in write-downs is due to a higher level of Duaklir® inventory held at the year end compared to forecast inventory requirements. There has been no reversal of any write down in the year ended 31 December 2019.

21. Trade and other receivables

	Group		Company	
	2019 £m	2018 £m	2019 £m	2018 £m
Trade receivables	12.4	3.7	–	–
Prepayments and accrued income	1.9	3.9	–	–
Other receivables	0.3	0.5	–	0.9
Receivables from subsidiary undertakings	–	–	35.1	281.7
Total trade and other receivables	14.6	8.1	35.1	282.6

Included within trade receivables is £0.6 million (2018: £0.4 million) of invoices that were more than 30 days past due at the end of the reporting year but which have not been impaired.

Receivables from subsidiary undertakings are amounts provided by the Company to its subsidiaries in order to undertake commercial operations. The receivables are unsecured and have no fixed date of repayment. Recoverability of the amounts is dependent on the future profitability of subsidiary undertakings. As at 31 December 2019, an expected credit loss of £347.8 million (2018: £91.4 million) 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	
	2019	2018	2019	2018
	£m	£m	£m	£m
British pound sterling	0.3	0.7	–	181.7
United States dollar	9.7	3.7	35.1	100.9
Swedish krona	0.1	0.1	–	–
Euro	1.6	1.8	–	–
Chinese yuan	1.4	–	–	–
	13.1	6.3	35.1	282.6

22. Cash and cash equivalents

The Group and Company cash and cash equivalents are held with institutions with the following Fitch IBCA long-term rating:

	Group		Company	
	2019	2018	2019	2018
	£m	£m	£m	£m
AA	0.6	0.6	–	–
AA-	14.4	31.4	0.1	0.1
A+	11.7	–	–	–
A	–	7.1	–	–
BBB	0.3	1.6	–	–
	27.0	40.7	0.1	0.1

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

	Group		Company	
	2019	2018	2019	2018
	£m	£m	£m	£m
British pound sterling	1.8	23.2	0.1	0.1
United States dollar	22.9	13.0	–	–
Euro	1.8	4.0	–	–
Swedish krona	0.2	0.5	–	–
Chinese yuan	0.3	–	–	–
	27.0	40.7	0.1	0.1

Notes to the financial statements, continued

23. Trade and other payables

	Group		Company	
	2019 £m	2018 £m	2019 £m	2018 £m
Trade payables	9.1	19.1	0.1	0.1
Social security and other taxes	0.3	0.3	—	—
Accruals	29.3	7.6	0.2	0.5
Other payables	0.9	1.7	—	—
Payables to subsidiary undertakings	—	—	7.6	5.5
Total trade and other payables	39.6	28.7	7.9	6.1

Trade payables are unsecured and are usually paid within 30 days of recognition.

The carrying amounts of trade and other payables are considered to be the same as their fair values, due to their short-term nature.

24. Financial assets and financial liabilities

The Group's financial instruments comprise cash and cash equivalents, short-term bank deposits, trade and other receivables, trade and other payables, contingent consideration and finance lease liabilities. 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:

	2019 £m	2018 £m
Financial assets		
Financial assets at amortised cost		
Trade and other receivables	14.6	8.1
Cash and cash equivalents	27.0	40.7
	41.6	48.8
Financial liabilities		
Financial liabilities at amortised cost		
Trade and other payables	39.6	28.7
Borrowings	109.9	—
Non-contingent consideration	—	80.3
Financial liabilities at fair value through profit or loss		
Contingent consideration	1.1	61.6
Lease liabilities	2.1	—
	152.7	170.6

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

Financial assets	2019 £m	2018 £m
Financial assets at amortised cost		
Cash and cash equivalents	0.1	0.1
Other receivables	—	0.9
Receivables from subsidiary undertakings	35.1	281.7
	35.2	282.7
Liabilities		
Financial liabilities at amortised cost		
Trade and other payables	0.1	0.6
Payables to subsidiary undertakings	7.6	5.5
	7.7	6.1

Cash balances comprise floating rate instant access deposits earning interest at prevailing bank 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 2019 or 31 December 2018.

Financial liabilities at fair value through profit or loss

The Group designates contingent consideration payable as fair value through profit or loss. The movement in the year is as follows:

Contingent consideration	2019 £m	2018 £m
At 1 January	61.6	33.6
Additional consideration payable on acquisition of LungFit™ PH	36.8	—
Unwinding of discount	11.6	23.9
Change in fair value	(93.4)	1.3
Settlement of consideration	(15.8)	—
Foreign exchange movement	0.3	2.8
At 31 December	1.1	61.6

The contingent consideration is made up of £1.1 million relating to Tudorza® (2018: £17.5 million) and £nil relating to Duaklir® (2018: £44.1 million).

On 21 June 2019, Circassia settled £15.8 million (\$20 million) payable to AstraZeneca under the agreement signed in 2017. This was offset by a loan from AstraZeneca. See note 25.

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.

Notes to the financial statements, continued

25. Borrowings

In June 2019, the Group entered into a loan facility with AstraZeneca to finance consideration payable under the collaboration agreement.

The following amounts were drawn down during the financial year:

21 June 2019	–	£3.8 million (\$5 million)
21 June 2019	–	£15.8 million (\$20 million)
7 August 2019	–	£82.3 million (\$100 million)
1 October 2019	–	£14.9 million (\$18.3 million)

The loan is a variable rate, United States dollar denominated loan, which is carried at amortised cost. It impacts the Group's exposure to cash flow interest rate risk and foreign exchange risk.

The table below analyses the Group's borrowings into relevant maturity groupings based on the remaining period at the balance sheet date to the contractual maturity date. As at 31 December, the contractual maturities of the Group's non-derivative financial liabilities were as follows:

	Current £m	Non-current £m	2019 Total £m	Current £m	Non-current £m	2018 Total £m
Loans	–	109.9	109.9	–	–	–

As at year end, the total balance of the loan consisted of £108.7 million (2018: £nil) principal loan amount and £1.2 million (2018: £nil) capitalised unpaid interest. On 27 May 2020, the Tudorza® and Duaklir® licences were handed back to AstraZeneca and the loan was set off in its entirety.

26. Deferred taxation

	Intangibles £m	Tax losses £m	Net deferred tax liability £m
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)
At 1 January 2019	10.9	(19.1)	(8.2)
Credit to the income statement	(1.6)	(9.2)	(10.8)
As at 31 December 2019	9.3	(28.3)	(19.0)

	2019 £m	2018 £m
Deferred tax liabilities	9.3	10.9
Deferred tax assets	(28.3)	(19.1)
Total deferred tax position	(19.0)	(8.2)

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

	2019 £m	2018 £m
Losses	61.0	58.0
Total unrecognised deferred tax asset	61.0	58.0

Swedish deferred tax assets and liabilities are recognised at a rate of 20.6% (2018: 20.6%).

UK deferred tax assets and liabilities are recognised at a rate of 17% (2018: 17%).

In the Spring Budget 2020, the Government announced that from 1 April 2020 the UK corporation tax rate would remain at 19% (rather than reducing to 17%, as previously enacted). This new law was substantively enacted on 17 March 2020. As the proposal to keep the rate at 19% had not been substantively enacted at the balance sheet date, its effects are not included in these financial statements. However, it is likely that the overall effect of the change, had it been substantively enacted by the balance sheet date, would be to increase the unrecognised potential deferred tax asset by £3.3 million.

The effect of COVID-19 is uncertain and the impact has not been included in the deferred tax asset calculation this year. The impact will be included in future years, and if sales do not resume growth then this would give rise to an impairment.

27. 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:

	2019 Number of ordinary shares (‘000)	2018 Number of ordinary shares (‘000)
PSP Scheme ¹	19,849	10,671
Unapproved Scheme ²	187	187
	20,036	10,858

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 for awards made before 2019 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. Options typically vest over a period of 3 years.

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:

	2019 Number of options (‘000)	2019 Weighted average exercise price per share option £	2018 Number of options (‘000)	2018 Weighted average exercise price per share option £
Outstanding at 1 January	10,858	0.04	9,042	0.05
Granted	13,721	0.0005	5,103	0.0008
Forfeited/lapsed	(4,374)	0.0008	(3,129)	0.0007
Exercised	(169)	0.0008	(158)	0.0005
Outstanding at 31 December	20,036	0.02	10,858	0.04
Vested and exercisable at 31 December	739	0.61	762	0.59

Notes to the financial statements, continued

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

Scheme	Grant year	Expiry year	Exercise price £	Share options 2019 '000	Share options 2019 '000
PSP 2014	2014	2024	0	150	284
PSP 2015	2015	2025	0.0008	119	291
PSP 2016	2016	2026	0.0008	284	2,510
PSP 2017	2017	2027	0.0008	2,614	3,029
PSP 2018	2018	2028	0.0008	3,894	4,557
PSP 2019	2019	2029	0.0008	12,788	–
Unapproved	2013–2014	2023–2024	2.416	187	187
Total				20,036	10,858

The weighted average remaining contractual life of share options outstanding at the end of the year was 9.0 years (2018: 8.4 years).

Options exercised in 2019 resulted in 169,418 (2018: 158,044) shares being issued at a weighted average price of £0.0008 (2018: £0.0005) each.

Valuation models

The fair value of PSP share options granted during the year was determined using the Monte Carlo Simulation model and the Finnerty Model dependent on the vesting period.

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:

	2019 £m	2018 £m
Exercise price	£0.0008	£0.0008
Share price	£0.32	£0.90
Expected volatility	36%	35%
Expected life	3 years	3 years
Expected dividends	0%	0%
Risk free interest rate	0.74%	0.89%

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 £0.24 per option (2018: £0.90).

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).

The Finnerty Model

For LTIP awards that are subject to an additional two-year post-vesting holding period, the Finnerty model (an at-market put option variant of the Black-Scholes model) has been used to determine a discount for the lack of marketability.

The following weighted average assumptions were used in calculating the fair values of the options granted during the year:

	2019
Exercise price	£0.0008
Share price	£0.19
Expected volatility	45%
Expected life	5 years
Expected dividends	0%
Risk free interest rate	0.38%

This discount has only been applied to the shares that are subject to the sales restriction (i.e. post any permitted sales for tax/legal purposes and any lapses from failing to meet performance conditions).

The weighted average fair value of options granted during the year determined using the Finnerty Model at the grant date was £0.18 per option (2018: nil).

Deferred shares

During the year the Group awarded 412,706 (2018: 251,377) deferred shares to Executive Directors as part of a deferred bonus for 2018. The shares are held by the Circassia Pharmaceuticals plc Employee Benefit Trust (the "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.

28. Share capital

	2019 £m	2018 £m
Authorised, called up and fully paid		
375,199,334 (2018: 357,286,434) ordinary shares of 0.08p each	0.3	0.3

Movements in ordinary shares	Number of shares	Par value £m
As at 1 January 2019	357,286,434	0.3
Share issue to BeyondAir	17,572,815	—
Share issue to Numis Securities	177,405	—
Employee share scheme issues	162,680	—
As at 31 December 2019	375,199,334	0.3

29. Share premium

Group and Company	2019 £m	2018 £m
At 1 January	622.5	602.2
Issue of new shares	8.0	20.4
Transaction costs arising on share issues	(0.1)	(0.1)
At 31 December	630.4	622.5

Notes to the financial statements, continued

30. Accumulated losses

	Group		Company	
	2019 £m	2018 £m	2019 £m	2018 £m
At 1 January	(512.0)	(394.9)	(289.9)	1.9
Change in accounting policy	(0.3)	—	—	—
Restated at 1 January	(512.3)	(394.9)	(289.9)	1.9
Loss for the year	(48.3)	(117.1)	(268.8)	(291.8)
At 31 December	(560.6)	(512.0)	(558.7)	(289.9)

31. 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 2018	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
Employee share option scheme	1.4	—	—	—	1.4
Reclassification of treasury shares	—	—	(0.2)	—	(0.2)
Currency translation differences	—	(1.6)	—	—	(1.6)
At 31 December 2019	13.0	8.7	(0.9)	(6.1)	14.7

Company	Share option reserve £m	Own shares reserve £m	Total other reserves £m
At 1 January 2018	8.6	—	8.6
Employee share option scheme	2.7	—	2.7
At 31 December 2018	11.3	—	11.3
Employee share option scheme	1.4	—	1.4
Reclassification of acquisition of own shares	—	(0.9)	(0.9)
At 31 December 2019	12.7	(0.9)	11.8

Nature and purpose of other reserves

Share option reserve

The share option reserve is used to recognise:

- the grant date fair value of options issued to employees but not exercised;
- the grant date fair value of shares issued to employees;
- the grant date fair value of deferred shares granted to employees but not yet vested; and
- the issue of shares held by the Circassia Pharmaceuticals plc Employee Benefit Trust (the “Trust”) to employees.

Translation reserve

Exchange differences arising on translation of the foreign controlled entity are recognised in other comprehensive income and accumulated in a separate reserve within equity. The cumulative amount is reclassified to profit or loss when the net investment is disposed of.

Transactions with non-controlling interests

This reserve is used to record the differences which arise as a result of transactions with non-controlling interests that do not result in a loss of control.

Treasury shares reserve/own shares reserve

This reserve arose when the Parent Company purchased own shares through the Circassia Pharmaceuticals plc Employee Benefit Trust (the "Trust") to satisfy the issue of shares to employees under the Deferred Bonus Share Plan (DBSP) and the Performance Share Plan (PSP) in relation to 2014.

In the previous year, these shares were classified as a loan from the Trust in Circassia Limited, however during the year it came to light that these shares had been gifted to the Trust and therefore recognised as an own shares reserve in the Parent Company.

The details of shares purchased by the Trust are as follows:

Scheme	Number of shares	Nominal value of shares £	Amount of consideration paid £m
DSBP 2014	110,845	0.0008	0.3
DSBP 2015	156,036	0.0008	0.4
DSBP 2017	251,377	0.0008	0.2
Total	518,258	0.0008	0.9

32. Cash (used in)/generated from operations

Reconciliation of loss before tax to net cash used in operations

		Group		Company
	Notes	2019 £m	2018 £m	2018 £m
Loss from continuing operations before tax		(59.1)	(55.8)	(268.8)
Loss from discontinued operations before tax	10	—	(78.8)	—
Loss before tax		(59.1)	(134.6)	(268.8)
Adjustments for:				
Finance income	8	(0.2)	(0.3)	(6.5)
Finance costs	8	18.8	12.0	—
Depreciation charge of property, plant and equipment	14	0.3	0.6	—
Depreciation charge of right-of-use assets		0.5	—	—
Amortisation	17	14.4	3.8	—
Goodwill impairment	16	4.1	4.4	—
Intangible assets impairment	17	86.1	70.6	—
Profit on sale of fixed assets		—	(0.1)	—
Impairment of investments	18	—	—	12.5
Share of loss of joint venture	19	—	0.1	—
Fair value (gain)/loss on contingent royalty consideration	7	(77.5)	1.1	—
Fair value (gain)/loss on LungFit™ PH contingent liability	7	(15.9)	—	—
Change in fair value of deferred consideration	7	—	(5.4)	—
Share based payment charge	5	1.4	2.7	—
Foreign exchange on non-operating cash flows		(0.5)	6.7	—
Changes in working capital:				
(Increase)/decrease in trade and other receivables		(7.1)	10.9	—
Increase in credit loss provision		—	0.1	256.4
Increase in inventories		(2.7)	(0.1)	—
Increase/(decrease) in trade and other payables		8.5	(23.8)	(0.3)
Cash (used in)/generated from operations		(28.9)	(51.3)	(6.7)

Notes to the financial statements, continued

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

	2019 £m	2018 £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

Non-cash investing and financing activities disclosed in other notes are:

- Acquisition of right-of-use assets – note 15
- Acquisition of LungFit™ PH licence through the issue of shares – note 28

33. Contingent liabilities and assets

At the end of 2019, BeyondAir issued a notice stating that it had terminated its Licensing Agreement for LungFit™ PH with Circassia for material breach. Circassia strongly refutes BeyondAir's allegations and believes there are no grounds for termination. Circassia intends to assert claims in accord with the dispute resolution provisions of the License Agreement to recover its economic losses as a result of BeyondAir's actions, including amounts paid to BeyondAir under the Agreement and loss of future economic benefits that would have accrued to Circassia but for BeyondAir's actions.

There were no contingent liabilities at 31 December 2019 or at 31 December 2018.

34. Operating lease commitments

The Group leases various offices, warehouses and vehicles under non-cancellable operating leases expiring within one year to over five years. The total of future minimum lease payments payable under the Group's non-cancellable operating leases for each of the following periods is as follows:

	2019 £m	2018 £m
Within one year	—	1.2
Later than one year but not later than five years	—	1.4
Later than five years	—	1.1

From 1 January 2019, the group has recognised right-of-use assets for these leases, except for short-term and low-value leases which are classified as operating leases. See note 15.

The total of future minimum sublease payments expected to be received for the Chicago property no longer utilised by the Group is £1.0 million (2018: £1.3 million).

35. Commitments

There were no capital commitments as at 31 December 2019 or at 31 December 2018.

36. 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 are as follows:

Name	Ownership interest	
	2019 £m	2018 £m
Griffiths R I	27.30%	0.00%
AstraZeneca PLC	18.94%	19.89%
Invesco Asset Management	13.65%	24.11%
Harwood Capital LLP	8.00%	0.00%
Lombard Odier Asset Management Europe	5.14%	0.00%

There were no transactions with related parties during the years ended 31 December 2019 and 2018.

Company

The following transactions with subsidiaries occurred in the year:

	2019 £m	2018 £m
Rendering of services to Circassia Limited ¹	1.2	1.2
Settlement of liabilities on behalf of the subsidiaries	–	(2.5)
Net transfer of funds to subsidiaries	6.1	89.2
	7.3	87.9

¹ Remuneration costs (excluding share option charges) relating to the Executive Directors of Circassia Group plc in respect of services rendered to Circassia Limited.

	2019 £m	2018 £m
Balances due from subsidiary companies	35.1	281.7
Balances due to subsidiary companies	(7.6)	(5.5)

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. Nothing was paid into the Trust by the Company during the year ended 31 December 2019 (2018: £198,293).

No shares were purchased by the Trust during the year ended 31 December 2019 (2018: 251,377). As at 31 December 2019 a cash balance of £4,586 (2018: £4,658) was held by the Trust.

37. Events occurring after the reporting date

On 9 April 2020, it was announced that the development and commercialisation agreement between Circassia and AstraZeneca was terminating. On the completion date of 27 May 2020, AstraZeneca acquired the U.S. commercial rights to Tudorza® and Duaklir® together with certain ancillary rights and assets, from Circassia the consideration for which was equal to, and satisfied by way of set-off against, the entirety of the loan amount outstanding from the Company to AstraZeneca, together with accrued interest owed by the Company to AstraZeneca.

On 30 April 2020, a special resolution was passed to approve the change of the Company's name and with effect from 1 May 2020, the name of the Company was changed from Circassia Pharmaceuticals plc to Circassia Group plc.

Notes to the financial statements, continued

38. Change in accounting policy

This note explains the impact of the adoption of IFRS 16 Leases on the Group's financial statements and discloses the new accounting policies that have been applied from 1 January 2019 in note 1.

The Group has adopted IFRS 16 retrospectively from 1 January 2019 but has not restated comparatives for the 2018 reporting period, as permitted under the specific transitional provisions in the standard. The reclassifications and the adjustments arising from the new leasing rules are therefore recognised in the opening balance sheet on 1 January 2019.

(a) Adjustments recognised on adoption of IFRS 16

On adoption of IFRS 16, the group recognised lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of IAS 17 Leases. These liabilities were measured at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate as of 1 January 2019. The weighted average lessee's incremental borrowing rate applied to the lease liabilities on 1 January 2019 was 3.5%.

	1 January 2019 £m
Operating lease commitments disclosed as at 31 December 2018	3.7
Discounted using the lessee's incremental borrowing rate of at the date of initial application	3.1
Less: low-value leases recognised on a straight-line basis as expense	(0.2)
Less: adjustments relating to changes in the index or rate affecting variable payments	(0.4)
Lease liability recognised as at 1 January 2019	2.5
Of which are:	
Current lease liabilities	0.6
Non-current lease liabilities	1.9
	2.5

The associated right-of-use assets for property leases were measured on a retrospective basis as if the new rules had always been applied. Other right-of-use assets were measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments relating to that lease recognised in the balance sheet as at 31 December 2018. There were no onerous lease contracts that would have required an adjustment to the right-of-use assets at the date of initial application.

The recognised right-of-use assets relate to the following types of assets:

	1 January 2019 £m
Motor vehicles	0.1
Leasehold assets	2.3
Total right-of-use assets	2.4

The change in accounting policy affected the following items in the balance sheet on 1 January 2019:

- right-of-use assets – increase by £2.4 million
- prepayments – decrease by £0.1 million
- finance lease liabilities – increase by £2.5 million

The net impact on accumulated losses on 1 January 2019 was an increase of £0.3 million.

Practical expedients applied

In applying IFRS 16 for the first time, the Group has used the following practical expedients permitted by the standard:

- the use of a single discount rate to a portfolio of leases with reasonably similar characteristics
- reliance on previous assessments on whether leases are onerous
- the accounting for operating leases with a remaining lease term of less than 12 months as at 1 January 2019 as short-term leases, and
- the use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

The Group has also elected not to reassess whether a contract is or contains a lease at the date of initial application. Instead, for contracts entered into before the transition date the group relied on its assessment made applying IAS 17 and IFRIC 4 Determining whether an Arrangement contains a Lease.

Reconciliation of alternative performance measures

The costs presented in the strategic report exclude depreciation and amortisation in order to aid comparison with the previous financial year. As these are alternative performance measures, a reconciliation has been provided below:

	Research and development			
	2019 underlying continuing operations	2018 underlying continuing operations	2019 total	2018 total
Expenditure per the statement of comprehensive income	(19.1)	(10.8)	(109.5)	(89.4)
Depreciation	0.1	0.2	0.1	0.2
Amortisation	12.6	2.0	12.6	2.0
Key performance indicator	(6.4)	(8.6)	(96.8)	(87.2)

	Administrative expenditure			
	2019 underlying continuing operations	2018 underlying continuing operations	2019 total	2018 total
Expenditure per the statement of comprehensive income	(12.6)	(11.4)	(13.7)	(11.8)
Depreciation	0.7	0.3	0.7	0.3
Amortisation	—	—	—	—
Key performance indicator	(11.9)	(11.1)	(13.0)	(11.5)

	Sales and marketing			
	2019 underlying continuing operations	2018 underlying continuing operations	2019 total	2018 total
Expenditure per the statement of comprehensive income	(57.5)	(54.4)	(57.5)	(57.3)
Depreciation	—	—	—	—
Amortisation	1.8	1.9	1.8	1.9
Key performance indicator	(55.7)	(52.5)	(55.7)	(55.4)

	EBITDA			
	2019 underlying continuing operations	2018 underlying continuing operations	2019 total	2018 total
Operating loss	(43.0)	(37.2)	(134.5)	(119.1)
Depreciation	0.8	0.5	0.8	0.5
Amortisation	14.4	3.9	14.4	3.9
EBITDA	(27.8)	(32.8)	(119.3)	(114.7)

Additionally, sales are presented in the strategic report at a constant exchange rate to mitigate the exchange rate fluctuations. As these are alternative performance measures, a reconciliation has been provided below to statutory revenues:

	2019			2018				
	Statutory revenue	Impact of foreign exchange movements	Underlying revenue at constant exchange rate	Statutory revenue	Impact of foreign exchange movements	Underlying revenue at constant exchange rate	Statutory revenue percentage movement	Underlying revenue at constant exchange rate percentage movement
US	8.7	—	8.7	7.2	0.4	7.6	21%	14%
UK	1.6	—	1.6	1.3	—	1.3	23%	23%
Germany	2.2	—	2.2	2.1	—	2.1	5%	5%
Italy	0.1	—	0.1	0.1	—	0.1	(70%)	(37%)
China	6.6	—	6.6	3.0	(0.2)	2.8	120%	136%
Partner markets	11.4	—	11.4	9.7	(0.3)	9.4	18%	21%
Total clinical	30.6	—	30.6	23.4	(0.1)	23.3	31%	31%
Global research	3.5	—	3.5	3.7	—	3.7	(5%)	(5%)
Other revenues	0.5	—	0.5	0.3	—	0.3	67%	67%
Total NIOX®	34.6	—	34.6	27.4	(0.1)	27.3	26%	27%
Tudorza®	27.0	—	27.0	20.9	0.6	21.5	29%	26%
Duaklir®	0.8	—	0.8	—	—	—	100%	100%
Total sales	62.4	—	62.4	48.3	0.5	48.8	29%	28%

Advisors and contact details

Financial calendar

— Annual General Meeting:

23 July 2020

— Interim results for the six months

ending 30 June 2020: Q3 2020

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 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 document 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.

Annual report designed
and produced by:
www.thinkerdoer.com

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