



# Interim report and accounts 2018

Circassia Pharmaceuticals plc



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## About Circassia

Circassia is a world-class specialty pharmaceutical business focused on respiratory disease. Circassia sells its novel, market-leading NIOX<sup>®</sup> asthma management products directly to specialists in the United States, United Kingdom and Germany, and in a wide range of other countries through its network of partners. In 2017, the Company established a commercial collaboration with AstraZeneca in the United States in which it promotes the chronic obstructive pulmonary disease (COPD) treatment Tudorza<sup>®</sup> and has the commercial rights to NDA-stage COPD product Duaklir<sup>®</sup>.

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

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## Introduction from the Chief Executive

In the first six months of the year we have made good financial progress.

**Steven Harris**  
Chief Executive Officer



During 2018 we have accelerated our transition into a commercially-focused organisation as part of our strategy to build a high growth, profitable specialty pharmaceutical business. In the first six months of the year we have made good financial progress, increasing our revenues from both NIOX<sup>®</sup> and Tudorza<sup>®</sup>, delivering R&D cost savings and significantly reducing our net loss and cash outflow.

Building on this progress, we are further expanding our commercial capabilities and continuing to pursue additional products to commercialise through our platform. In the coming weeks we plan to launch our new sales team in China, and in the next six months we look forward to the FDA completing its review of the Duaklir<sup>®</sup> NDA and Tudorza<sup>®</sup> sNDA. With the team making encouraging progress right across Circassia, we are working hard to make 2018 a transformational year for the Company, as we lay the foundations to transition to profitability.

**Steven Harris**  
Chief Executive Officer

# Operational and financial highlights

## NIOX® progress

- Sales increased 12% at CER<sup>1</sup> to £14.0 million (H1 2017 CER: £12.5 million)
- Clinical sales (non-research sales<sup>2</sup>) increased 11% at CER vs H1 2017
- US clinical revenues grew 13% at CER compared with H1 2017
- Reimbursement increased to 80% of US covered lives
- NIOX VERO® upgrade in market testing

## US COPD portfolio progress

- Tudorza® profit share revenues increased 4% at CER to £14.4 million vs H2 2017
- Tudorza® prescriptions continued to stabilise during H1 2018
- Duaklir®<sup>3</sup> NDA accepted for review; PDUFA action date 31 March 2019
- Tudorza® sNDA under review for inclusion of unique clinical data in label

## Commercial expansion progress

- China expansion on track; sales force launch anticipated by year end
- UK team expansion to exploit highly supportive NICE guidelines for FeNO testing in asthma

## AstraZeneca agreement progress

- New shares issued to AstraZeneca increasing holding to 19.9%
- \$26.7 million consideration for new shares paid to AstraZeneca as R&D contributions
- Vendor loan backstop extended to cover remaining \$18.3 million R&D payments due by end 2019
- Commitment to FCA to seek shareholder approval to move to AIM if free float remains below 25%

+55%

Revenues increased 55% to £28.4 million  
(H1 2017: £18.3 million)

## Financial progress

Key performance indicators (KPIs)	H1 2018 KPI: underlying continuing operations	H1 2017 KPI: underlying continuing operations <sup>4</sup>	H1 2018: total	H1 2017: total
Revenue	£28.4m	£18.3m	£28.4m	£18.3m
R&D	(£5.7m)	(£7.1m)	(£6.9m)	(£27.2m)
G&A	(£5.2m)	(£4.6m)	(£5.5m)	(£5.1m)
S&M	(£27.7m)	(£21.1m)	(£27.7m)	(£21.6m)
EBITDA	(£12.1m)	(£16.8m)	(£13.6m)	(£35.5m)
Net cash flow <sup>5</sup>	(£8.7m)	(£23.4m) H2 2017	(£8.7m)	(£34.5m)
Cash <sup>6</sup> at period end	£50.8m at 30 June 2018	£59.5m at 31 Dec 2017	£50.8m	£82.9m

<sup>1</sup> Constant exchange rates (CER) for H1 2017 represent reported numbers re-stated using H1 2018 average exchange rates; management believes CER better represents underlying Group performance due to currency fluctuations against sterling

<sup>2</sup> Direct clinical sales to clinicians, hospitals and distributors; research sales to pharmaceutical companies for use in clinical studies

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

<sup>4</sup> Restated to show results of respiratory R&D in non-underlying operations

<sup>5</sup> Net cashflow includes movements in cash, cash equivalents and short-term deposits

<sup>6</sup> Cash, cash equivalents and short-term deposits



Circassia has made rapid progress in its strategic transition into a commercially-focused specialty pharmaceutical company, containing its R&D expenditure and reallocating resources to focus on commercial growth.

During 2018, Circassia has made rapid progress in its strategic transition into a commercially-focused specialty pharmaceutical company, containing its R&D expenditure and reallocating resources to focus on commercial growth. The Company has significantly expanded its commercial infrastructure in China and added a number of distributors to its international network of partners promoting NIOX<sup>®</sup>. It is increasing its UK sales force and rolling out new promotional campaigns for both Tudorza<sup>®</sup> and NIOX<sup>®</sup>. The Company has also significantly reduced its R&D headcount and halted internal investment in its respiratory pipeline. Subsequently, it has started out-licensing / partnering discussions to attract potential external funding to advance these programmes, while retaining potential financial upside.

As a result, the Company is making good progress across its business and during the first half of the year continued to grow its revenues while significantly reducing underlying R&D expenditure compared with the same period in 2017.

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

NIOX<sup>®</sup> is used by physicians around the world to improve asthma diagnosis and management. It is the leading point-of-care system for measuring fractional exhaled nitric oxide (FeNO), an important biomarker of the major underlying cause of asthma, type 2 airway inflammation. Circassia sells NIOX<sup>®</sup> direct in the United States, UK and Germany, and through a network of international partners in a wide range of other countries. The Company plans to initiate direct sales in China, alongside its existing distributor base, at the end of the year.

### Continuing sales growth

NIOX<sup>®</sup> revenues continued to grow during the first half of 2018. Global sales totalled £14.0 million, an increase of 12% at constant exchange rates (CER) compared with the same period the year before. Sales for clinical use grew at a similar rate (11% at CER), while sales to pharmaceutical companies for use in clinical trials increased at a faster rate, growing 20% at CER. Revenues continued to increase in markets where the Company sold direct, increasing 13% in the United States at CER, 45% in the UK and 11% in Germany. Revenues in China, where the Company did not sell direct during the first half of the year, have fluctuated historically based on the local importer's order pattern. With destocking in the first six months of 2018, sales decreased 13% at CER compared with the same period the previous year, which followed a 36% increase during 2017. Circassia anticipates revenues will grow at a more predictable rate following the launch of its direct sales team in China later in the year.

### Expanding access

During 2018, Circassia has continued NIOX<sup>®</sup> market access activities in a number of countries. In the United States, the team increased the Company's key accounts with healthcare systems, multi-site groups, group purchasing organisations and physician purchasing groups to 80. In addition, payor coverage has increased by an additional 37 million lives, including 22 million covered by Aetna following the health insurer's recent policy update to include FeNO testing as 'medically necessary' for asthma patients. As a result, approximately 80% of all US covered lives now have access to NIOX<sup>®</sup>. In Europe, Circassia is focused on gaining wider reimbursement in key markets, such as Germany where the team is making progress with local payors. In the UK, the Company is expanding its commercial team, leveraging new NICE guidelines to target Clinical Commissioning Groups and Health Boards. In China, the market access team is also making progress, with a number of additional provinces now reimbursing FeNO testing.

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### Geographic expansion

In addition to Circassia's direct sales infrastructure, the Company sells its NIOX<sup>®</sup> products through a global network of distributors. Throughout 2018 the Company has focused on expanding this distribution base and added new partners in Mexico and Thailand. Discussions are also ongoing in several other countries, including Canada. This expansion is closely co-ordinated with Circassia's regulatory and supply chain functions to exploit new NIOX VERO<sup>®</sup> approvals. During 2018, the distribution management team also continued promotional support activities, including the provision of new NIOX<sup>®</sup> marketing materials, brand building at national conferences and face-to-face training in a number of key markets.

### NIOX<sup>®</sup> brand building

Throughout 2018 Circassia has continued NIOX<sup>®</sup> brand building initiatives, including the ongoing roll-out of its digital strategy. This includes online advertising and web-based promotion focused on new NICE guidelines that recommend FeNO testing in asthma diagnosis. In the UK, the team is leveraging these guidelines to introduce NIOX<sup>®</sup> into primary care and Circassia is sponsoring the Primary Care Respiratory Academy's educational activities and learning resources that relate to FeNO testing.

Circassia has also undertaken a range of promotional activities at major medical congresses, including the American Thoracic Society. At the recent European Respiratory Society International Congress, the world's largest meeting for respiratory specialists, the Company launched its new NIOX<sup>®</sup> international marketing campaign. It also used the event to bring together NIOX<sup>®</sup> distributors from around the world to train on the new campaign materials.

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

Circassia is developing a NIOX VERO<sup>®</sup> upgrade to build on the system's existing strengths and offer customers an improved user experience. This is designed to exploit features available in consumer electronics while avoiding the cost and complexity associated with modifying the core FeNO measurement technology. This product update is making good progress, and during the first half of 2018 the Company completed market research of potential screen upgrades and concept testing of a number of additional features is ongoing.

### US COPD portfolio

In 2017, Circassia and AstraZeneca established a commercial collaboration in the United States for the COPD products Tudorza<sup>®</sup> and Duaklir<sup>®</sup>. Under the initial Tudorza<sup>®</sup> profit share arrangement, Circassia took responsibility for the product's promotion while AstraZeneca continued its manufacture, distribution, pharmacovigilance, development and regulatory activities. Circassia also has the commercialisation rights to NDA-stage combination treatment Duaklir<sup>®</sup>.

### AstraZeneca agreement amendment

Under the terms of the original agreement, AstraZeneca took a 14.2% stake in Circassia as upfront consideration. A further deferred payment of \$100 million is payable on the earlier of Duaklir<sup>®</sup> approval or 30 June 2019. Circassia also has an option to acquire the full Tudorza<sup>®</sup> commercial rights, which is exercisable from H2 2018, with the amount payable dependent on the product's sales and Duaklir<sup>®</sup> approval. Both the deferred and option payments may be converted into a vendor loan in the event that third-party financing is unavailable.

During the first half of 2018, AstraZeneca and Circassia agreed to amend the original agreement. Under this amendment, AstraZeneca increased its holding in Circassia to 19.9%. Circassia subsequently paid the \$26.7 million proceeds from this subscription towards the \$45 million of R&D contributions due to AstraZeneca by the end of 2019. The amendment also extended the original vendor loan back stop to cover the outstanding R&D contribution of \$18.3 million. Based on these payments, Circassia anticipates a total of approximately \$9 million of R&D tax credits from HMRC, a proportion of which has now been received.

As a related-party transaction under the Listing Rules, the amendment required the publication of a Financial Conduct Authority (FCA) approved circular and approval by independent shareholders, which was granted on 16 July. The subsequent issue of equity to AstraZeneca reduced the free float in Circassia's shares to approximately 10%. Under the Listing Rules, companies are required to maintain a minimum 25% free float, which excludes shareholdings of more than 5% and those held by Directors. As a result, the Company committed to the FCA that if its free float does not reach the required level by 27 December 2018 it will seek shareholder approval to move to AIM, which does not have the same requirement. With a strong shareholder base and minimal movement in its free float in recent months, the Company has determined to initiate the activities required to admit its shares to trading on AIM and anticipates convening a shareholder vote to approve such a move in the coming weeks.

# Operating and strategy review continued

<sup>7</sup> Channel BioConsulting LLC analysis  
January 2017

## Tudorza® commercial progress

Tudorza® (aclidinium bromide) is a long-acting muscarinic antagonist (LAMA) used in the long-term maintenance treatment of COPD. It is administered via the simple-to-use, multi-dose Pressair® dry powder inhaler and is approved in many countries worldwide, including the United States. With the US COPD treatment market estimated at over \$5 billion in 2017, Tudorza® represents an important commercial opportunity for Circassia, and third-party estimates suggest the product has annual peak sales potential of over \$90 million<sup>7</sup>.

Circassia's US promotional strategy for Tudorza® targets existing customers and COPD high prescribers. During 2018, the Company has rolled out a new 'TUNIGHT + TUMORROW' marketing campaign, which focuses on the benefits of twice-daily dosing, with a morning and evening dose delivering significantly improved lung function. The campaign features new sales materials, healthcare professionals' website, paid digital search advertisements, banner adverts, promotion at leading conferences and presentations to nurse practitioners.

Since the Company started promoting the product in 2017, Circassia's salesforce has continued to exceed Tudorza® call targets and prescription levels have responded positively following the previous sustained period of decline. As a result, by the beginning of 2018 Circassia was halting this earlier decline and during the first half of the year prescriptions have continued to stabilise. With the rate of decline in 2017 prior to Circassia's full promotion greatly reduced during the first six months of 2018, prescriptions averaged approximately 4,700 per week during the period, providing a foundation to return the product to growth. Circassia's Tudorza® profit share revenues totalled £14.4 million during the first half of 2018, which based on channel mix was 4% ahead at CER of the £13.8 million the Company received in the second half of 2017.

## Tudorza® regulatory progress

During 2018, Tudorza® has made good regulatory progress. In June, the Company announced the filing of a supplemental New Drug Application (sNDA) to include compelling new clinical data from the ASCENT study in Tudorza®'s label. The FDA subsequently accepted the filing for review and set a Prescription Drug User Fee Act (PDUFA) target action date of 31 March 2019.

The phase IV ASCENT study was conducted in patients with moderate-to-very severe COPD and cardiovascular disease and / or risk factors. The results demonstrate that Tudorza® is effective at reducing COPD exacerbations without increasing cardiovascular

events and at decreasing hospitalisations due to COPD exacerbations in this at-risk population. Cardiovascular disease is the most common and significant comorbidity of COPD, with approximately 30% of COPD patients dying from cardiovascular conditions. If the sNDA is approved, Tudorza® will be the only LAMA in the United States with these data in its label. Headline results from this unique, large-scale study were presented at the American Thoracic Society 2018 International Conference in May.

## Duaklir® regulatory progress

Duaklir® is a fixed-dose combination COPD product containing the LAMA aclidinium bromide and long-acting beta agonist (LABA) formoterol fumarate. It is delivered via the Pressair® multi-dose dry powder inhaler and is approved in approximately 50 countries worldwide. Duaklir® represents a significant commercial opportunity for Circassia, with third-party estimates suggesting the product may have peak sales potential of over \$180 million per annum<sup>7</sup>.

Following Circassia's acquisition of the Duaklir® US commercialisation rights in 2017, the product has made good progress. During the second half of 2017, Duaklir® successfully completed its phase III AMPLIFY study, meeting the co-primary efficacy endpoints, and an NDA seeking marketing authorisation was submitted in the first half of 2018. The FDA recently accepted the filing for review and set a PDUFA target completion date of 31 March 2019.

Circassia is advancing its launch planning for Duaklir® and has completed a number of market research projects to inform its market access and promotional strategies. The Company has convened an opinion leader advisory board, appointed an advertising agency and plans to complete further market research to inform Duaklir®'s product positioning, messaging and creative campaign in the near future. As part of its launch planning, the Company is also refining its broader commercialisation strategy, to focus sales team resources and optimise customer targeting and territory definition. This is designed to provide the potential for a focused COPD sales force, achieving Tudorza® targets, while supporting NIOX® with a mix of sales team, telesales and experience program resources.

## Commercial infrastructure expansion

As part of its strategic transition, the Company is continuing to broaden its commercialisation capabilities. Following the significant expansion of its US commercial team in 2017, Circassia has focused on rapidly growing its China organisation during 2018.

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In the last two years Circassia has come a long way. It has largely completed its transformation from an R&D-focused organisation into a strong commercial business with a unique commercialisation platform and compelling respiratory products.

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Previously, the Company's Beijing-based team was focused on supporting local distributors, undertaking promotion, opinion leader development, speaker programmes and market access activities. Circassia is now significantly expanding these capabilities to enable the Company to promote NIOX<sup>®</sup> alongside its existing distributor base. Circassia anticipates that this new commercial infrastructure will increase NIOX<sup>®</sup> revenues, while also providing a strategic platform to attract potential third-party products for commercialisation in this major market. The expansion includes the recruitment of a full support team with marketing, sales training, commercial operations and compliance expertise, and back office functions including finance, IT and HR. This team is now in place and will soon be complemented by a sales force of approximately 85. Recruitment is progressing well, with regional managers already in the field, and Circassia plans to launch the full sales team by the end of the year. Once established, the sales force will target approximately 2,000 leading hospitals that are not currently NIOX<sup>®</sup> customers, alongside the 400 that are served by the Company's existing distributors.

Alongside this major expansion in China, Circassia is expanding its UK commercial team to leverage the new NICE guidelines published at the end of 2017. These are highly supportive of FeNO testing in asthma diagnosis and the addition of new Key Account Managers will allow the team to focus a proportion of its promotional effort on the primary care sector, while continuing to target specialist centres and payor organisations.

#### **Cost containment**

Circassia's investment strategy includes building on previous cost savings and refocusing resources to support commercial expansion. During 2016 and 2017, Circassia consolidated its facilities in the US, UK and Sweden and substantially cut the size of its R&D team. In 2018, it has continued its cost containment initiatives, most notably halting internal investment in its respiratory pipeline and seeking partners to develop the products. As a result, Circassia has reduced its R&D team by approximately a third since the beginning of the year, and during the first half of 2018 decreased underlying R&D expenditure by 20% compared with the same period the year before. The Company's R&D investment is now focused on development of the NIOX VERO<sup>®</sup> upgrade as well as regulatory, medical affairs, pharmacovigilance, quality and supply chain functions that support its marketed products.

During the coming months, Circassia plans to continue its focus on corporate expenditure, including reducing intellectual property costs and further consolidating its Oxford facilities. Corporate cost

reductions typically lag cuts to R&D, and while the Company's administrative expenditure did not fall during the first six months of 2018 versus the same period the previous year, due to restructuring, increased business development and legal costs, underlying spending fell by 13% compared with the second half of 2017.

As a result, Circassia is making progress in its cost containment strategy announced in April 2018. As previously announced, the Company plans to refocus spending, in particular into the expansion of its commercial team in China and US launch preparations for Duaklir<sup>®</sup>.

#### **Summary and outlook**

During the first half of 2018, Circassia has made rapid progress implementing its strategy. The Company's revenues and commercial capabilities continued to grow, its underlying cost base remained carefully controlled and its loss for the period and cash outflow were significantly reduced.

During the second half of the year, Circassia intends to build on this progress. The expansion of its commercial team in China is progressing well and the Company anticipates completing the recruitment and launch of its sales team in the coming months. The Company plans to complete the growth of its UK sales force, and in the United States the commercial team is accelerating preparations for the launch of Duaklir<sup>®</sup>, and an expanded label for Tudorza<sup>®</sup>, following the FDA's recent acceptance of both applications for review.

In the coming months, the Company plans to continue the development of its NIOX VERO<sup>®</sup> upgrade. It also plans to exploit its broader commercial platform, targeting a larger potential customer base, and to continue the roll out of its new promotional campaigns for NIOX<sup>®</sup> and Tudorza<sup>®</sup>.

During the remainder of the year, Circassia anticipates ongoing revenue growth and containment of non-commercial costs. Cash use fell significantly to under £10 million in the first half of 2018 and the Company is well on track to substantially reduce its net loss and cash outflow for the full year. Consequently, with over £50 million of cash on the balance sheet at the end of the first half of the year, Circassia remains well-resourced to pursue its commercial strategy.

In the last two years Circassia has come a long way. It has largely completed its transformation from an R&D-focused organisation into a strong commercial business with a unique commercialisation platform and compelling respiratory products. As a result, Circassia is coming ever closer to achieving its ambition of becoming a self-sustaining specialty pharmaceutical business, as it continues its trajectory to profitability.

Loss for the period significantly reduced by 31% mainly due to increased revenues and gross profit following the AstraZeneca collaboration, combined with a decrease in operating costs from both continuing non-underlying operations and discontinued operations.

**Loss for the period significantly reduced by 31% mainly due to increased revenues and gross profit following the AstraZeneca collaboration, combined with a decrease in operating costs from both continuing non-underlying operations and discontinued operations.**

Continuing operations include revenue and costs derived from the collaboration with AstraZeneca, in particular the sale of Tudorza® and development of Duaklir®, as well as sales of NIOX® and costs for the existing underlying Circassia business. Continuing operations are further divided into underlying and non-underlying operations.

Non-underlying operations include irregular and non-recurring expenditure, such as those relating to the internal respiratory pipeline, and the AstraZeneca R&D contribution.

Under its refocused strategy announced in April 2018, Circassia has reduced R&D expenditure and is seeking to out-license/partner its internal respiratory pipeline of directly substitutable generic products and novel formulations of currently approved drugs.

Discontinued operations include direct costs and overheads associated with the previous allergy programmes for which the Company decided to stop all further development in April 2017. The loss relating to the allergy business reduced to £0.2 million (H1 2017: £4.7 million), with no further costs expected.

The table below sets out the Group's results for H1 2018 compared with H1 2017, separated into continuing underlying operations, continuing non-underlying operations and discontinued operations.

	Underlying operations		Non-underlying operations		Total continuing operations		Discontinued operations <sup>1</sup>		Total	
	H1 2018	H1 2017	H1 2018	H1 2017	H1 2018	H1 2017	H1 2018	H1 2017	H1 2018	H1 2017
	£m	Restated <sup>2</sup> £m	£m	Restated <sup>2</sup> £m	£m	Restated <sup>4</sup> £m	£m	£m	£m	Restated <sup>4</sup> £m
Revenue	28.4	18.3	–	–	28.4	18.3	–	–	28.4	18.3
Cost of sales	(4.2)	(4.7)	–	–	(4.2)	(4.7)	–	–	(4.2)	(4.7)
<b>Gross profit</b>	<b>24.2</b>	13.6	–	–	<b>24.2</b>	13.6	–	–	<b>24.2</b>	13.6
<b>Gross margin</b>	<b>85%</b>	74%	–	–	<b>85%</b>	74%	–	–	<b>85%</b>	74%
Research and development	(5.7)	(7.1)	(1.0)	(15.7)	(6.7)	(22.8)	(0.2)	(4.4)	(6.9)	(27.2)
Sales and marketing	(27.7)	(21.1)	–	–	(27.7)	(21.1)	–	(0.5)	(27.7)	(21.6)
Administrative expenses	(5.2)	(4.6)	(0.3)	(0.4)	(5.5)	(5.0)	–	(0.1)	(5.5)	(5.1)
<b>Total expenditure</b>	<b>(38.6)</b>	(32.8)	<b>(1.3)</b>	(16.1)	<b>(39.9)</b>	(48.9)	<b>(0.2)</b>	(5.0)	<b>(40.1)</b>	(53.9)
<b>EBITDA</b>	<b>(12.1)</b>	(16.8)	<b>(1.3)</b>	(13.7)	<b>(13.4)</b>	(30.5)	<b>(0.2)</b>	(5.0)	<b>(13.6)</b>	(35.5)
<b>Operating loss</b>	<b>(14.4)</b>	(19.2)	<b>(1.3)</b>	(16.1)	<b>(15.7)</b>	(35.3)	<b>(0.2)</b>	(5.0)	<b>(15.9)</b>	(40.3)
Other gains and (losses)	0.1	(0.1)	(2.3)	2.7	(2.2)	2.6	–	–	(2.2)	2.6
Share of loss of joint venture	–	–	–	–	–	–	(0.1)	(0.5)	(0.1)	(0.5)
Finance income net	–	0.1	(6.0)	(1.5)	(6.0)	(1.4)	–	–	(6.0)	(1.4)
<b>Loss before tax</b>	<b>(14.3)</b>	(19.2)	<b>(9.6)</b>	(14.9)	<b>(23.9)</b>	(34.1)	<b>(0.3)</b>	(5.5)	<b>(24.2)</b>	(39.6)
Taxation	0.3	1.1	0.3	3.4	0.6	4.5	0.1	0.8	0.7	5.3
<b>Loss for the financial period</b>	<b>(14.0)</b>	(18.1)	<b>(9.3)</b>	(11.5)	<b>(23.3)</b>	(29.6)	<b>(0.2)</b>	(4.7)	<b>(23.5)</b>	(34.3)
<b>Cash<sup>3</sup></b>									<b>50.8</b>	82.9

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

<sup>2</sup> Restated to show the results of the respiratory business in non-underlying operations.

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

<sup>4</sup> Restated to show Foreign exchange differences within 'Other gains and (losses)' (previously shown within 'Finance income and costs').

**Julien Cotta**  
Chief Financial Officer



## Revenue

Circassia's revenues of £28.4 million (H1 2017: £18.3 million) include Tudorza® revenues of £14.4 million (H1 2017: £5.2 million) and NIOX® revenues of £14.0 million (H1 2017: £13.1m).

Tudorza® revenues derive from the joint profit arrangement with AstraZeneca from sales of the product. AstraZeneca records in-market sales, cost of sales and other operational costs, Circassia records the costs of the field force and promotion and the companies share the remaining profits equally. As a result, Circassia's Tudorza® revenues reflect both its costs and share of the profit. Revenue from the AstraZeneca collaboration of £14.4 million is higher compared to H1 2017, as sales were only recognised from 12 April 2017, being the date the agreement became unconditional, and is 4% ahead at CER of the £13.8 million the Company received in the second half of 2017.

NIOX® revenues include clinical sales of £11.7 million (H1 2017: £11.0 million), research sales of £2.1 million (H1 2017: £1.9 million) and other revenues of £0.2 million (H1 2017: £0.2 million), which include freight. NIOX® clinical revenues represent sales to physicians, hospitals and distributors for use in clinical practice, while research sales are those to pharmaceutical companies for use in clinical studies.

## Gross profit

Gross margin increased from 74% to 85%. This was mainly due to the contribution of revenues from the AstraZeneca collaboration, which are earned at a 100% gross margin. The gross margin was higher in H1 2018 than in H1 2017 based on receipt of these revenues for the full six month period. Gross profit on NIOX® sales was £9.8 million (H1 2017: £8.4 million), with a gross margin of 70% (H1 2017: 64%). The increase was mainly due to the weakening of sterling against the dollar.

## Research and development activities

Research and development costs decreased to £6.9 million (H1 2017: £27.2 million). This was mainly due to a decrease in non-underlying costs, notably the non-recurring AstraZeneca research and development contribution of £14.6 million in H1 2017, and a decrease in discontinued operations following the halting of expenditure on allergy programmes.

## Sales and marketing

Sales and marketing costs increased during H1 2018 to £27.7 million (H1 2017: £21.6 million). This was mainly due to the expanded US field force being in place for the full period as well as building commercial operations in China.

## Administrative expenditure

Administrative expenditure, which includes overheads specific to corporate functions, centrally managed support functions and corporate costs, increased to £5.5 million (H1 2017: £5.1 million). This was mainly due to restructuring, business development and legal costs.

## Other gains and losses

Other losses increased to £2.2 million (H1 2017: £2.6 million gain). This was mainly due to unrealised foreign exchange losses on consideration payable to AstraZeneca due to the weakening of sterling against the dollar.

## Net finance income

Net finance costs were £6.0 million (H1 2017: £1.4 million). This is a non-cash charge to the income statement for the period that is the difference in the discounted consideration payable to AstraZeneca recorded on the balance sheet and the consideration payable. This discounted amount reflects the time value of money.

## Share of loss of joint venture

A joint venture between Circassia and McMaster University was established previously to collaborate on the development of allergy immunotherapies. Loss for the period in respect of the joint venture was £0.1 million (H1 2017: £0.5 million), which has been included in discontinued operations.

## R&D tax credits

The tax credit on qualifying expenditure for the period was £0.7 million (H1 2017: £5.3 million). The decrease since the previous year reflects the reducing R&D expenditure on the Group's internal respiratory programmes and the non-recurring R&D contribution to AstraZeneca in 2017. The R&D tax credit relating to the allergy portfolio is included in discontinued operations.

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

### Loss after tax and loss per share

Basic loss per share for the period was 7p (H1 2017: 11p) reflecting a loss for the financial period of £23.5 million (H1 2017: £34.3 million), with the loss per share for continuing operations of 7p (H1 2017: 10p) reflecting a loss for the financial period of £23.3 million (H1 2017: £29.6 million). This decrease in loss per share mainly arose due to the increase in Tudorza® revenues and the reduction in R&D expenditure, in particular, the AstraZeneca research and development contribution.

### Statement of financial position

The Group's net assets at 30 June 2018 were £198.0 million (31 December 2017: £224.8 million). The decrease is mainly caused by a lower trade receivables balance, combined with a decrease in the Company's deposits balance.

Current liabilities at the end of the period were £27.7 million (31 December 2017: £30.8 million). The decrease is mainly due to a reduction in R&D expenditure.

Current tax assets at 30 June 2018 were £10.5 million (31 December 2017: £6.5 million), representing the R&D tax credit due from HM Revenue and Customs (HMRC). An R&D tax credit of £10.9 million was received in July 2018.

### Cash flow

The Group's cash position (including cash, cash equivalents and short-term deposits) decreased from £59.5 million at 31 December 2017 to £50.8 million at 30 June 2018.

In terms of cash usage, £7.4 million was used in operations (H1 2017: £34.2 million), with the decrease reflecting higher revenues and a net decrease in the overall cost base of the business, mainly due to the non-recurring AstraZeneca research and development contribution in H1 2017.

Exchange differences on cash and cash equivalents arose as a result of translation of foreign currency balances at the beginning and end of the relevant period. The exchange loss for the period was £1.5 million (H1 2017: £0.6 million gain). The increase compared with H1 2017 was due to greater fluctuations in exchange rates, in particular, the dollar.

### Summary and outlook

The outlook for the second half of 2018 is positive, reflecting the Company's increasing focus on commercial expansion and its intention to build on the cost containment measures achieved in 2017. With further savings in the non-commercial organisation, together with the benefit of a full year of Tudorza® sales and growing NIOX® revenues, the overall net loss and cash outflow for the full year is expected to decrease significantly.

### Julien Cotta

Chief Financial Officer

# Principal risks and uncertainties

**Circassia has considered the principal risks and uncertainties facing the Group for the remaining six months of this year and does not consider them to have changed from those set out on pages 33 to 38 of the 2017 Annual report and accounts except in respect of risks relating to: (a) the Group's increased investment in China; (b) the Company's free float (where much of the uncertainty has been removed); and (c) research and development risks, which are reduced in scope following the Group's decision to out-license its pipeline of early stage respiratory products. A summary of these risks is as follows:**

## 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 is expanding its operations in China where it has seen significant growth in previous years. However, there is no guarantee that this investment will lead to increased commercial success in the Chinese market.

## Compliance with healthcare regulations

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

## Regulatory approvals

The Group may not receive regulatory approval for those of its products which are in development or regulatory review. 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.

## Unforeseen side effects

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

## Supply Chain

The Group relies on third parties for the supply of key materials and services, such as AstraZeneca for Tudorza®. Problems at these contractors, such as technical issues, contamination, and regulatory actions may lead to delays or even loss of supply or inadequate supply of these materials and services either prior to launch or thereafter.

## Research and development risks

The Group may not be successful in its efforts to develop the next generation of its NIOX® device. This could have an impact on the long-term success of the NIOX® business.

## Intellectual property, know how, and trade secrets

The Group may be affected by challenges relating to the validity of its or its licensed patents. If these challenges are successful, then the Group may be exposed to generic competition.

The Group could also be sued for infringement of third party patent rights or not be able to secure intellectual property protection, or sufficient protection, in relation to products which are acquired or in development.

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.

The Group licenses certain intellectual property rights from third parties. The rights that are licensed to the Group as part of the collaboration with AstraZeneca relating to Tudorza® and Duaklir® fall within this category. If the Group fails to comply with its obligations under these licence agreements it may enable the other party to terminate the agreement.

## 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.

## Free float

The FCA requires issuers with a premium listing to maintain at least 25% free float in their listed shares. The Company continues to have a free float significantly below this level. The Company has committed to the FCA that if the level of free float cannot be increased to 25% by 27 December 2018 then it will seek shareholder approval to move to AIM (which does not have this requirement). In order to expedite this process, the Company has determined to initiate the activities required to admit its shares to trading on AIM, and anticipates convening a shareholder vote to approve such a move in the coming weeks. There is therefore some residual uncertainty about the timing of this move.

## Financial operations

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

Foreign exchange fluctuations may adversely affect the Group's results and financial condition.

Adverse decisions of regulators, including tax authorities, or changes in tax treaties, laws, or the interpretation of those laws, could reduce or eliminate research and development tax credits which the Group currently receives in the United Kingdom.

## Brexit

At the referendum held on 23 June 2016, the UK voted to leave the EU. The Group faces a range of risks associated with this decision. For example, the vote to leave the EU may lead to changes in the regulatory system by which medical devices and pharmaceutical products are approved for use.

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

# Condensed interim consolidated statement of comprehensive income for the six months ended 30 June 2018

	Notes	30 June 2018			30 June 2017		
		Underlying operations Unaudited £m	Non-underlying items Unaudited £m	Total Unaudited £m	Underlying operations Unaudited Restated <sup>1,2</sup> £m	Non-underlying items Unaudited Restated <sup>1,2</sup> £m	Total Unaudited Restated <sup>2</sup> £m
<b>Continuing operations</b>							
Revenue		28.4	–	28.4	18.3	–	18.3
Cost of sales		(4.2)	–	(4.2)	(4.7)	–	(4.7)
<b>Gross profit</b>		<b>24.2</b>	<b>–</b>	<b>24.2</b>	<b>13.6</b>	<b>–</b>	<b>13.6</b>
Research and development costs		(5.7)	(1.0)	(6.7)	(7.1)	(15.7)	(22.8)
Sales and marketing		(27.7)	–	(27.7)	(21.1)	–	(21.1)
Administrative expenses		(5.2)	(0.3)	(5.5)	(4.6)	(0.4)	(5.0)
<b>Operating loss</b>	4	<b>(14.4)</b>	<b>(1.3)</b>	<b>(15.7)</b>	<b>(19.2)</b>	<b>(16.1)</b>	<b>(35.3)</b>
Other gains and (losses)	5	0.1	(2.3)	(2.2)	(0.1)	2.7	2.6
Finance costs	6	(0.1)	(6.0)	(6.1)	(0.1)	(1.5)	(1.6)
Finance income	6	0.1	–	0.1	0.2	–	0.2
<b>Loss before tax</b>		<b>(14.3)</b>	<b>(9.6)</b>	<b>(23.9)</b>	<b>(19.2)</b>	<b>(14.9)</b>	<b>(34.1)</b>
Taxation		0.3	0.3	0.6	1.1	3.4	4.5
<b>Loss for the financial period from continuing operations</b>		<b>(14.0)</b>	<b>(9.3)</b>	<b>(23.3)</b>	<b>(18.1)</b>	<b>(11.5)</b>	<b>(29.6)</b>
<b>Discontinued operations</b>							
Loss for the period from discontinued operations attributable to owners of the parent	7	–	(0.2)	(0.2)	–	(4.7)	(4.7)
<b>Loss for the period attributable to owners of the parent</b>		<b>(14.0)</b>	<b>(9.5)</b>	<b>(23.5)</b>	<b>(18.1)</b>	<b>(16.2)</b>	<b>(34.3)</b>
<b>Other comprehensive (expense)/income</b>							
<b>Items that may be subsequently reclassified to profit or loss</b>							
Currency translation differences		(4.6)	–	(4.6)	1.8	–	1.8
<b>Total other comprehensive (expense)/income for the period</b>		<b>(4.6)</b>	<b>–</b>	<b>(4.6)</b>	<b>1.8</b>	<b>–</b>	<b>1.8</b>
<b>Total comprehensive expense for the period</b>		<b>(18.6)</b>	<b>(9.5)</b>	<b>(28.1)</b>	<b>(16.3)</b>	<b>(16.2)</b>	<b>(32.5)</b>

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

		30 June 2018 £	30 June 2017 £
<b>Basic and diluted loss per share</b>			
Loss per share from continuing operations	15	(0.07)	(0.10)
Total loss per share	15	(0.07)	(0.11)

<sup>1</sup> Restated to show the results of the respiratory business as non-underlying. See note 8 for details.

<sup>2</sup> Restated to show Foreign exchange differences within 'Other gains and losses' (previously shown within 'Finance income and costs').

The notes on pages 16 to 24 are an integral part of these condensed interim consolidated financial statements.

# Condensed interim consolidated statement of financial position as at 30 June 2018

	Notes	30 June 2018 £m Unaudited	31 December 2017 £m Audited
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment		1.0	1.4
Goodwill	10	9.7	10.0
Intangible assets	11	194.6	199.7
Deferred tax assets	9	15.7	15.7
Investment in joint venture	12	0.1	0.5
Prepayment for business combination	13	77.9	77.9
Non-current tax assets	9	4.0	7.3
		<b>303.0</b>	<b>312.5</b>
<b>Current assets</b>			
Inventories		4.7	5.0
Trade and other receivables		11.8	18.9
Current tax assets	9	10.5	6.5
Short-term bank deposits		10.0	15.0
Cash and cash equivalents		40.8	44.5
		<b>77.8</b>	<b>89.9</b>
<b>Total assets</b>		<b>380.8</b>	<b>402.4</b>
<b>Equity and liabilities</b>			
Ordinary shares	17	0.3	0.3
Share premium	17	602.2	602.2
Other reserves	18	14.0	17.2
Accumulated losses		(418.5)	(394.9)
<b>Total equity</b>		<b>198.0</b>	<b>224.8</b>
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Deferred tax liabilities	9	24.1	24.1
Non-contingent consideration	13	72.1	68.7
Contingent consideration	13	38.1	33.6
Non-current trade payables	14	20.8	20.4
		<b>155.1</b>	<b>146.8</b>
<b>Current liabilities</b>			
Trade and other payables	14	27.7	30.8
		<b>27.7</b>	<b>30.8</b>
<b>Total liabilities</b>		<b>182.8</b>	<b>177.6</b>
<b>Total equity and liabilities</b>		<b>380.8</b>	<b>402.4</b>

The notes on pages 16 to 24 are an integral part of these condensed interim consolidated financial statements.

# Condensed interim consolidated statement of cash flows for the six months ended 30 June 2018

	Notes	30 June 2018 £m Unaudited	30 June 2017 £m Unaudited
<b>Cash flows from operating activities</b>			
Cash used in operations	16	(7.4)	(34.2)
Interest and bank charges paid		(0.1)	(0.1)
Net cash used in operating activities		(7.5)	(34.3)
<b>Cash flows from investing activities</b>			
Interest received		0.1	0.5
Joint venture distributions to owners		0.3	–
Purchase of intangible assets		(0.1)	–
Purchase of property, plant and equipment		–	(0.5)
Decrease in short term bank deposits		5.0	–
Net cash generated from investing activities		5.3	–
<b>Cash flows from financing activities</b>			
Costs offset against share premium		–	(0.8)
Net cash used in financing activities		–	(0.8)
<b>Net decrease in cash and cash equivalents</b>			
Cash and cash equivalents at 1 January		44.5	97.4
Exchange (loss)/gain on cash and cash equivalents		(1.5)	0.6
Cash and cash equivalents at 30 June		40.8	62.9

The notes on pages 16 to 24 are an integral part of these condensed interim consolidated financial statements.

## Condensed interim consolidated statement of changes in equity

	Notes	Share capital £m	Share premium £m	Other <sup>1</sup> reserves £m	Accumulated losses £m	Total equity £m
<b>At 1 January 2018 (audited)</b>		0.3	602.2	17.2	(395.0)	224.8
Comprehensive expense:						
Loss for the period		–	–	–	(23.5)	(23.5)
Other comprehensive expense:						
Currency translation differences	18	–	–	(4.6)	–	(4.6)
Total comprehensive income/ (expense)		0.3	602.2	12.6	(418.5)	196.6
Transactions with owners:						
Employee share option scheme	18	–	–	1.4	–	1.4
<b>At 30 June 2018 (unaudited)</b>		<b>0.3</b>	<b>602.2</b>	<b>14.0</b>	<b>(418.5)</b>	<b>198.0</b>
<b>At 1 January 2017 (audited)</b>		0.2	563.8	12.5	(295.8)	280.7
Comprehensive expense:						
Loss for the period		–	–	–	(34.3)	(34.3)
Other comprehensive income:						
Currency translation differences		–	–	1.8	–	1.8
Total comprehensive income/ (expense)		–	–	1.8	(34.3)	(32.5)
Transactions with owners:						
Issue of ordinary shares		0.1	38.4	–	–	38.5
<b>At 30 June 2017 (unaudited)</b>		<b>0.3</b>	<b>602.2</b>	<b>14.3</b>	<b>(330.1)</b>	<b>286.7</b>

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

The notes on pages 16 to 24 are an integral part of these condensed interim consolidated financial statements.

# Notes to the condensed interim consolidated financial statements

## 1. General information

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

The condensed consolidated interim financial statements were approved for issue on 27 September 2018.

The condensed consolidated interim financial statements do not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006. Statutory accounts for the year ended 31 December 2017 were approved by the Board of Directors on 24 April 2018 and delivered to the Registrar of Companies. The report of the auditors on those accounts was unqualified, did not contain an emphasis of matter paragraph and did not contain any statement under section 498 of the Companies Act 2006.

The condensed consolidated interim financial statements have not been audited or reviewed.

### Basis of preparation

The condensed consolidated interim financial statements for the six months ended 30 June 2018 have been prepared in accordance with the Disclosure and Transparency Rules of the Financial Conduct Authority (previously the Financial Services Authority) and IAS 34 'Interim financial reporting', as adopted by the European Union.

The condensed consolidated interim financial statements should be read in conjunction with the annual financial statements for the year ended 31 December 2017, which have been prepared in accordance with IFRSs as adopted by the European Union.

### Going concern

The Group has sufficient cash and cash equivalents to meet its day-to-day working capital requirements. Though the Group continues to make losses, the Directors have reviewed the current and projected financial position of the Group, taking into account existing cash balances. On the basis of this review, the Directors have not identified any material uncertainties to the Group's ability to meet its liabilities as they fall due for the foreseeable future.

### Accounting policies

The accounting policies adopted are consistent with those of the previous financial year except as described below.

### 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 period. 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 are presented within 'Other gains and losses'. In the condensed interim financial statements for the period ended 30 June 2017 foreign exchange differences were presented within 'Finance costs or income'.

The change in the presentation reflects the fact that historically the foreign exchange differences were to a large extent driven by movements on foreign cash balances whereas following the AstraZeneca collaboration agreement the foreign exchange differences also arise from translation of monetary liabilities and as such the change in presentation to 'Other gains and losses' was deemed appropriate. This constitutes a voluntary change in accounting policy and has been applied retrospectively in these condensed interim financial statements resulting in 'Finance income' reducing by £2.6 million for the period to 30 June 2017 and 'Other gains' increasing by £2.6 million. There has been no impact to total loss for the current or previous financial period as a result of the policy change.

There are not considered to be any new standards, amendments to IFRS's and interpretations effective for the financial year ending 31 December 2018 that would have a material impact on the Group.

### Use of estimates and assumptions

The preparation of interim financial statements requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results may differ from these estimates.

In preparing these condensed interim financial statements, the significant judgements made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the annual financial statements for the year ended 31 December 2017 except as disclosed below.

### Financial instruments

The Group's financial instruments comprise cash and cash equivalents, short-term bank deposits, receivables and payables arising directly from operations. The Directors consider that the fair values of the Group's financial instruments do not differ significantly from their carrying values.

## 2. Financial and capital risk management

The condensed interim financial statements do not include all financial and capital risk management information and disclosures required in the annual financial statements; they should be read in conjunction with the Group's annual financial statements for the year ended 31 December 2017. The viability consideration has been disclosed in the last annual report and the Directors believe that the year-end position remains unchanged.

The majority of operating costs are denominated in sterling, United States dollars, euro or Swedish krona. Foreign exchange risk arises from future commercial transactions and recognised assets and liabilities. The Directors expect foreign exchange volatility to continue to affect the Group's results and the resulting impact will be assessed in the annual report.

### 3. Operating segments

The chief operating decision-maker (the Executive Directors) is responsible for making key operating decisions in the Group. Assessment of performance and decisions regarding the allocation of resources are made by operating segment. Performance of each segment is assessed on revenue and operating profit/(loss). The operating segments are identified within the Group by product portfolios:

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

The allergy operating segment is classified as a discontinued operation. Information about this discontinued segment is provided in note 7.

The table below presents revenue from external customers and operating profit/(loss) information regarding the Group's operating segments for the six months ended 30 June 2018 and 2017. Costs shared between the segments are not allocated to individual segments for decision making purposes. These are disclosed under the column headed 'Unallocated'.

	Underlying operations			Non-underlying operations	Total £m
	NIOX <sup>®</sup> £m	US AZ collaboration £m	Unallocated £m	Respiratory £m	
<b>Six months to 30 June 2018</b>					
Revenue	14.0	14.4	–	–	28.4
Operating (loss)/profit	(6.9)	1.5	(9.0)	(1.3)	(15.7)
<b>Six months to 30 June 2017</b>					
Revenue	13.1	5.2	–	–	18.3
Operating loss	(12.0)	(13.4)	(8.7)	(1.2)	(35.3)

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

There have been no material changes in total assets or total liabilities from the amounts disclosed in the last annual financial statements.

### 4. Operating loss

Included within the operating loss for the six months ended 30 June 2017 is a £14.6 million R&D contribution to AstraZeneca relating to research and development costs of Tudorza<sup>®</sup> and Duaklir<sup>®</sup>.

Transaction costs totalling £1.9 million were incurred on the collaboration arrangement with AstraZeneca, of which £0.3 million is included within the operating loss to 30 June 2017 and £1.6 million was offset against the share premium reserve.

### 5. Other gains and (losses)

	Six months ended 30 June	
	2018 £m	2017 Restated <sup>1</sup> £m
Net foreign exchange loss	0.1	(0.1)
Foreign exchange (loss)/gain on non-underlying items	(2.3)	2.7
<b>Total other gains and (losses)</b>	<b>(2.2)</b>	<b>2.6</b>

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

Foreign exchange loss on non-underlying items of £2.3 million (30 June 2017: £2.7 million gain) is made up foreign exchange loss of £1.6 million (30 June 2017: £2.7 million gain) on the non-contingent consideration and foreign exchange loss of £0.7 million (30 June 2017: £nil) on the contingent royalty consideration. See note 13 for further details.



## 8. Non-underlying items

Management primarily manage the business and measure performance based on the results of "underlying operations". Significant irregularly occurring and exceptional items and items relating to programmes the Company now intends to out license/partner are classified as "non-underlying" items and are excluded from the underlying measures. The following non-underlying items have been recognised in the income statement for the period:

	Notes	Six months ended 30 June	
		2018 £m	2017 £m
<b>Charged to research and development costs</b>			
In-house respiratory programme costs		(0.7)	(1.1)
Restructuring costs		(0.3)	–
AstraZeneca R&D contribution		–	(14.6)
		(1.0)	(15.7)
<b>Charged to administrative expenses</b>			
Transaction costs in relation to AstraZeneca collaboration		–	(0.3)
Legal and patent costs relating to in-house respiratory programmes		(0.3)	(0.1)
		(0.3)	(0.4)
<b>Credited to other gains and losses</b>			
Foreign exchange movement on non-contingent consideration	5	(1.6)	2.7
Foreign exchange movement on contingent royalty consideration	5	(0.7)	–
		(2.3)	2.7
<b>Charged to finance costs</b>			
Non-contingent consideration: unwinding of discount	6	(1.8)	(1.5)
Contingent royalty consideration: unwinding of discount	6	(3.8)	–
Non-current trade payables: unwinding of discount	6	(0.4)	–
		(6.0)	(1.5)
<b>Loss before tax</b>			
Credited to taxation		0.3	3.4
<b>Loss from continuing operations</b>			
Loss from discontinued operations		(9.3)	(11.5)
		(0.2)	(4.7)
<b>Total loss</b>			
		(9.5)	(16.2)

### In-house respiratory programme costs

Under its refocused strategy announced in April 2018, Circassia ceased investment in the Respiratory CGU and is seeking to out-license/partner its respiratory pipeline of directly substitutable generic products and novel formulations of currently approved drugs. As a result, respiratory programmes are not considered to be part of the underlying operations for the period ended 30 June 2018. The respiratory programme costs are classified as non-underlying items. To enable comparison respiratory programme results for the period ended 30 June 2017 are also presented in non-underlying items.

### Restructuring costs

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

### AstraZeneca R&D contribution

The cost in the period to 30 June 2017 includes a R&D contribution accrual of £14.6 million for Tudorza® and Duaklir® product development. An R&D tax credit of £3.2 million related to this expenditure is included in the taxation line for non-underlying items.

### Non-contingent consideration

The £2.3 million loss (30 June 2017: gain of £2.7 million) relating to foreign exchange movement on non-contingent consideration relates to the impact of the strengthening (2017: weakening) dollar on translation of the \$100 million deferred non-contingent consideration payable to AstraZeneca. The consideration was measured by discounting the liability with £1.8 million (30 June 2017: £1.5 million) increasing in the liability due to the passage of time (unwinding of discount) recognised as a finance cost for the period.

### Contingent royalty consideration

Contingent royalty consideration relates to the amount of royalties payable to AstraZeneca on the future Duaklir® sales. The liability was remeasured to fair value at the period end with no change in fair value (30 June 2017: £nil). The £0.7 million (30 June 2017: £nil) foreign exchange movement relates to the impact of the strengthening dollar on translation of the contingent royalty consideration.

### Loss from discontinued operations

The costs relating to the discontinued allergy operation are deemed to be an exceptional item to be excluded from the underlying operations, see note 7 for further details.

# Notes to the condensed interim consolidated financial statements continued

## 9. Taxation

### R&D tax credit

Included within the £14.5 million tax debtor is an R&D tax credit of £0.6 million (H1 2017: £4.5 million) relating to the six months ended 30 June 2018. This represents the credit receivable by the Group for the period as well as adjustments to prior years. These have been estimated at a rate of 14.5% for qualifying expenditure, being the prevailing R&D tax credit rate at the time. An uplift of 130% has been applied to all qualifying expenditure in line with R&D tax rules.

Deferred taxation	Intangibles £m	Tax losses £m	Net deferred tax liability £m
At 1 January 2018	24.1	(15.7)	8.4
<b>At 30 June 2018</b>	<b>24.1</b>	<b>(15.7)</b>	<b>8.4</b>
		30 June 2018 £m	31 December 2017 £m
Deferred tax liabilities		24.1	24.1
Deferred tax assets		(15.7)	(15.7)
<b>Total deferred tax position</b>		<b>8.4</b>	<b>8.4</b>

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

	30 June 2018 £m	31 December 2017 £m
Losses	64.8	60.3
<b>Total unrecognised deferred tax asset</b>	<b>64.8</b>	<b>60.3</b>

## 10. Goodwill

	£m
At 31 December 2017	
Cost	84.5
Accumulated impairment	(74.5)
Net book amount	10.0
<b>Six months ended 30 June 2018</b>	
Opening net book amount	10.0
Exchange differences	(0.3)
<b>Closing net book amount</b>	<b>9.7</b>
At 30 June 2018	
Cost	84.2
Accumulated impairment	(74.5)
<b>Net book amount</b>	<b>9.7</b>

Under its refocused strategy, Circassia ceased investment in the Respiratory CGU and is seeking to out-license/partner its respiratory pipeline of directly substitutable generic products and novel formulations of currently approved drugs.

Management has revised its forecast of the future performance of the Respiratory CGU based on the current strategic plans. The recoverable amount of the CGU was determined based on value in use calculations using a consistent methodology to that disclosed in the 2017 annual report.

No impairment loss has been recognised in the six-month period ended 30 June 2018 as the carrying value of the Respiratory CGU can be supported by the fair value generated by the future out-licensing/partnering activity.

As there were no indicators for impairment of any of the other CGUs, management has not updated any of the other impairment calculations.

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

	30 June 2018 £m	31 December 2017 £m
<b>Cash generating unit</b>		
NIOX®	5.1	5.4
Respiratory	4.4	4.4
AstraZeneca collaboration	0.2	0.2
	<b>9.7</b>	<b>10.0</b>

## 11. Intangible assets

	IPR&D £m	Customer relationships £m	Technology £m	Other £m	Total intangible assets £m
<b>At 31 December 2017</b>					
Cost	161.9	34.6	50.3	1.6	248.4
Accumulated amortisation and impairment	(37.1)	(4.8)	(5.2)	(1.6)	(48.7)
<b>Net book amount</b>	<b>124.8</b>	<b>29.8</b>	<b>45.1</b>	<b>–</b>	<b>199.7</b>
<b>Six months ended 30 June 2018</b>					
Opening net book amount	124.8	29.8	45.1	–	199.7
Additions	–	–	–	0.1	0.1
Amortisation charge	–	(0.9)	(1.0)	–	(1.9)
Impairment	–	–	–	–	–
Exchange differences	–	(1.8)	(1.5)	–	(3.3)
<b>Closing net book amount</b>	<b>124.8</b>	<b>27.1</b>	<b>42.6</b>	<b>0.1</b>	<b>194.6</b>
<b>At 30 June 2018</b>					
Cost	161.9	34.6	50.3	1.7	248.5
Accumulated amortisation and impairment	(37.1)	(7.5)	(7.7)	(1.6)	(53.9)
<b>Net book amount</b>	<b>124.8</b>	<b>27.1</b>	<b>42.6</b>	<b>0.1</b>	<b>194.6</b>

Due to change in strategy, Circassia ceased investment in the Respiratory CGU. This is considered to be an indicator of impairment in the Respiratory CGU intangible assets as at 30 June 2018. Impairment review was performed as outlined in note 10 with no impairment charges recognised in the period.

## 12. Investment in joint venture

	Six months ended 30 June 2018 £m	Year ended 31 December 2017 £m
<b>At 1 January</b>	<b>0.5</b>	0.9
Share of (loss)/profit	(0.1)	(0.2)
Distributions to owners	(0.3)	(0.2)
<b>At period end</b>	<b>0.1</b>	0.5

The Adiga Life Sciences joint venture managed clinical research organisations (CRO's) in Canada in respect of allergy programmes on behalf of Circassia. As the allergy programmes are no longer being continued, the results of the joint venture for the six months ended 30 June 2018 and 2017 have been included within discontinued operations in the condensed interim consolidated statement of comprehensive income, see note 7.

## 13. Business combinations

### Prepayment for business combination

On 12 April 2017, Circassia's collaboration and profit share arrangement with AstraZeneca became unconditional. Under the agreement, Circassia secured certain US commercial rights to Tudorza® and Duaklir®. On that day Circassia issued 47,355,417 ordinary shares with a value of \$50 million to AstraZeneca. In addition, Circassia will pay AstraZeneca deferred non-contingent consideration of \$100 million on the earlier of: (i) 30 June 2019; and (ii) the approval of Duaklir® by the FDA; and royalties on sales of Duaklir® in the United States.

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

# Notes to the condensed interim consolidated financial statements continued

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

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

## Tudorza® option

If the option to secure the remaining commercial rights and economic benefits of Tudorza® is taken, Circassia will make further payments to AstraZeneca of up to \$80 million dependent on the level of Tudorza® sales in the United States and if Duaklir® gains FDA approval. Such payments are not considered to be a present obligation until the option becomes exercisable therefore this has not been recognised as a liability in the interim financial statements for the six months ended 30 June 2018.

Until the Tudorza® option is exercised, the Group promotes the chronic obstructive pulmonary disease (COPD) treatment Tudorza® in the US in accordance with the collaboration and profit share arrangement. The commission fees receivable are based on Tudorza® product in-market sales and promotion activities performed by Circassia.

<b>Deferred non-contingent consideration</b>	<b>30 June 2018 £m</b>	<b>31 December 2017 £m</b>
Opening	68.7	71.4
Unwinding of discount	1.8	2.7
Foreign exchange movement	1.6	(5.4)
<b>At period end</b>	<b>72.1</b>	68.7

<b>Contingent Duaklir® royalty consideration</b>	<b>30 June 2018 £m</b>	<b>31 December 2017 £m</b>
Opening	33.6	39.7
Change in fair value	–	(3.2)
Unwinding of discount	3.8	–
Foreign exchange movement	0.7	(2.9)
<b>At period end</b>	<b>38.1</b>	33.6

## 14. Trade and other payables

<b>Payable within one year</b>	<b>30 June 2018 £m</b>	<b>31 December 2017 £m</b>
Trade payables	21.4	22.7
Social security and other taxes	0.3	0.3
Accruals	5.2	6.7
Other payables	0.8	1.1
<b>Total trade and other payables</b>	<b>27.7</b>	30.8
<b>Payable after one year</b>		
Trade payables	20.8	20.4
<b>Total non-current other payables</b>	<b>20.8</b>	20.4

## 15. Net loss per ordinary share

Basic loss per share is calculated by dividing the loss attributable to ordinary equity holders of the parent company by the weighted average number of ordinary shares in issue during the period.

		Continuing operations	Discontinued operations	Total
<b>For the period ending 30 June 2018</b>				
Loss attributable to ordinary equity owners of the parent company	£m	(23.3)	(0.2)	(23.5)
Weighted average number of ordinary shares in issue	Number	333,466,262	333,466,262	333,466,262
<b>Loss per share</b>		<b>(£0.07)</b>	<b>(£0.00)</b>	<b>(£0.07)</b>
<b>For the period ending 30 June 2017</b>				
Loss attributable to ordinary equity owners of the parent company	£m	(29.6)	(4.7)	(34.3)
Weighted average number of ordinary shares in issue	Number	305,720,065	305,720,065	305,720,065
<b>Loss per share</b>		<b>(£0.10)</b>	<b>(£0.01)</b>	<b>(£0.11)</b>

As net losses were recorded in the six months ended 30 June 2018 and 2017, the dilutive potential shares are anti-dilutive and therefore were excluded from the earnings per share calculation.

## 16. Cash used in operations

### Reconciliation of loss before tax to net cash used in operations

	Six months ended 30 June	
	2018 £m	2017 £m
Loss from continuing operations before tax	(23.9)	(34.1)
Loss from discontinued operation before tax	(0.3)	(5.5)
Loss before tax	(24.2)	(39.6)
Adjustment for:		
Finance income	(0.1)	(0.2)
Finance costs	6.1	1.6
Depreciation	0.4	0.3
Amortisation (note 11)	1.9	2.1
Share of joint venture loss (note 12)	0.1	0.5
Share based payment charge	1.4	–
Foreign exchange on non-operating items	2.3	(3.0)
Changes in working capital:		
Decrease/(increase) in trade and other receivables	7.1	(3.1)
(Increase)/decrease in inventories	0.3	(1.4)
(Decrease)/increase in trade and other payables	(2.7)	8.6
<b>Net cash used in operations</b>	<b>(7.4)</b>	<b>(34.2)</b>

## 17. Share capital and share premium

	Number of shares (millions)	Share capital £m	Share premium £m
Balance as at 1 January 2018	332.6	0.3	602.2
<b>At 31 December 2018</b>	<b>332.6</b>	<b>0.3</b>	<b>602.2</b>
	Number of shares (millions)	Share capital £m	Share premium £m
Balance as at 1 January 2017	284.9	0.2	563.8
Issue of new shares	47.7	0.1	40.0
Expenses offset against share premium	–	–	(1.6)
<b>At 31 December 2017</b>	<b>332.6</b>	<b>0.3</b>	<b>602.2</b>

# Notes to the condensed interim consolidated financial statements continued

## 18. Other reserves

	Share option reserve £m	Translation reserve £m	Treasury reserve £m	Transactions with non-controlling interests £m	Total other reserves £m
<b>At 1 January 2018</b>	8.9	15.1	(0.7)	(6.1)	17.2
Employee share option scheme	1.4	–	–	–	1.4
Currency translation differences	–	(4.6)	–	–	(4.6)
<b>At 30 June 2018</b>	<b>10.3</b>	<b>10.5</b>	<b>(0.7)</b>	<b>(6.1)</b>	<b>14.0</b>
At 1 January 2017	6.4	12.9	(0.7)	(6.1)	12.5
Employee share option scheme	2.5	–	–	–	2.5
Currency translation differences	–	2.2	–	–	2.2
<b>At 31 December 2017</b>	<b>8.9</b>	<b>15.1</b>	<b>(0.7)</b>	<b>(6.1)</b>	<b>17.2</b>

## 19. Related party transactions

There have been no new IAS 24 related-party transactions in the first six months of the current financial year. The post-period AstraZeneca transaction described in note 20 was a related-party transaction under the Listing Rules.

## 20. Events occurring after the reporting date

### AstraZeneca share issue

On 18 July 2018, Circassia issued 23,725,800 ordinary shares with a value of £20.4 million to AstraZeneca such that AstraZeneca's holding increased from 14.2% to 19.9%. Circassia used the proceeds to fund a deferred R&D contribution of \$20 million payable by the end of 2018 and part fund a final R&D contribution of \$25 million payable by the end of 2019.

The financial effects of the above transaction have not been brought to account at 30 June 2018.

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## Statement of Directors' responsibilities

The Directors confirm that these condensed interim financial statements have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and that the interim management report includes a fair review of the information required by DTR 4.2.7 and DTR 4.2.8, namely:

- an indication of important events that have occurred during the first six months and their impact on the condensed set of financial statements, and a description of the principal risks and uncertainties for the remaining six months of the financial year; and
- material related-party transactions in the first six months and any material changes in the related-party transactions described in the last annual report. The Directors of Circassia Pharmaceuticals plc are listed on page 26.

The Directors are responsible for the maintenance and integrity of the Group's website [www.circassia.com](http://www.circassia.com). Legislation in the UK governing the preparation and dissemination of interim financial statements may differ from legislation in other jurisdictions.

### On behalf of the Board

**Steven Harris**  
Chief Executive Officer

**Julien Cotta**  
Chief Financial Officer

27 September 2018

# Shareholder information

## Indicative financial calendar

- Preliminary results for the 12 months ending 31 December 2018: H1 2019
- Annual General Meeting: H1 2019

## Registrars

All administrative enquiries relating to shareholdings and requests to receive corporate documents by email should, in the first instance, be directed to Equiniti. Shareview is Equiniti's shareholder portal offering access to services and information to help manage your shareholdings and inform your important investment decisions.

## Shareview Portfolio

Shareview Portfolio is an online portfolio management tool which enables you to view and manage all the shareholdings you have, where Equiniti is the Registrar, in one place. It is free to use and provides access to a wide range of market information and investment services. Please visit [www.shareview.co.uk](http://www.shareview.co.uk).

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

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Calls to this number are charged at 10p per minute plus network extras. Lines are open 8:30am to 5:30pm Monday to Friday.

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## Independent Auditors

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Chartered Accountants and Statutory Auditors  
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London WC2N 6RH

## Directors

**Dr Francesco Granata**  
(Chairman)

**Steven Harris**  
(Chief Executive Officer and co-founder)

**Julien Cotta**  
(Chief Financial Officer)

**Dr Rod Hafner**  
(Senior Vice President Research and Development)

**Russell Cummings**  
(Non-Executive Director)

**Lota Zoth**  
(Independent Non-Executive Director)

**Jo Le Couilliard**  
(Independent Non-Executive Director)

**Sharon Curran**  
(Independent Non-Executive Director)

**Dr Heribert Staudinger**  
(Independent Non-Executive Director)

### **Forward-looking statements**

This document contains certain projections and other forward-looking statements with respect to the financial condition, results of operations, businesses and prospects of Circassia. The use of terms such as "may", "will", "should", "expect", "anticipate", "project", "estimate", "intend", "continue", "target" or "believe" and similar expressions (or the negatives thereof) are generally intended to identify forward-looking statements. These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors that could cause actual results or developments to differ materially from those expressed or implied by these forward-looking statements. Any of the assumptions underlying these forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in the forward-looking statements may not actually be achieved. Nothing contained in this press release should be construed as a profit forecast or profit estimate. Investors or other recipients are cautioned not to place undue reliance on any forward-looking statements contained herein. Circassia undertakes no obligation to update or revise (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or other circumstances.



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