

**CIRCASSIA PHARMACEUTICALS PLC
INTERIM RESULTS FOR THE SIX MONTHS ENDED 30 JUNE 2019**

Oxford, UK – 26 September 2019: Circassia Pharmaceuticals plc (“Circassia” or “the Company”) (LSE: CIR), a speciality pharmaceutical company focused on respiratory disease, today announces its unaudited interim results for the six months ended 30 June 2019 and a post-period update.

Highlights

- 40% revenue growth to £27.9 million in H1 2019 vs £19.9 million H2 2018
- 25% reduction in underlying continuing non-commercial costs to £7.6 million vs £10.1 million H2 2018
- Growth drivers in place to achieve £60 million - £65 million full year 2019 revenues (2018: £48.3 million)
- Dramatic reduction in net cash outflow post period end
- Strong focus on cost control to continue transition to self-sustainability

Financial progress

Key performance indicators* (KPIs)	H1 2019 underlying continuing operations	H2 2018 underlying continuing operations	H1 2019 total	H2 2018 total
Revenue	£27.9m	£19.9m	£27.9m	£19.9m
R&D ¹	(£2.8m)	(£4.0m)	(£2.8m)	(£81.4m)
G&A ¹	(£4.8m)	(£6.1m)	(£4.8m)	(£6.2m)
S&M ¹	(£25.1m)	(£25.8m)	(£25.1m)	(£28.7m)
EBITDA	(£12.4m)	(£20.7m)	(£12.4m)	(£101.1m)
Cash ² at period end	£21.0m	£40.7m	£21.0m	£40.7m

*KPI six-month comparison (H1 2019 vs H2 2018) reflects rapid and significant change following the establishment of dedicated sales forces in the US, Tudorza® option exercise on 31 December 2018 and transition to NIOX® direct sales in China

Post-period update and outlook

- Cash balance of £19.8 million at 31 August 2019 (£21.0 million at 30 June 2019)
- Net cash outflow expected to dramatically reduce during H2 2019 compared to H1 2019
- Key revenue drivers in place (NIOX® direct sales in China; Duaklir® launch imminent; Tudorza® full control; LungFit PH³ (previously AirNOvent) launch planning)
- Full year 2019 revenue expectation £60 million - £65 million
- Focus on cost control to achieve positive EBITDA on approximately £75 million net annual sales
- AstraZeneca five-year loan draw down to address outstanding transaction-related consideration

NIOX® progress

- Sales increased 32% to £18.5 million (H1 2018 CER⁴: £14.0 million) and 40% compared with H2 2018 (CER £13.2 million)
- Clinical (non-research⁵) revenues increased 38% compared with H1 2018 CER
- US and China sales increased 10% and 193% respectively vs H1 2018 CER
- Italy direct sales team launched September 2019

Tudorza® progress

- Revenues £9.3 million (H1 2018 CER: £14.4 million following release of accrued rebates); revenues 43% higher than H2 2018 CER (£6.5 million)
- Product licence transferred to Circassia at end of June 2019 providing additional commercial flexibility; distribution, pricing and market access strategies introduced to drive net revenue growth
- Rebates significantly reduced in first two months of H2 2019 and revenues increased 61% to £5.0 million vs H1 2019 two-month average
- Exacerbation reduction and cardiovascular safety data added to label

Duaklir® progress

- NDA approved March 2019
- Launch preparations complete; launch imminent

LungFit PH progress (previously AirNOvent)

- FDA filing anticipated in Q4 2019

Steven Harris, Circassia's Chief Executive, said: "Circassia made good financial and commercial progress in the first half of 2019, and we are delighted this has accelerated significantly in the past two months as our recent strategic changes begin to deliver results. During 2019, NIOX® revenues increased in all our direct markets, as well as those served by our partners, with particularly impressive growth in China following the launch of our new sales team. Since taking full control of Tudorza® in the United States at the end of June we have seen encouraging growth in net revenues, validating our newly-introduced commercial strategy."

"As a result Circassia continues to make strong progress, dramatically reducing net cashflow outflow in the first two months of H2 2019, which we anticipate maintaining during the remainder of the year. With our ongoing focus on controlling our cost base and with multiple growth drivers in place, including the imminent launch of Duaklir® in the US and our new sales teams in China and Italy focused on growing NIOX® revenues, we look forward to further boosting our performance over the rest of the year. By building on our performance in the first two months of the second half, we plan to continue our drive towards profitability and our goal of building a self-sustaining specialty pharmaceutical business."

Analyst meeting and webcast

An analyst meeting will take place today at 9.30am at finnCap, 60 New Broad Street, London, EC2M 1JJ. A webcast of the presentation will be available on the Company's website.

Contacts

Circassia

Steven Harris, Chief Executive Officer

Tel: +44 (0) 1865 405 560

Julien Cotta, Chief Financial Officer

Rob Budge, Corporate Communications

Peel Hunt (Nominated Adviser and Joint Broker)

James Steel / Dr Christopher Golden

Tel: +44 (0) 20 7418 8900

finnCap (Joint Broker)

Geoff Nash / Alice Lane

Tel: +44 (0) 20 7220 0500

Numis Securities (Joint Broker)

James Black / Freddie Barnfield

Tel: +44 (0) 20 7260 1000

FTI Consulting

Simon Conway / Ciara Martin

Tel: +44 (0) 20 3727 1000

About Circassia

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

¹Excludes depreciation and amortisation

²Includes cash, cash equivalents and short-term deposits

³LungFit PH is not an approved name and may not be the final commercial name

⁴Constant exchange rates (CER) for H1 and H2 2018 represent reported numbers re-stated using H1 2019 average exchange rates; management believes CER comparisons better represent underlying performance due to currency fluctuations against sterling

⁵Clinical revenues represent sales to clinicians, hospitals and distributors; research revenues represent sales to pharmaceutical companies for use in clinical studies

Forward-looking statements

This press release 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.

OPERATING REVIEW

During 2019 Circassia has made good progress across its business. The Company has capitalised on its new sales force in China and dedicated NIOX® and COPD teams in the United States, completed the transfer of Tudorza®'s US licence to Circassia from AstraZeneca, introduced a focused market access strategy for the product and completed preparations for the US launch of Duaklir®, which we expect imminently. At the beginning of the year, the Company further expanded its portfolio, acquiring the US and Chinese commercial rights to the late-stage nitric oxide product, LungFit PH (previously AirNOvent).

As a result of these strategic initiatives, the foundations for ongoing growth are now in place, and therefore the Company expects to accelerate its financial transformation. Notably, during the past two months Circassia has dramatically reduced its net cash outflow and drawn down on a five-year vendor loan from AstraZeneca that addresses the outstanding consideration related to the companies' Tudorza® and Duaklir® transaction.

In the coming months, Circassia plans to build on this progress as it launches Duaklir® in the United States, establishes its new direct sales team in Italy and focuses on continuing to grow Tudorza® net revenues since gaining full commercial control of the product in June. With LungFit PH's US filing anticipated in the near future, and potential launch in the second half of 2020, Circassia is advancing ever closer to achieving its goal of building a successful, self-sustaining specialty pharmaceutical business.

NIOX®

NIOX® is used around the world to improve asthma diagnosis and management by measuring fractional exhaled nitric oxide (FeNO), an important biomarker of the major underlying cause of asthma, type 2 airway inflammation. Circassia sells the product directly in the United States, China, UK and Germany, and recently launched a direct sales team in Italy. The Company also sells NIOX® through its international network of partners in more than 40 further countries.

Increasing sales

During the first half of 2019, NIOX® sales increased significantly, with global revenues of £18.5 million 32% ahead of the same period the previous year at constant exchange rates (CER) and 40% higher than the second half of 2018 (CER). Revenues grew across the Company's NIOX® business, with sales for clinical use 38% higher (CER) compared with H1 2018 and research use remaining at a similar level. In Circassia's direct markets sales continued to grow, with revenues in the US, UK and Germany 10%, 29% and 9% (CER) ahead respectively compared with the same period the prior year, while in China NIOX® achieved substantial growth of 193% (CER) following the launch of the Company's direct sales team at the end of 2018. Circassia's partner markets also achieved growth during the first half of 2019, with revenues 22% higher (CER) than the same period the year before.

Market expansion

During 2019, Circassia continued its market expansion activities. The Company completed recruitment of its new direct sales force in China following the team's launch at the end of the previous year, and focused on consolidating and extending NIOX®'s footprint beyond the installed base serviced by its previous distribution partners. In addition, the China commercial team maintained its focus on market access and reimbursement for FeNO testing is now in place in 13 provinces.

In the UK, the Company strengthened its commercial platform, adding further analyst and marketing expertise. In Italy, Circassia recently launched a modest direct sales force, which it anticipates expanding as this potentially significant market becomes established. In the United States, payor coverage continued to grow, with over 234 million Americans now having access to NIOX®, and Circassia was awarded a group purchasing contract by Premier, one of the leading healthcare improvement companies in the country.

The Company continued to roll out its digital strategy to support local market expansion. In China, it launched a country-specific version of the NIOX.com web portal. In the UK and Ireland, it maintained its online advertising presence, and in the United States introduced search engine advertising and continued its email marketing campaign.

In addition to the activities in the Company's direct markets, Circassia also extended the territories served by its partners. It received approvals in Malaysia, Saudi Arabi and Thailand allowing promotion of NIOX® in these new markets. Circassia also increased its international network, which now covers over 40 countries, adding new partners in Albania, Bulgaria and the United Arab Emirates.

Product innovation and recognition

During 2019, NIOX VERO® was recognised for its innovative contribution to healthcare by a number of organisations. In the United States, Circassia was awarded the Innovative Technology Supplier of the Year for 2018 by Vizient Inc., the largest healthcare performance improvement company in the country. In the UK, the Company received a manufacturer of the year award from the Association for Respiratory Technology & Physiology.

Circassia intends to build on its market-leading position in the FeNO field with the launch of NIOX VERO® PLUS at the forthcoming European Respiratory Society International Congress. This innovative accessory expands the NIOX® franchise, building on previous market research that showed strong satisfaction with the VERO® device and identified a number of areas to enhance the user experience. The new easy-to-install upgrade offers customers major enhancements to the system's screen and graphical interface while retaining the VERO®'s core technology.

Tudorza®

Tudorza® (aclidinium bromide, twice-daily administered via the easy-to-use Pressair® inhaler) is a long-acting muscarinic antagonist (LAMA) indicated in the United States for the maintenance treatment of COPD. LAMA therapies achieved estimated revenues of \$2 billion in the US in 2018, with Tudorza® accounting for approximately 2.6% of prescriptions. As a result, Tudorza® has significant potential, with a modest improvement in market share and / or a move to higher value channels representing a growth opportunity.

Circassia acquired the full US rights to Tudorza® from AstraZeneca on the exercise of its option at the end of 2018. From the start of 2019 the Company has recorded Tudorza®'s in-market sales and receives the full profits from its commercialisation. During 2019, Circassia refocused its sales capabilities with the launch of a dedicated COPD sales force, improving promotional efficiency, customer targeting and sales territory definition, and preparing for the imminent launch of Duaklir®. At the end of June 2019, Tudorza®'s licence transferred to Circassia providing the Company with the additional flexibility to introduce focused distribution, pricing and market access strategies at the beginning of the second half of the year. The Company also launched its Tudorza® healthcare professional and patient websites featuring a new \$10 copay guarantee for commercial channels.

Increasing sales

During the first half of 2019, despite the disruption associated with the launch of the dedicated COPD sales force, Tudorza® revenues of £9.3 million were more than 43% higher (CER) than the second half of 2018, although they were lower than the same period the year before (H1 2018: £14.4 million CER) following the release of accrued rebates during H1 2018 by AstraZeneca.

During H1 2019, Circassia introduced a new sales model with rapid re-targeting and hyper-frequency calls following its successful piloting at the end of 2018. At the beginning of 2019, Tudorza®'s largest competitors reduced the scale of their sales teams and Circassia leveraged its competitive share of voice, improving physician interaction and introducing a 'no hassle' brand promise ensuring commercial prescriptions are filled. Following the transfer of the product's licence, Circassia has built on this model, introducing a commercial strategy to reduce rebates and distribution costs, move away from unfavourable contracts, target growth in higher value channels and increase the wholesale acquisition cost which was previously significantly lower than the market leader Spiriva®. Initial results from this approach are encouraging. Despite the disruption due to the change of prescription identification codes associated with the product's transfer to Circassia, net revenues totalling £5.0 million in July and August were approximately 61% higher than the two-month average during the first half of the current year, with overall rebate levels reduced to under 60% compared with over 70% in H1 2019.

Label expansion

In March 2019, the United States Food and Drug Administration (FDA) approved the expansion of Tudorza®'s label to include clinical data from the phase IV ASCENT study. These new data demonstrate that Tudorza® is effective at reducing COPD exacerbations and associated hospitalisations with no increase in major cardiovascular adverse events in patients with moderate-to-very severe COPD and cardiovascular disease

and / or significant risk factors. Tudorza® is the only LAMA with these data in its US prescribing information, which provides an important differentiation from other products as an estimated 30% of COPD patients die from cardiovascular conditions. Since taking control of the product's market access strategy, the Company is now leveraging these data in payor discussions.

Duaklir®

Duaklir® is a combination therapy approved in the United States for the maintenance treatment of COPD. It combines the long-acting beta agonist (LABA) formoterol fumarate with the LAMA acclidinium bromide, administered twice-daily via the Pressair® inhaler. The product targets the significant US LAMA / LABA market, which is predicted to grow rapidly from an estimated \$1 billion in 2019 to over \$1.5 billion in the coming five years.

Launch planning

In March 2019, the FDA approved Duaklir®'s New Drug Application. The approval was based on a broad clinical database, which included data from three phase III studies and the Tudorza® phase IV ASCENT study. The product's label offers a number of competitive advantages. It is the only twice-daily LAMA / LABA in the US to feature in its prescribing information exacerbation reduction data and 24-hour profile demonstrating FEV1 improvement. Duaklir®'s label also includes data demonstrating its rapid onset of action with a clinically significant improvement in FEV1 within five minutes.

During 2019, Duaklir® launch planning has progressed well and with the product's launch imminent preparations are now complete. Following FDA approval, the Company launched Duaklir.com with an email sign-up facility for launch information, and has recently introduced paid-for search advertising. The Company plans complementary positioning for Tudorza® and Duaklir®, with continuity of the user-friendly Pressair® inhaler used by both products, a seamless fit with twice-daily dosing providing additional night-time bronchodilation and the acclidinium LAMA component providing the proven ability to reduce exacerbations.

Circassia also has full commercial control of the product from launch and intends to build on its recent learnings with Tudorza®. Consequently, it will leverage its COPD sales force's competitive share-of-voice with a high frequency, rapid re-targeting sales model, introduce a 'no hassle' brand promise guaranteeing commercial prescriptions are filled and focus on high value, profitable accounts.

LungFit PH (previously AirNOvent)

In early 2019, Circassia further expanded its specialty respiratory portfolio, acquiring the US and Chinese commercial rights to ventilator-compatible nitric oxide product AirNOvent (now LungFit PH) from AIT Therapeutics Inc. (now BeyondAir Inc.). Under the terms of the acquisition, Circassia paid \$10.5 million in upfront and milestone payments, following the successful completion of a pre-submission FDA meeting in February. This consideration was satisfied through the issuance of new ordinary shares in the Company, with future milestones also payable in Circassia shares. Milestones include \$12.6 million on FDA approval for use in the treatment of hypoxic respiratory failure associated with persistent pulmonary hypertension of the newborn (PPHN) and \$1.05 million on the product's launch in China, both of which are payable in cash or shares. Additional royalty payments will be based on gross profits from product sales.

BeyondAir is responsible for LungFit PH's development, manufacture and US regulatory filings and plans to submit the product to the FDA in Q4 2019 seeking Premarket Approval (PMA) for use in the treatment of PPHN. Following approval, Circassia anticipates launching the product in H2 2020. Circassia is responsible for managing the regulatory process in China, and is planning a submission strategy under the Chinese NMPA (National Medical Products Administration) process that references an existing approval of the product, such as the United States' PMA once granted.

Product overview

LungFit PH uses an electric voltage to produce nitric oxide from the nitrogen and oxygen in air. Inhaled nitric oxide is approved for use in the US in the treatment of hypoxic respiratory failure associated with PPHN. PPHN is potentially fatal and occurs in approximately 1,500 – 26,200 newborns in the United States. Management of the condition can be complex, involving a number of treatments, including supplemental oxygen and inhaled nitric oxide.

In the US, the currently available nitric oxide product, INOMAX®, is used in neonatal intensive care units (NICUs) and its delivery system administers nitric oxide from pressurised cylinders in conjunction with ventilator systems. In 2018, the product generated revenues estimated at over \$400 million in the US. In

China, the annual number of births is over four times higher than the United States, and market intelligence indicates local use of industrial gases with INOMAX® not currently available.

Circassia intends to commercialise LungFit PH through its existing commercial platform in the United States and China where its NIOX® sales teams already target top hospitals. In the US, the product offers a number of potential benefits compared with the local competition. LungFit PH is smaller, significantly lighter and more convenient than INOMAX®, and because it has no cylinders does not require special storage and handling facilities. This offers the potential to take market share in the NICU segment, as well as extending the market to smaller clinics that do not have the facilities required to manage nitric oxide cylinders.

Corporate progress

During 2019, Circassia has maintained its resolute focus on building a self-sustaining, commercially-focused specialty pharmaceutical business. The Company has made good progress building on the second half of 2018, and with multiple growth drivers now in place is well positioned to continue to advance during the remainder of the year.

Financial progress

During the first half of 2019, Circassia continued to control its costs. The Company reduced its underlying R&D expenditure compared with the previous six months and its regulatory, medical affairs, quality and supply chain teams are now focused on commercial support activities. Additionally, its administrative expenditure decreased compared with H2 2018. Commercial expenditure was maintained at a similar level to the second half of 2018 while the Company completed its Chinese direct sales platform. At the same time, revenues were significantly higher compared with H2 2018 and consequently the Company substantially reduced its underlying EBITDA loss for the period. Net cash outflow was higher in H1 2019 than the second half of the prior year due to the additional working capital required to sell NIOX® directly in China and the timing of R&D tax credits. However, net cash outflow is anticipated to reduce dramatically in H2 2019 reflecting expected sales growth, continued cost control and favourable working capital movements on Tudorza® sales.

Circassia has already made good progress during the first two months of the second half, reducing total net cash outflow to £1.2 million and the Company now has multiple revenue growth drivers in place, notably NIOX® direct sales including in China, full commercial control of Tudorza®, the imminent launch of Duaklir® and introduction of LungFit PH, once approved. As a result, Circassia anticipates achieving revenues of £60 million - £65 million for full year 2019, and in addition to its focus on increasing sales, the Company is stepping up its cost control, targeting the achievement of positive EBITDA on an annual revenue level of approximately £75 million.

AstraZeneca collaboration

During 2019, Circassia addressed the outstanding consideration relating to its transaction to acquire the US commercial rights to Tudorza® and Duaklir® through a five-year vendor loan provided by AstraZeneca. Under the terms of the companies' agreement, Circassia has now drawn down \$125 million, and will access the final \$18.3 million R&D payment due to AstraZeneca at the end of 2019.

Team development

With Circassia's transition to a commercially-focused specialty pharmaceutical business now complete, the Company recently strengthened its commercial expertise with the appointment of Jonathan Emms as Chief Operating Officer. In this newly-created role, he will oversee the Company's operational and commercial strategy, drawing on his extensive US, European and global commercial experience. Prior to joining Circassia, Jonathan was Chief Commercial Officer for Pfizer's Internal Medicines organisation and was previously elected President of the Association of the British Pharmaceutical Industry (ABPI). He also gained significant respiratory experience at GSK where he previously held a number of roles.

Outlook

Circassia has made good progress across its business during 2019, and with a number of growth drivers in place is well positioned to build on this foundation. The Company has continued to increase NIOX® revenues with growth in all of its direct markets as well as in its partnered territories. With its direct sales force now established in China, Circassia anticipates ongoing growth in this major market, while its dedicated sales team continues to increase revenues in the United States. In Italy, the Company's newly-launched direct sales team has the potential to significantly expand the use of NIOX®, while the imminent European launch of NIOX VERO® PLUS will expand the product franchise.

In the United States, Circassia now has full commercial control of Tudorza® following the exercise of its option at the end of 2018 and transfer of the product licence at the end of H1 2019. With the introduction of its focused sales model and market access strategy, the Company has the opportunity to return the product to growth, increasing net revenues, and has made encouraging progress during the start of the second half of the year. In the near future Circassia plans to further expand its US COPD franchise with the imminent launch of Duaklir®. With full commercial control from launch, the Company intends to leverage the learnings from Tudorza®, adopting a 'no hassle' brand promise and focus on high value channels, while capitalising on Duaklir®'s differentiated label.

In a short period of time, Circassia has transformed its business, building a strong commercial platform across the world's major markets with a growing portfolio of exciting respiratory products. The Company has the foundations for robust growth firmly in place and looks forward to continuing its financial transformation over the remainder of the year. By building on its performance in the first two months of the second half, Circassia plans to continue its drive towards profitability and its goal of creating a self-sustaining specialty pharmaceutical business.

FINANCIAL REVIEW

The first half of 2019 has been a period of significant transformation for Circassia after exercising the option to acquire full US commercial rights to Tudorza® and implementing a direct sales strategy in China. Additionally, the Group has maintained control of overall costs and investment in its commercial platform.

The table below sets out the Group's results for the period ended 30 June 2019, separated into continuing and discontinued operations. Continuing operations are further divided into underlying and non-underlying operations. Continuing underlying operations include Tudorza® revenues and sales of NIOX®, as well as the costs of the underlying business. These key performance indicators are used by management to manage the business and measure performance.

Non-underlying operations include irregular and non-recurring expenditure, namely foreign exchange movements and other non-cash losses relating to 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 historic allergy programmes for which all development ceased in April 2017.

	Underlying operations		Non-underlying operations		Total continuing operations		Discontinued operations ¹		Total	
	H1 2019	H1 2018	H1 2019	H1 2018	H1 2019	H1 2018	H1 2019	H1 2018	H1 2019	H1 2018
	£m	£m	£m	£m	£m	£m	£m	£m	£m	£m
Revenue	27.9	28.4	-	-	27.9	28.4	-	-	27.9	28.4
Cost of sales	(7.6)	(4.2)	-	-	(7.6)	(4.2)	-	-	(7.6)	(4.2)
Gross profit	20.3	24.2	-	-	20.3	24.2	-	-	20.3	24.2
Gross margin	73%	85%	-	-	73%	85%	-	-	73%	85%
Research and development ³	(2.8)	(4.5)	-	-	(2.8)	(4.5)	-	(1.2)	(2.8)	(5.7)
Sales and marketing ³	(25.1)	(26.7)	-	-	(25.1)	(26.7)	-	-	(25.1)	(26.7)
Administrative expenses ³	(4.8)	(5.1)	-	-	(4.8)	(5.1)	-	(0.3)	(4.8)	(5.4)
Total expenditure	(32.7)	(36.3)	-	-	(32.7)	(36.3)	-	(1.5)	(32.7)	(37.8)
Depreciation and amortisation	(6.9)	(2.3)	-	-	(6.9)	(2.3)	-	-	(6.9)	(2.3)
EBITDA	(12.4)	(12.1)	-	-	(12.4)	(12.1)	-	(1.5)	(12.4)	(13.6)
Operating loss	(19.3)	(14.4)	-	-	(19.3)	(14.4)	-	(1.5)	(19.3)	(15.9)
Other (losses)/gains	(0.1)	0.1	(1.1)	(2.3)	(1.2)	(2.2)	-	-	(1.2)	(2.2)
Share of loss of joint venture	-	-	-	-	-	-	-	(0.1)	-	(0.1)
Net finance costs	-	-	(8.9)	(6.0)	(8.9)	(6.0)	-	-	(8.9)	(6.0)
Loss before tax	(19.4)	(14.3)	(10.0)	(8.3)	(29.4)	(22.6)	-	(1.6)	(29.4)	(24.2)
Taxation	0.4	0.3	-	-	0.4	0.3	-	0.4	0.4	0.7
Loss for the financial period	(19.0)	(14.0)	(10.0)	(8.3)	(29.0)	(22.3)	-	(1.2)	(29.0)	(23.5)
Cash⁴									21.0	50.8

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

² Restated to show the results of the in-house respiratory programme as discontinued.

³ Excludes depreciation and amortisation.

⁴ Includes cash, cash equivalents and short-term deposits.

Revenue

Circassia's revenues of £27.9 million (H1 2018: £28.4 million) include Tudorza® revenues of £9.3 million (H1 2018: £14.4 million) and NIOX® revenues of £18.5 million (H1 2018: £14.0 million).

During 2018, Tudorza® revenues derived from the Group's profit share arrangement with AstraZeneca. AstraZeneca recorded in-market sales, cost of sales and other operational costs while Circassia recorded the costs of the field force and promotion and the companies each recorded 50% of the resultant profit. On 31 December 2018, Circassia completed the exercise of its option to take full commercial control of Tudorza® in the United States, and during 2019 received the full benefits of commercialisation and recorded both the product's sales and costs. Tudorza® revenues were higher in H1 2018 mainly due to higher volume of sales and the release of accrued rebates. Circassia recorded Tudorza® revenues of £6.5 million in H2 2018, which increased by over 40% to £9.3 million in H1 2019.

NIOX® revenues include clinical sales of £16.1 million (H1 2018: £11.7 million), research sales of £2.2 million (H1 2018: £2.1 million) and other revenues of £0.2 million (H1 2018: £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. The increase in NIOX® clinical sales was mainly due to the implementation of direct sales operation in China, where revenues increased by over 190%.

Gross profit

Gross margin decreased from 85% to 73% which mainly related to Tudorza®. Exercise of the Tudorza® option marked the end of the AstraZeneca collaboration agreement in which revenues were recorded at 100% gross margin. Following the exercise of the option, Circassia now records both the product's sales and costs. The gross margin during the period was 77%. Gross profit on NIOX® sales was £13.7 million (H1 2018: £9.8 million), with a gross margin of 74% (H1 2018: 70%). The increase was mainly due to the weakening of sterling against the dollar.

Research and development activities

Research and development costs decreased to £2.8 million (H1 2018: £5.7 million). This was mainly due to lower headcount combined with the capitalisation of qualifying device development spend in relation to NIOX VERO® PLUS, and a decrease in discontinued operations following the halting of expenditure on allergy and respiratory programmes.

Sales and marketing

Sales and marketing costs decreased to some extent during H1 2019 to £25.1 million (H1 2018: £26.7 million). This was mainly due to lower labour costs in the United States following the realignment of the US field force offset to some extent by higher costs relating to commercial operations in China.

Administrative expenditure

Administrative expenditure, which includes overheads specific to corporate functions, centrally managed support functions and corporate costs, decreased to £4.8 million (H1 2018: £5.4 million). This was mainly due to a decrease in discontinued operations, in particular restructuring and patent costs relating to respiratory programmes halted during H1 2018.

Depreciation and amortisation

Depreciation and amortisation increased to £6.9 million (H1 2018: £2.3 million). This was mainly due to the commencement of the amortisation charge relating to the Tudorza® CMP asset (Currently Marketed Product) and Duaklir® IPR&D asset (In-Process Research & Development).

Other gains and losses

Other losses decreased to £1.2 million (H1 2018: £2.2 million), mainly due to unrealised foreign exchange losses on consideration payable to AstraZeneca due to the weakening of sterling against the dollar.

Net finance costs

Net finance costs were £8.9 million (H1 2018: £6.0 million). This is a non-cash charge to the income statement for the period reflecting 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

The historic joint venture between Circassia and McMaster University was established to collaborate on the development of allergy immunotherapies. Loss for the period in respect of the joint venture of £nil (H1 2018: £0.1 million) reflects the previous cessation of the programmes, and has been included in discontinued operations.

R&D tax credits

The tax credit on qualifying expenditure for the period was £0.4 million (H1 2018: £0.7 million). The decrease since the previous year reflects the halting of R&D expenditure on the Group's internal respiratory programmes.

Loss after tax and loss per share

Basic loss per share for the period was 8p (H1 2018: 7p) reflecting a loss for the financial period of £29.0 million (H1 2018: £23.5 million). The loss per share for continuing operations of 8p (H1 2018: 7p) reflecting a loss for the financial period of £29.0 million (H1 2018: £22.3 million). The increase in loss per share mainly arose due to amortisation of AstraZeneca collaboration assets, combined with an increase in net finance costs.

Statement of financial position

The Group's net assets at 30 June 2019 were £103.2 million (31 December 2018: £125.9 million). The decrease is mainly caused by the unwinding of discounts on contingent and non-contingent consideration combined with a decrease in the Company's cash and cash equivalents balance.

Current liabilities at the end of the period were £109.5 million (31 December 2018: £124.4 million). The decrease is mainly due to the settlement of contingent consideration to AstraZeneca, which has been offset by a loan repayable within five years and is therefore classified as non-current.

Total tax assets at 30 June 2019 were £4.4 million (31 December 2018: £4.0 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 £40.7 million at 31 December 2018 to £21.0 million at 30 June 2019. The main cash flows were £19.2 million (\$25 million) settlement of deferred consideration (H1 2018: £nil) to AstraZeneca, which was offset by a five-year loan, along with £8.0 million proceeds from issue of shares (H1 2018: £nil) to AIT in exchange for the rights to LungFit PH. Post-period, Circassia has drawn down a further \$100 million from the AstraZeneca loan to settle the outstanding deferred consideration, and the Group anticipates drawing the final \$18.3 million due at the end of the year.

In terms of cash use, £18.0 million was used in operations (H1 2018: £7.4 million), with the increase reflecting lower gross margins due to the Tudorza® option exercise and higher use of working capital following the implementation of direct sales in China.

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 £0.1 million (H1 2018: £1.5 million). The decrease compared with H1 2018 was due to more favourable exchange rates, in particular against the dollar.

Summary and outlook

Circassia anticipates significant sales growth during the second half of 2019, with a number of factors expected to contribute to the increase. In particular, the Company expects increased Tudorza® revenues following the recent transfer of the product licence and initial Duaklir® sales later this year following its imminent launch. The Company also plans to continue its cost control, and with favourable working capital movements on Tudorza® sales anticipates a dramatic reduction in net cash outflow. As a result, Circassia looks forward to continuing its trajectory towards self-sustainability, with an ongoing focus on achieving positive EBITDA at approximately £75 million annual sales level.

PRINCIPAL RISKS AND UNCERTAINTIES

Circassia has considered the principal risks and uncertainties facing the Group for the first six months of 2019 and does not consider them to have changed from those set out on pages 28 to 33 of the 2018 Annual report and accounts. 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.

Compliance with healthcare regulations

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

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® and Duaklir®. 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. The Group's commercialisation plans for LungFit PH rely on our partner, Beyond Air, for the development and supply of that product.

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.

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

The Group continues to face a range of risks associated with the UK's vote to leave the EU. For example, this decision 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 2019

	Notes	30 June 2019			30 June 2018		
		Underlying operations	Non-underlying items	Total	Underlying operations	Non-underlying items	Total
		Unaudited	Unaudited	Unaudited	Restated ¹ Unaudited	Restated ¹ Unaudited	Unaudited
		£m	£m	£m	£m	£m	£m
Continuing operations							
Revenue		27.9	-	27.9	28.4	-	28.4
Cost of sales		(7.6)	-	(7.6)	(4.2)	-	(4.2)
Gross profit		20.3	-	20.3	24.2	-	24.2
Research and development		(3.7)	-	(3.7)	(5.7)	-	(5.7)
Sales and marketing		(26.0)	-	(26.0)	(27.7)	-	(27.7)
Administrative expenses		(9.9)	-	(9.9)	(5.2)	-	(5.2)
Operating loss	4	(19.3)	-	(19.3)	(14.4)	-	(14.4)
Other (losses) and gains	5	(0.1)	(1.1)	(1.2)	0.1	(2.3)	(2.2)
Finance costs	6	(0.1)	(8.9)	(9.0)	(0.1)	(6.0)	(6.1)
Finance income	6	0.1	-	0.1	0.1	-	0.1
Loss before tax		(19.4)	(10.0)	(29.4)	(14.3)	(8.3)	(22.6)
Taxation		0.4	-	0.4	0.3	-	0.3
Loss for the financial period from continuing operations		(19.0)	(10.0)	(29.0)	(14.0)	(8.3)	(22.3)
Discontinued operations							
Loss for the period from discontinued operations attributable to owners of the parent	7	-	-	-	-	(1.2)	(1.2)
Loss for the period attributable to owners of the parent		(19.0)	(10.0)	(29.0)	(14.0)	(9.5)	(23.5)
Other comprehensive expense							
Items that may be subsequently reclassified to profit or loss							
Currency translation differences		(2.6)	-	(2.6)	(4.6)	-	(4.6)
Total other comprehensive expense for the period		(2.6)	-	(2.6)	(4.6)	-	(4.6)
Total comprehensive expense for the period		(21.6)	(10.0)	(31.6)	(18.6)	(9.5)	(28.1)

¹Restated to show the results of the in-house respiratory programme as discontinued

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

		30 June 2019		30 June 2018
		£		Restated ¹
				£
Basic and diluted loss per share				
Loss per share from continuing operations	15	(£0.08)		(£0.07)
Total loss per share	15	(£0.08)		(£0.07)

¹Restated to show the results of the in-house respiratory programme as discontinued

The notes on pages 17 to 27 are an integral part of these condensed interim consolidated financial statements.

**CONDENSED INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT 30 JUNE 2019**

		30 June 2019	31 December 2018
		£m	£m
	Notes	Unaudited	Audited
Assets			
Non-current assets			
Property, plant & equipment		0.7	0.5
Right-of-use assets	19	2.3	-
Goodwill	10	9.1	9.3
Intangible assets	11	241.2	221.4
Deferred tax assets	9	19.1	19.1
Investment in joint venture	12	-	0.1
Non-current tax assets	9	-	3.0
		272.4	253.4
Current assets			
Inventories		6.0	4.2
Trade and other receivables		12.6	8.1
Current tax assets	9	4.4	1.0
Short-term bank deposits		-	-
Cash and cash equivalents		21.0	40.7
		44.0	54.0
Total assets		316.4	307.4
Equity and liabilities			
Ordinary shares	17	0.3	0.3
Share premium	17	630.4	622.5
Other reserves	18	13.7	15.1
Accumulated losses		(541.2)	(512.0)
Total equity		103.2	125.9
Liabilities			
Non-current liabilities			
Borrowings	13	19.7	-
Deferred tax liabilities	9	10.9	10.9
Finance lease liability	13	1.8	-
Contingent consideration	13	71.3	46.2
		103.7	57.1
Current liabilities			
Finance lease liability	13	0.8	-
Non-contingent consideration	13	78.7	80.3
Contingent consideration	13	1.7	15.4
Trade and other payables	13, 14	28.3	28.7
		109.5	124.4
Total liabilities		213.2	181.5
Total equity and liabilities		316.4	307.4

The notes on pages 17 to 27 are an integral part of these condensed interim consolidated financial statements.

CONDENSED INTERIM CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE SIX MONTHS ENDED 30 JUNE 2019

	Notes	Share capital £m	Share premium £m	Other ¹ reserves £m	Accumulated losses £m	Total equity £m
At 1 January 2019 (audited)		0.3	622.5	15.1	(512.0)	125.9
Change in accounting policy	19	-	-	-	(0.2)	(0.2)
Restated total equity at 1 January 2019		0.3	622.5	15.1	(512.2)	125.7
Comprehensive expense:						
Loss for the period		-	-	-	(29.0)	(29.0)
Other comprehensive expense:						
Currency translation differences	18	-	-	(2.6)	-	(2.6)
Total comprehensive income /(expense)		0.3	622.5	12.5	(541.2)	94.1
Transactions with owners:						
Issue of ordinary shares	17	-	7.9	-	-	7.9
Employee share option scheme	18	-	-	1.2	-	1.2
At 30 June 2019 (unaudited)		0.3	630.4	13.7	(541.2)	103.2
At 1 January 2018 (audited)		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		-	-	(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		-	-	1.4	-	1.4
At 30 June 2018 (unaudited)		0.3	602.2	14.0	(418.5)	198.0

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

The notes on pages 17 to 27 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 2019**

	Notes	30 June 2019 Unaudited £m	30 June 2018 Unaudited £m
Cash flows from operating activities			
Cash generated from operations	16	(18.0)	(7.4)
Interest paid		(0.1)	(0.1)
Net cash used in operating activities		(18.1)	(7.5)
Cash flows from investing activities			
Interest received		0.1	0.1
Joint venture distributions to owners		0.1	0.3
Purchase of intangible assets		(9.0)	(0.1)
Purchase of property, plant and equipment		(0.2)	-
Settlement of deferred consideration		(19.2)	-
Decrease in short term bank deposits		-	5.0
Net cash (used in)/generated from investing activities		(28.2)	5.3
Cash flows from financing activities			
Proceeds from issues of shares		8.0	-
Costs offset against share premium		(0.1)	-
Proceeds from borrowings		19.2	-
Principal elements of lease payments		(0.4)	-
Net cash generated from financing activities		26.7	-
Net decrease in cash and cash equivalents		(19.6)	(2.2)
Cash and cash equivalents at 1 January		40.7	44.5
Exchange loss on cash and cash equivalents		(0.1)	(1.5)
Cash and cash equivalents at 30 June		21.0	40.8

The notes on pages 17 to 27 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 Alternative Investments Market of 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 26 September 2019.

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 2018 were approved by the Board of Directors on 1 May 2019 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

This condensed consolidated interim financial report for the period ended 30 June 2019 has been prepared in accordance with Accounting Standard IAS 34 *Interim Financial Reporting*.

The interim report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended 31 December 2018 and any public announcements made by Circassia Pharmaceuticals plc during the interim reporting period.

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 and corresponding interim reporting period, except for those listed and the adoption of new and amended standards as set out below.

Tudorza® revenue

Revenue for the first six months of the year represent net invoice value less estimated rebates, returns and chargebacks, which are considered to be key estimates. Sales are recognised when the control of the goods has been transferred to a third party. This is usually when title passes to the customer, either on shipment or on receipt of goods by the customer, depending on local trading terms. In markets where returns are significant, estimates of returns are accounted for at the point revenue is recognised.

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.

New and amended standards adopted by the Group

A number of new or amended standards became applicable for the current reporting period, and the Group had to change its accounting policies and make retrospective adjustments as a result of adopting IFRS 16 Leases.

The impact of the adoption of the leasing standard and the new accounting policies are disclosed in note 19 below. The other standards did not have any impact on the Group's accounting policies and did not require retrospective adjustments.

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 2018, except for those listed below.

Tudorza® rebate accruals

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 built up on a customer-by-customer 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).

Total accrued rebates and chargebacks in the six months ended 30 June 2019 amounted to £20.7 million (2018: £nil).

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 2018. 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 Chief Executive Officer) is responsible for making key operating decisions in the Group. Assessment of performance and decisions regarding the allocation of resources are made by operating segment. The operating segments are identified within the Group by product portfolios:

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

The allergy and respiratory operating segments have been classified as discontinued operations. Information about these discontinued segments is provided in note 7.

The table below information regarding the Group's operating segments six months ended 30 June 2019 and 2018. Costs shared between the segments are not allocated to individual segments for decision making purposes. These are disclosed under the column headed 'Unallocated'.

	NIOX®	US AZ collaboration	Unallocated	Total
	£m	£m	£m	£m
Six months ended 30 June 2019				
Revenue	18.5	9.3	0.1	27.9
Operating loss	(1.6)	(6.1)	(11.6)	(19.3)
Six months ended 30 June 2018				
Restated ¹				
Revenue	14.0	14.4	-	28.4
Operating (loss)/ profit	(6.9)	1.5	(9.0)	(14.4)

¹Restated to show the results of the in-house respiratory programme as discontinued

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

There are no material items which are unusual by their nature, size or incidence for both six months ended 30 June 2019 and 2018.

5. Other (losses) and gains

	Six months ended 30 June	
	2019	2018
	£m	£m
Net foreign exchange (loss)/ gain	(0.1)	0.1
Foreign exchange loss on non-underlying items	(1.1)	(2.3)
Total other (losses) and gains	(1.2)	(2.2)

Foreign exchange loss on non-underlying items of £1.1 million (30 June 2018: £2.3 million) is made up foreign exchange loss of £0.4 million (30 June 2018: £1.6 million) on the non-contingent consideration and foreign exchange loss of £0.7 million (30 June 2018: £0.7 million) on the contingent royalty consideration.

6. Finance costs and income

	Six months ended 30 June	
	2019	2018
	£m	£m
Finance costs:		
Interest and bank charges payable	(0.1)	(0.1)
Non-contingent consideration: unwinding of discount	(3.1)	(1.8)
Contingent royalty consideration: unwinding of discount	(5.4)	(3.8)
Non-current trade payables: unwinding of discount	(0.4)	(0.4)
Total finance costs	(9.0)	(6.1)
Finance income:		
Bank interest receivable	0.1	0.1
Total finance income	0.1	0.1

7. 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 in-house 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.

Loss for the period	Notes	Six months ended 30 June	
		2019	2018
		£m	£m
Expenditure		-	(1.5)
Share of loss of joint venture	12	-	(0.1)
Loss before tax		-	(1.6)
Taxation		-	0.4
Loss from discontinued operations		-	(1.2)

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 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	
		2019	2018
		£m	Restated ¹ £m
Credited to other gains and losses			
Foreign exchange movement on non-contingent consideration	5	(0.4)	(1.6)
Foreign exchange movement on contingent royalty consideration	5	(0.7)	(0.7)
		(1.1)	(2.3)
Charged to finance costs			
Non-contingent consideration: unwinding of discount	6	(3.1)	(1.8)
Contingent royalty consideration: unwinding of discount	6	(5.4)	(3.8)
Non-current trade payables: unwinding of discount	6	(0.4)	(0.4)
		(8.9)	(6.0)
Loss before tax		(10.0)	(8.3)
Credited to taxation		-	-
Loss from continuing operations		(10.0)	(8.3)
Loss from discontinued operations	7	-	(1.2)
Total loss		(10.0)	(9.5)

¹ Restated to show the results of the in-house respiratory programme as discontinued. See note 7 for details.

Non-contingent consideration

The £0.4 million loss (30 June 2018: £1.6 million) relating to foreign exchange movement on non-contingent consideration relates to the impact of the strengthening (2018: 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 £3.1 million (30 June 2018: £1.8 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 Tudorza® and Duaklir® sales, and to AIT for future LungFit PH sales. The liability was remeasured to fair value at the period end with no change in fair value (30 June 2018: £nil). The £0.7 million (30 June 2018: £0.7 million) 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 and in-house respiratory programmes are deemed to be an exceptional item to be excluded from the underlying operations. See note 7.

9. Taxation

R&D tax credit

Included within the £4.4 million tax debtor is an R&D tax credit of £0.4 million (H1 2018: £0.6 million) relating to the six months ended 30 June 2019, and £1.0 million relating to the year ended 31 December 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	Tax losses	Net deferred tax liability
	£m	£m	£m
At 1 January 2019	10.9	(19.1)	(8.2)
At 30 June 2019	10.9	(19.1)	(8.2)
		30 June 2019	31 December 2018
		£m	£m
Deferred tax liabilities		10.9	10.9
Deferred tax assets		(19.1)	(19.1)
Total deferred tax position		(8.2)	(8.2)

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

	30 June 2019	31 December 2018
	£m	£m
Losses	63.9	58.0
Total unrecognised deferred tax asset	63.9	58.0

10. Goodwill

	£m
At 31 December 2018	
Cost	88.2
Accumulated impairment	(78.9)
Closing net book amount	9.3
Six months ended 30 June 2019	
Opening net book amount	9.3
Exchange differences	(0.2)
Closing net book amount	9.1
At 30 June 2019	
Cost	88.0
Accumulated impairment	(78.9)
Closing net book amount	9.1

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

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

	30 June 2019	31 December 2018
	£m	£m
Cash generating unit		
NIOX®	5.0	5.2
AstraZeneca collaboration	4.1	4.1
	9.1	9.3

11. Intangible assets

	IPR&D	CMP	Customer relationships	Technology	Intellectual property	Other	Total intangible assets
	£m	£m	£m	£m	£m	£m	£m
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
Six months ended 30 June 2019							
Opening net book amount	73.1	97.4	27.2	23.4	-	0.3	221.4
Additions	-	-	-	-	28.1	0.4	28.5
Amortisation charge	(1.1)	(3.8)	(0.9)	(1.0)	-	-	(6.8)
Exchange differences	-	-	(1.0)	(0.9)	-	-	(1.9)
Closing net book amount	72.0	93.6	25.3	21.5	28.1	0.7	241.2
At 30 June 2019							
Cost	161.9	97.4	34.6	50.3	28.1	2.3	374.6
Accumulated amortisation and impairment	(89.9)	(3.8)	(9.3)	(28.8)	-	(1.6)	(133.4)
Net book amount	72.0	93.6	25.3	21.5	28.1	0.7	241.2

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

12. Investment in joint venture

	Six months ended 30 June 2019	Year ended 31 Dec 2018
	£m	£m
At 1 January	0.1	0.5
Share of loss	-	(0.1)
Distributions to owners	(0.1)	(0.3)
At period end	-	0.1

The Adiga Life Sciences joint venture managed clinical research organisations (CROs) in Canada in respect of allergy programmes on behalf of Circassia. As the allergy programmes are no longer being continued, the results of the joint venture six months ended 30 June 2019 and 2018 have been included within discontinued operations in the condensed interim consolidated statement of comprehensive income, see note 7.

13. Borrowings

In June 2019, the Group entered into a loan facility with AstraZeneca to finance consideration payable under the collaboration agreement. The total amount available under the facility is \$143.3 million, of which \$25 million (£19.7 million) was drawn down as at 30 June 2019.

The loan is a fixed rate, United States dollar denominated loan, which is carried at amortised cost. It does not impact the Group's exposure to cash flow interest rate risk, however does impact the Group's foreign exchange 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. As at 30 June 2019, the contractual maturities of the Group's non-derivative financial liabilities were as follows:

	Less than 6 months	Between 6 and 12 months	Between 1 and 2 years	Between 2 and 5 years	Over 5 years	Total
	£m	£m	£m	£m	£m	£m
At 30 June 2019						
Borrowings	-	-	-	19.7	-	19.7
Finance lease liabilities	0.4	0.4	0.5	1.3	-	2.6
Non-contingent consideration	78.7	-	-	-	-	78.7
Contingent consideration	0.9	0.8	2.4	22.9	46.0	73.0
Trade and other payables	28.3	-	-	-	-	28.3
Total	108.3	1.2	2.9	43.9	46.0	202.3

14. Trade and other payables

30 June 2019 31 December 2018

	£m	£m
Payable within one year		
Trade payables	22.1	19.1
Social security and other taxes	0.4	0.3
Accruals	5.6	7.6
Other payables	0.2	1.7
Total trade and other payables	28.3	28.7

15. 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 30 June 2019 and 2018, the dilutive potential shares are anti-dilutive and therefore excluded from the earnings per share calculation.

	Continuing operations	Discontinued operations	Total
Six months ended 30 June 2019			
Loss attributable to ordinary equity owners of the parent company (£m)	(29.0)	-	(29.0)
Weighted average number of ordinary shares in issue (Number)	372,212,140	372,212,140	372,212,140
Loss per share	(£0.08)	(£0.00)	(£0.08)
Six months ended 30 June 2018			
Loss attributable to ordinary equity owners of the parent company (£m)	(22.3)	(1.2)	(23.5)
Weighted average number of ordinary shares in issue (Number)	333,466,262	333,466,262	333,466,262
Loss per share	(£0.07)	(£0.00)	(£0.07)

16. Cash used in operations

Reconciliation of loss before tax to net cash used in operations

	Six months ended 30 June	
	2019	2018 Restated ¹
	£m	£m
Loss from continuing operations before tax	(29.4)	(22.6)
Loss from discontinued operation before tax	-	(1.6)
Loss before tax	(29.4)	(24.2)
Adjustment for:		
Finance income (note 6)	(0.1)	(0.1)
Finance costs (note 6)	9.0	6.1
Depreciation	0.1	0.4
Amortisation (note 11)	6.8	1.9
Share of joint venture loss (note 12)	-	0.1
Share based payment charge	1.2	1.4
Foreign exchange on non-operating items	1.1	2.3
Changes in working capital:		
(Increase)/ decrease in trade and other receivables	(4.5)	7.1
(Increase)/ decrease in inventories	(2.2)	0.3
Decrease in trade and other payables	-	(2.7)
Net cash used in operations	(18.0)	(7.4)

¹Restated to show the results of the in-house respiratory programme as discontinued

17. Share capital and share premium

	Number of shares	Share capital	Share premium
	millions	£m	£m
At 1 January 2019	357.3	0.3	622.5
Issue of new shares	17.8	-	8.0
Expenses offset against share premium	-	-	(0.1)
At 30 June 2019	375.1	0.3	630.4

	Number of shares	Share capital	Share premium
	millions	£m	£m
At 1 January 2018	333.5	0.2	602.2
Issue of new shares	23.8	0.1	20.4
Expenses offset against share premium	-	-	(0.1)
At 31 December 2018	357.3	0.3	622.5

18. Other reserves

	Share option reserve	Translation reserve	Treasury reserve	Transactions with non-controlling interests	Total other reserves
	£m	£m	£m	£m	£m
At 1 January 2019	11.6	10.3	(0.7)	(6.1)	15.1
Employee share option scheme	1.2	-	-	-	1.2
Currency translation differences	-	(2.6)	-	-	(2.6)
At 30 June 2019	12.8	7.7	(0.7)	(6.1)	13.7
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	15.1	(0.7)	(6.1)	15.1

19. Changes in accounting policies

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 19(b) below.

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%.

	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:

	30 June 2019	1 January 2019
	£m	£m
Motor vehicles	0.1	0.1
Leasehold assets	2.2	2.4
Total right-of-use assets	2.3	2.5

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

- right-of-use assets – increase by £2.3 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 £0.2 million.

(i) Impact on earnings per share

Earnings per share for the six months to 30 June 2019 was not impacted as a result of the adoption of IFRS 16.

(ii) 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
- the exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application, 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*.

(b) The group's leasing activities and how these are accounted for

The group leases various offices, warehouses, equipment and cars. Rental contracts are typically made for fixed periods of 3 to 10 years but may have extension options as described in (ii) below. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants, but leased assets may not be used as security for borrowing purposes.

Until the 2018 financial year, leases of property, plant and equipment were classified as either finance or operating leases. Payments made under operating leases (net of any incentives received from the lessor) were charged to profit or loss 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. Each lease payment is allocated between the liability 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. The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable
- variable lease payment that are based on an index or a rate
- amounts expected to be payable by the lessee under residual value guarantees
- the exercise price of a purchase option if the lessee is reasonably certain to exercise that option, and
- payments of penalties for terminating the lease, if the lease term reflects the lessee exercising that option.

The lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be determined, the lessee's incremental borrowing rate is used, being the rate that the lessee would have to pay to borrow the funds necessary to obtain an asset of similar value in a similar economic environment with similar terms and conditions.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability
- any lease payments made at or before the commencement date less any lease incentives received
- any initial direct costs, and
- restoration costs.

Payments associated with short-term leases and 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.

20. Related party transactions

There have been no new IAS 24 related-party transactions in the first six months of the current financial year.

21. Events occurring after the reporting date

On 7 August 2019, Circassia settled the non-contingent consideration due to AstraZeneca, and subsequently drew down \$100 million under the existing loan facility with AstraZeneca.

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, 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 29.

The Directors are responsible for the maintenance and integrity of the Group's website 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
26 September 2019

Julien Cotta
Chief Financial Officer

SHAREHOLDER INFORMATION

Indicative financial calendar

Preliminary results for the 12 months ending 31 December 2019: H1 2020
Annual General Meeting: H1 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.

Addresses for correspondence

Head office

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

Tel: +44 (0)1865 405560
Fax: +44 (0)7092 987560

General enquiries: info@circassia.com
Investors: IR@circassia.com
Website: www.circassia.com

Registrars

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

Shareholder support: 0871 384 2030

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

Directors

Dr Francesco Granata (Chairman)
Steven Harris (Chief Executive Officer and co-founder)
Julien Cotta (Chief Financial Officer)
Jonathan Emms (Chief Operating Officer)
Jo Le Couilliard (Independent Non-Executive Director)
Sharon Curran (Independent Non-Executive Director)