



Interim report and accounts 2020

Circassia Group plc
(formerly Circassia Pharmaceuticals plc)

Circassia in brief

Circassia is a leading medical device business focused on respiratory disease. The Company sells its market-leading NIOX[®] asthma management products directly to specialists in the United States, United Kingdom, China and Germany, and in a wide range of other countries through its network of distribution partners. For more information please visit www.circassia.com.

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Operational and financial highlights

Operational highlights

- Transformational transaction to hand COPD products (Tudorza[®] and Duaklir[®]) back to AstraZeneca completed 27 May 2020. Transition is proceeding well with a vastly reduced run off team
- Business now focussed exclusively on asthma diagnosis and management with the Company's market leading NIOX[®] device and associated consumables

Financial highlights

- NIOX[®] sales decreased 39% to £11.4 million (H1 2019: £18.6 million) as a result of COVID-19 impact
- Signs of gradual recovery in Q3 but still trading well below prior year
- COPD business during transition period largely unaffected by COVID-19. H1 revenues of £11.6 million 25% up on H1 2019 (£9.3 million)
- EBITDA loss for the continuing NIOX[®] business largely unchanged at £6.2 million (H1 2019: £6.0 million) despite revenue reduction of £7.2 million, reflecting substantial reduction in cost base
- Cash outflow of £17.4 million in H1 dominated by payments which will not recur in H2, including payment of £8.9 million for Tudorza[®] and Duaklir[®] inventory and redundancy and employment costs for the former COPD salesforce of £4.6 million
- Company is debt free with net cash of £9.6 million as of 30 June 2020

Post period update

- Further significant reduction in cost base of continuing business implemented
- New operational management structure put in place to reflect change of business focus
- Signs of gradual recovery in NIOX[®] clinical sales in Q3, but revenues remain well below prior year
- Equity facility of £5 million announced on 2 June 2020 being drawn down on 17 September 2020

Key performance indicators £m	H1 2020	H1 2019 Restated ¹
Revenue	£11.4m	£18.6m
R&D ²	(£1.7m)	(£2.3m)
S&M ²	(£7.7m)	(£12.7m)
G&A ²	(£4.6m)	(£4.8m)
EBITDA	(£6.2m)	(£6.0m)
Loss for the financial period from continuing operations	(£9.4m)	(£7.8m)
Loss for the financial period from discontinued operations	(£8.6m)	(£21.2m)
Loss for the financial period	(£18.0m)	(£29.0m)
Cash ³ at period end	£9.6m	£21.0m

¹ Restated to show the results of the COPD business as discontinued

² Excludes depreciation and amortisation

³ Includes cash, cash equivalents

Chairman's statement

“The decision to hand back the COPD products and focus the Group's activities on NIOX[®] has led to a significant reduction in the cost base of the Group reflecting its smaller size, reduced complexity and lower regulatory risk profile. The Group's underlying cost base in 2019 was £74 million and it had net debt of £83 million at 31 December 2019. The return of the COPD business to AstraZeneca eliminated the Group's debt. Cost saving opportunities in the Group's NIOX[®] business have been pursued diligently throughout the year to date and we anticipate that by the time we enter 2021, the underlying cost base of the ongoing business will have reduced from £35.3 million in 2019 to no more than £23 million on an annualised basis, excluding depreciation, amortisation and head office costs (expected to be approximately £1.6 million in 2021). While it remains difficult to predict revenues in the current COVID Pandemic, with this reduced cost base the Group would be expected to be EBITDA positive at 2019 revenue levels of £34.6 million.”

Following my appointment as Executive Chairman in December 2019, further board changes were made. Michael Roller was appointed as CFO in January 2020 and Garry Watts as Senior Independent Director in March 2020. The executive management of Circassia now consists of myself, Jonathan Emms (who joined Circassia in September 2019) as COO and Michael Roller.

Following a strategic review of the business which concluded that the cost base and level of debt was unsustainable, we negotiated an agreement with AstraZeneca to hand back to them the Tudorza[®] and Duaklir[®] products for the treatment of COPD, which had previously been the principal focus of the Group. The consideration for this was the forgiveness of debt and accrued interest owing to AstraZeneca of £123.1 million, leaving the group debt free and with net cash of £9.6 million at 30 June 2020. The COPD business, which is in a transition period following the transaction with AstraZeneca is presented as a discontinued activity in the interim financial statements. Our intention is to focus Circassia on its market leading medical device business, NIOX[®], which we believe to have considerable potential for growth, in order to improve shareholder value.

The ongoing COVID-19 pandemic has significantly impacted NIOX[®] revenues, but management is taking the appropriate cost actions to mitigate the impact of this on the Company's financial resources.

Business review

NIOX[®]

The NIOX[®] business has several appealing characteristics:

- A market leading position in FeNO testing, with close to 40 million tests performed since launch from an installed base of over 10,000 devices
- Competition is fragmented and currently has a small share of the market
- A market for FeNO testing which is still very underdeveloped in most of the principal healthcare markets around the world
- A strong recurring revenue model, with new mouthpieces and sensors required for each test

The performance of the NIOX[®] business has been adversely affected during the first half of the year by COVID-19; revenues are geographically very diverse, and in general those countries where infection numbers have been lower and management of the epidemic more effective have performed better, although the structure of how healthcare is delivered in different countries is also a factor. The extent of the disruption to sales caused by the impact of lockdowns is reflected in the fact that excluding China (where the timing of the lockdown was different), Q1 NIOX[®] clinical revenues were 6% up on prior year, whereas in Q2 they were 53% down on prior year. July and August have seen a recovery in sales, but still to a level well below the prior year.

We believe the principal growth drivers for the NIOX[®] business are as follows:

- Improvements in customer service, to ensure there is no reason why the clinician cannot utilise their device at all times
- The development of service offerings which generate new revenue streams and differentiate NIOX[®] from its competition
- Focus on growing the business by servicing the needs of the nascent market of IL-5 inhibitor drugs, many of which require the patient to have a FeNO test before they can be prescribed
- Further education to demonstrate the benefits of FeNO testing
- Development of a device for ‘home use’ which would avoid hospital visits
- Development of a specialised device to serve the global pharmaceutical clinical research market

COPD

In April 2020 we announced the transaction to hand the COPD products, Tudorza[®] and Duaklir[®], back to AstraZeneca and this involves a transition period during which Circassia continues to operate the business and its adjusted profits are shared equally with AstraZeneca. This transition period can be terminated by AstraZeneca with 8 weeks’ notice and has a long stop date of 31 March 2021.

Revenues in the COPD business in H1 were 25% up on H1 of 2019 at £11.6 million (H1 2019: £9.3 million) and have been unaffected by the impact of COVID-19. The operating loss of this business in H1 2020 excluding impairment was £6.2 million (H1 2019: £11.2 million). As a result of the much reduced sales and marketing costs during the transition period, the business has traded profitably during July and August.

Chairman's statement, continued

Lungfit

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

Company name change

Following the agreement in April 2020 to transfer Tudorza[®] and Duaklir[®] to AstraZeneca, the Company sought shareholder approval to change its name to Circassia Group plc. This change reflects the transformation in the Company's business and its exclusive focus on its world leading NIOX[®] products rather than pharmaceutical products. On 30 April 2020, shareholders approved the change and on 1 May 2020 the name change was formally adopted by the Company.

Equity financing facility

In June, the Company executed an equity financing facility with two of its principal shareholders, allowing it to call upon them for up to £5 million of additional equity finance at a price of 24.6p per share. While the underlying cash burn of the Company is expected to be very significantly reduced during the second half of the year, the Board considers it appropriate to draw down this equity financing given the ongoing uncertainty associated with COVID-19 and has today given notice of this to the two principal shareholders concerned. Taking into account the Company's existing cash resources and today's drawdown of the £5 million equity facility, the Company estimates it has sufficient cash to fund its current operations for at least the next 12 months. This assumes some gradual improvement in the NIOX[®] business from current levels and that there is no marked deterioration in trading of the COPD business during the run off period. Any more pronounced upturn in trading would extend this horizon significantly.

Accordingly, application has been made for 20,325,202 new Ordinary Shares of 0.08p each to be admitted to trading on AIM, which is expected to occur on or around 22 September 2020. The new Ordinary Shares will rank pari passu with the existing Ordinary Shares of the Company.

Following the issue of these new Ordinary Shares, the Company's issued share capital will comprise 397,335,301 Ordinary Shares. This figure may be used by shareholders as the denominator for the calculations by which they will determine whether they are required to notify their interest, or a change to their interest, in the Company under the AIM Rules.

Outlook

Going forward the objective of the Group is to grow the core NIOX[®] business globally through organic growth and increase Circassia's presence in key strategic markets. Investment in improving the product breadth and strengthening our sales and marketing effort is ongoing.

Good progress has been made in aligning the cost base with the requirements of the NIOX[®] business in a way that will support future growth post COVID-19. The ongoing pandemic means it is extremely difficult to predict revenues in the NIOX[®] business, and while these have recovered from the lows of the second quarter, they are still running some way below the level of the prior year.

While it remains difficult to predict revenues in the current COVID Pandemic, with this reduced cost base the Board would expect the Group to be EBITDA positive at 2019 revenue levels of £34.6 million.

Ian Johnson
Executive Chairman

Financial review

The first half of 2020 has been a period of uncertainty for Circassia due to the impact of the COVID-19 pandemic. On 27 May 2020, the Group handed back the rights to its COPD products to AstraZeneca, and as such the results of the COPD business are classified as a discontinued operation in the table opposite. The NIOX[®] business represents the continuing operations of the Group.

Revenue

NIOX[®] revenues for the period were £11.4 million (H1 2019: £18.6 million) which include clinical sales of £10.3 million (H1 2019: £16.1 million), research sales of £0.9 million (H1 2019: £2.2 million) and other revenues of £0.2 million (H1 2019: £0.2 million), which include freight. NIOX[®] clinical revenues represent sales to physicians and hospitals for use in clinical practice and to the Company's distributors, while research sales are those to pharmaceutical companies and contract research organisations (CROs) for use in clinical studies. The downturn in NIOX[®] sales was due to the COVID-19 pandemic.

Gross profit

Gross profit on NIOX[®] sales was £7.8 million (H1 2019: £13.8 million), with a gross margin of 68% (H1 2019: 74%). The decrease was mainly due to a lower proportion of higher margin direct sales in China, combined with a repurchase of £0.4 million of obsolete inventory from a distributor in China.

Sales and marketing

Sales and marketing costs decreased to £8.6 million (H1 2019: £13.6 million) which was mainly due to a reduction in the number of dedicated NIOX[®] sales representatives in the US.

Foreign exchange losses

Foreign exchange losses increased to £0.6 million (H1 2019: £0.1 million) as a result of the strengthening of sterling against the dollar.

R&D tax credits

The tax credit on qualifying expenditure for the period was £nil (H1 2019: £0.4 million). The decrease since the previous year reflects the cessation of qualifying R&D expenditure.

	Six months ended 30 June 2020 £m	Six months ended 30 June 2019 ¹ £m	12 months ended 31 December 2019 ¹ £m
Revenue	11.4	18.6	34.6
Cost of sales	(3.6)	(4.8)	(9.1)
Gross profit	7.8	13.8	25.5
Gross margin	68%	74%	74%
Research and development	(2.9)	(3.2)	(6.9)
Sales and marketing	(8.6)	(13.6)	(24.6)
Administrative expenses	(5.0)	(5.1)	(12.5)
Non-underlying expenditure	–	–	(45.3)
EBITDA	(6.2)	(6.0)	(15.3)
Operating loss	(8.7)	(8.1)	(63.8)
Net foreign exchange loss	(0.6)	(0.1)	(3.5)
Net finance costs	(0.1)	–	(0.1)
Non-underlying gains	–	–	39.8
Loss before tax	(9.4)	(8.2)	(27.6)
Taxation	–	0.4	10.8
Loss for the financial period from continuing operations	(9.4)	(7.8)	(16.8)
Loss for the financial period from discontinued operations	(8.6)	(21.2)	(31.5)
Loss for the financial period	(18.0)	(29.0)	(48.3)
Cash²	9.6	21.0	27.0

¹ Restated to show the results of the COPD business as discontinued.

² Includes cash and cash equivalents.

Financial review, continued

Loss after tax and loss per share

Basic loss per share for the period was 5p (H1 2019: 8p) reflecting a loss for the financial period of £18.0 million (H1 2019: £29.0 million). The loss per share for continuing operations of 3p (H1 2019: 2p) reflecting a loss for the financial period of £9.4 million (H1 2019: £7.8 million).

Loss from discontinued operations

Loss from discontinued operations decreased to £8.6 million (H1 2019: £21.2 million). This is mainly due to the AstraZeneca loan being written off when the Tudorza[®] and Duaklir[®] licences were handed back to AstraZeneca, offset by the associated impairment charge of the licence assets.

	Six months ended 30 June 2020 £m	Six months ended 30 June 2019 £m
Underlying trading loss	(17.7)	(21.2)
Loan write-off	123.1	–
Intangible asset impairment	(114.0)	–
Loss from discontinued operations	(8.6)	(21.2)

Statement of financial position

The Group's net assets at 30 June 2020 were £73.9 million (31 December 2019: £84.8 million).

Current liabilities at the end of the period were £37.7 million (31 December 2019: £41.3 million). The decrease is mainly due to lower trade payables as a result of lower operating expenditure. A VAT related balance of £11.3 million is included in both current assets and current liabilities; the amounts were received and paid in August.

Cash flow

The Group's cash position (including cash, cash equivalents and short-term deposits) decreased from £27.0 million at 31 December 2019 to £9.6 million at 30 June 2020.

This net cash outflow of £17.4 million for the six months ended 30 June 2020 includes a number of payments which will not be repeated in the second half of the year, namely £8.9 million of payments for Tudorza[®] and Duaklir[®] inventory; £4.6 million in respect of the salary, commission and severance paid to the COPD field force; £1.0 million in respect of 2019 contractual bonuses to current and former employees; and £0.3 million in professional fees related to the Tudorza[®] and Duaklir[®] transaction. Net of these items, the cash outflow for the period was £2.6 million.

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 gain for the period was £2.5 million (H1 2019: £0.1 million loss). The increase compared with H1 2019 was due to fluctuations in exchange rates, in particular against the dollar.

Cost Base

Management has focused on right sizing the cost base of the NIOX[®] business during the course of the year. The principal cost reduction initiative presently still in progress is in China, where we are transitioning from a direct sales model to a hybrid model, with a majority of the business being conducted through distributors. This should have the effect of reducing the fixed cost run rate in China from in excess of £6 million p.a. at the beginning of 2020 to less than £2.5 million a year by the beginning of 2021.

With revenues still significantly affected by the COVID-19 pandemic, management continues to keep a tight rein on costs in order to strike the appropriate balance between keeping operating losses to a minimum and retaining a sufficiently robust sales and marketing infrastructure to take full advantage of the upturn in revenues expected in the medium term.

Michael Roller
Chief Financial Officer

Principal risks and uncertainties

Circassia has considered the principal risks and uncertainties facing the Group for the first six months of 2020 and does not consider them to have changed from those set out on pages 34 to 43 of the 2019 Annual report and accounts. Although an agreement has been concluded to hand back the Tudorza[®] and Duaklir[®] products to AstraZeneca, it has during the period continued to sell these products under the transitional arrangement associated with the hand back. A summary of these risks is as follows:

Commercial success

The Group's competitors – some 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 sold by and 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. 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 those patents which it owns or licenses. 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. 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. Moving forward it anticipates that it should become profit making once the Tudorza[®] and Duaklir[®] licences are transferred back to AstraZeneca and the effects of COVID-19 on the short term trading of the NIOX[®] business have ceased.

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

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.

COVID-19

The ongoing COVID-19 pandemic represents an ongoing risk to the business. While hitherto there has been no impact on the business' ability to serve its customers, there can be no certainty as to how the pandemic may develop in the countries in which the Company operates, or what restrictions governments may put in place.

Condensed interim consolidated statement of comprehensive income for the six months ended 30 June 2020

Notes	Six months ended 30 June 2020 Unaudited £m	Six months ended 30 June 2019 Unaudited Restated ¹ £m	12 months ended 31 December 2019 Audited Restated ¹ £m
Continuing operations			
Revenue	11.4	18.6	34.6
Cost of sales	(3.6)	(4.8)	(9.1)
Gross profit	7.8	13.8	25.5
Research and development	(2.9)	(3.2)	(6.9)
Sales and marketing	(8.6)	(13.6)	(24.6)
Administrative expenses	(5.0)	(5.1)	(12.5)
Non-underlying expenses	–	–	(45.3)
Operating loss	(8.7)	(8.1)	(63.8)
Net foreign exchange loss	(0.6)	(0.1)	(3.5)
Finance costs	(0.2)	(0.1)	(0.3)
Finance income	0.1	0.1	0.2
Non-underlying gains	–	–	39.8
Loss before tax	(9.4)	(8.2)	(27.6)
Taxation	–	0.4	10.8
Loss for the financial period from continuing operations	(9.4)	(7.8)	(16.8)
Discontinued operations			
Loss for the period from discontinued operations attributable to owners of the parent	4 (8.6)	(21.2)	(31.5)
Loss for the period attributable to owners of the parent	(18.0)	(29.0)	(48.3)
Other comprehensive expense			
Items that may be subsequently reclassified to profit or loss			
Currency translation differences	6.2	(2.6)	(1.6)
Total other comprehensive expense for the period	6.2	(2.6)	(1.6)
Total comprehensive expense for the period	(11.8)	(31.6)	(49.9)

¹ Restated to show the results of the COPD operating segment as discontinued.

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

		£	£	£
Basic and diluted loss per share				
Loss per share from continuing operations	7	(0.03)	(0.02)	(0.04)
Total loss per share	7	(0.05)	(0.08)	(0.13)

The notes on pages 15 to 20 are an integral part of these condensed interim consolidated financial statements.

Condensed interim consolidated statement of financial position as at 30 June 2020

	Notes	30 June 2020 Unaudited £m	30 June 2019 Unaudited £m	31 December 2019 Audited £m
Assets				
Non-current assets				
Property, plant & equipment		0.2	0.7	0.5
Right-of-use assets		1.7	2.3	1.9
Goodwill		5.2	9.1	4.8
Intangible assets		46.7	241.2	163.0
Deferred tax assets	5	28.3	19.1	28.3
		82.1	272.4	198.5
Current assets				
Inventories		7.1	6.0	6.5
Trade and other receivables		23.2	12.6	14.6
Current tax assets	5	0.2	4.4	0.2
Cash and cash equivalents		9.6	21.0	27.0
		40.1	44.0	48.3
Total assets		122.2	316.4	246.8
Equity and liabilities				
Share capital		0.3	0.3	0.3
Share premium		630.6	630.4	630.4
Other reserves		21.6	13.7	14.7
Accumulated losses		(578.6)	(541.2)	(560.6)
Total equity		73.9	103.2	84.8
Liabilities				
Non-current liabilities				
Borrowings		–	19.7	109.9
Lease liabilities		1.3	1.8	1.5
Deferred tax liabilities	5	9.3	10.9	9.3
Contingent consideration		–	71.3	–
		10.6	103.7	120.7
Current liabilities				
Trade and other payables	6	36.6	28.3	39.6
Non-contingent consideration		–	78.7	–
Lease liabilities		0.6	0.8	0.6
Contingent consideration		0.5	1.7	1.1
		37.7	109.5	41.3
Total liabilities		48.3	213.2	162.0
Net current assets/(liabilities)		2.4	(65.5)	7.0
Total equity and liabilities		122.2	316.4	246.8

The notes on pages 15 to 20 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 2020

	Notes	Six months ended 30 June 2020 Unaudited £m	Six months ended 30 June 2019 Unaudited £m	12 months ended 31 December 2019 Audited £m
Cash flows from operating activities				
Cash generated from operations	8	(19.3)	(18.0)	(28.9)
Interest paid		(0.1)	(0.1)	(0.1)
Tax credit received		–	–	3.9
Net cash used in operating activities		(19.4)	(18.1)	(25.1)
Cash flows from investing activities				
Interest received		0.1	0.1	0.3
Joint venture distributions to owners		–	0.1	0.1
Purchase of intangible assets		(0.3)	(9.0)	(10.0)
Purchase of property, plant and equipment		–	(0.2)	(0.3)
Net cash used in from investing activities		(0.2)	(9.0)	(9.9)
Cash flows from financing activities				
Proceeds from issues of shares		0.2	8.0	8.0
Costs offset against share premium		–	(0.1)	(0.1)
Proceeds from borrowings		–	–	14.9
Principal elements of lease payments		(0.5)	(0.4)	(0.9)
Net cash (used in)/generated from financing activities		(0.3)	7.5	21.9
Net decrease in cash and cash equivalents		(19.9)	(19.6)	(13.1)
Cash and cash equivalents at 1 January		27.0	40.7	40.7
Exchange gain/(loss) on cash and cash equivalents		2.5	(0.1)	(0.6)
Cash and cash equivalents at 30 June		9.6	21.0	27.0

The notes on pages 15 to 20 are an integral part of these condensed interim consolidated financial statements.

Notes to the condensed interim consolidated financial statements

1. General information

Circassia Group plc is a public limited company which is listed on the Alternative Investment 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 17 September 2020.

The condensed consolidated interim financial statements have not been audited or reviewed. 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 2019 were approved by the Board of Directors on 16 June 2020 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.

Basis of preparation

This condensed consolidated interim financial report for the period ended 30 June 2020 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 2019 and any public announcements made by Circassia Group plc during the interim reporting period.

Going concern

In assessing the appropriateness of the going concern assumption, the Board has considered the availability of funding alongside the possible cash requirements of the Group and Company, taking into account the unprecedented circumstances caused by COVID-19. After due consideration, the directors have concluded that there is a reasonable expectation that the Group has adequate resources to continue in operational existence for at least 12 months from the date of this report.

Accounting policies

The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period.

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 2019.

Financial instruments

The Group's financial instruments comprise cash and cash equivalents, 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.

Notes to the condensed interim consolidated financial statements, continued

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 2019. 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 British pound sterling, United States dollar, Swedish krona, euro and Chinese yuan. Foreign exchange risk arises from future commercial transactions and recognised assets and liabilities. 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 is the Executive Chairman, (previously the Chief Executive Officer) who 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
- COPD (2019: USAZ collaboration) relates to the Tudorza[®] and Duaklir[®] Pressair[®] products marketed in the United States, where they are indicated for the maintenance treatment of patients with COPD.

The COPD business was handed back to AstraZeneca on 27 May 2020. Information about this discontinued segment is provided in note 4.

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

The table below presents information regarding the Group's operating segments for the six months ended 30 June 2020 and 2019.

	NIOX [®] £m	Head office costs £m	Total £m
Six months ended 30 June 2020			
Revenue	11.4	—	11.4
Operating loss	(7.4)	(1.3)	(8.7)
Six months ended 30 June 2019			
Restated ¹			
Revenue	18.6	—	18.6
Operating loss	(6.5)	(1.6)	(8.1)
12 months ended 31 December 2019			
Restated ¹			
Revenue	34.6	—	34.6
Operating loss	(14.3)	(4.2)	(18.5)

¹ Restated to show the results of the COPD operating segment 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. Discontinued operations

On 27 May 2020, Circassia signed an agreement to hand back the Tudorza[®] and Duaklir[®] licences to AstraZeneca and as such, the results of the COPD operating segment are reported as a discontinued operation.

Financial information relating to the discontinued operation is set out below:

Loss for the period

	Six months ended 30 June 2020	Six months ended 30 June 2019	12 months ended 31 December 2019 Restated ¹
	£m	£m	£m
Revenue	11.6	9.3	27.8
Cost of sales	(1.2)	(2.8)	(7.1)
Gross profit	10.4	6.5	20.7
Expenditure	(16.6)	(17.7)	(45.2)
Goodwill and intangible asset impairment	(114.0)	–	(46.2)
Operating loss	(120.2)	(11.2)	(70.7)
Other gains and (losses) – net	114.8	(1.1)	57.7
Finance costs	(3.2)	(8.9)	(18.5)
Loss from discontinued operations	(8.6)	(21.2)	(31.5)
Net cash outflow from ordinary activities	(6.1)	(0.5)	(25.8)
Net cash inflow from financing activities	–	–	14.9
Net cash used in discontinued operations	(6.1)	(0.5)	(10.9)

¹ Restated to show the results of the COPD operating segment as discontinued

Other gains and losses include a £123.1 million gain (30 June 2019: nil) relating to the write off of the AstraZeneca loan and accrued interest, and £8.3 million (30 June 2019: £1.1 million) loss on foreign exchange.

Finance costs include £3.0 million (30 June 2019: £0.1 million) of interest charged on the loan from AstraZeneca, and £0.2 million (30 June 2019: £8.9 million) relating to the unwinding of discounts on amounts payable to AstraZeneca.

Notes to the condensed interim consolidated financial statements, continued

5. Taxation

R&D tax credit

The current tax asset relates to an R&D tax credit of £0.2 million relating to qualifying expenditure incurred in the year ended 31 December 2019. 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 31 December 2019	9.3	(28.3)	(19.0)
At 30 June 2019	10.9	(19.1)	(8.2)
At 30 June 2020	9.3	(28.3)	(19.0)

	30 June 2020 £m	30 June 2019 £m	31 December 2019 £m
Deferred tax liabilities	9.3	10.9	9.3
Deferred tax assets	(28.3)	(19.1)	(28.3)
Total deferred tax position	(19.0)	(8.2)	(19.0)

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

	30 June 2020 £m	30 June 2019 £m	31 December 2019 £m
Losses	64.4	63.9	61.0
Total unrecognised deferred tax asset	64.4	63.9	61.0

6. Trade and other payables

	30 June 2020 £m	30 June 2019 £m	31 December 2019 £m
Trade payables	6.3	22.1	9.1
Social security and other taxes	0.6	0.4	0.3
Accruals	18.2	5.6	29.3
Other payables	11.5	0.2	0.9
Total trade and other payables	36.6	28.3	39.6

7. 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 2020 and 2019, the dilutive potential shares are non-dilutive and therefore excluded from the earnings per share calculation.

Six months ended 30 June 2020	Continuing operations	Discontinued operations	Total
Loss attributable to ordinary equity owners of the parent company (£m)	(10.0)	(8.0)	(18.0)
Weighted average number of ordinary shares in issue (Number)	348,722,920	348,722,920	348,722,920
Loss per share	(0.03)	(0.02)	(0.05)

Six months ended 30 June 2019	Continuing operations Restated ¹	Discontinued operations Restated ¹	Total
Loss attributable to ordinary equity owners of the parent company (£m)	(7.8)	(21.2)	(29.0)
Weighted average number of ordinary shares in issue (Number)	372,212,140	372,212,140	372,212,140
Loss per share	(0.02)	(0.06)	(0.08)

12 months ended 31 December 2019	Continuing operations Restated ¹	Discontinued operations Restated ¹	Total
Loss attributable to ordinary equity owners of the parent company (£m)	(16.8)	(31.5)	(48.3)
Weighted average number of ordinary shares in issue (Number)	373,703,488	373,703,488	373,703,488
Loss per share	(0.04)	(0.08)	(0.13)

¹ Restated to show the results of the COPD operating segment as discontinued

Notes to the condensed interim consolidated financial statements, continued

8. Cash used in operations

Reconciliation of loss before tax to net cash used in operations

	Six months ended 30 June 2020	Six months ended 30 June 2019	12 months ended 31 December 2019 Restated ¹
	£m	£m	£m
Loss from continuing operations before tax	(9.4)	(8.2)	(27.6)
Loss from discontinued operation before tax	(8.6)	(21.2)	(31.5)
Loss before tax	(18.0)	(29.4)	(59.1)
Adjustment for:			
Finance income	(0.1)	(0.1)	(0.2)
Finance costs	3.3	9.0	18.8
Depreciation	0.6	0.1	0.8
Amortisation	5.7	6.8	14.4
Impairment of goodwill	–	–	4.1
Impairment of intangible assets	114.0	–	86.1
Write-off of loan and accrued interest	(123.1)	–	–
Share based payment charge	0.7	1.2	1.4
Fair value gain on contingent consideration	–	–	(93.4)
Foreign exchange on non-operating items	7.6	1.1	(0.5)
Changes in working capital:			
Increase in trade and other receivables	(6.7)	(4.5)	(7.1)
Increase in inventories	–	(2.2)	(2.7)
(Decrease)/increase in trade and other payables	(3.3)	–	8.5
Net cash used in operations	(19.3)	(18.0)	(28.9)

¹ Restated to show the results of the COPD operating segment as discontinued

9. Related party transactions

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

10. Events occurring after the reporting date

On 2 June 2020, Circassia entered into an equity finance facility with two of its major shareholders. Under the terms of the facility, the shareholders committed to subscribe for up to a total of £5 million of new ordinary shares in Circassia if a request is made by the company before 30 November 2020.

On 17 September 2020, Circassia requested to draw down the total facility value of £5 million. It is anticipated that the funds will be received around 22 September 2020.

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 Group plc are listed on page 40.

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

Ian Johnson
Executive Chairman

Michael Roller
Chief Financial Officer

17 September 2020

Shareholder information

Indicative financial calendar

Preliminary results for the 12 months ending 31 December 2020: H1 2021

Annual General Meeting: H1 2021

Registrars

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

Shareview Portfolio

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

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

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Lines are open 8:30am to 5:30pm

Monday to Friday.

Directors

Ian Johnson

(Executive Chairman)

Michael Roller

(Chief Financial Officer)

Jonathan Emms

(Chief Operating Officer)

Garry Watts (Senior Independent Non-Executive Director)

Jo LeCouilliard

(Independent Non-Executive Director)

Sharon Curran

(Independent Non-Executive Director)

Forward-looking statements

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