CIRCASSIA

Circassia Pharmaceuticals plc

Interim report and accounts 2016

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About Circassia

Circassia is a specialty biopharmaceutical business with established commercial infrastructure, marketed products, a pipeline of near-term therapies and portfolio of particle-engineered treatments targeting major market opportunities. Circassia sells its novel, market-leading NIOX® asthma management products directly to specialists in the United States and Germany. Its products are also promoted in a number of other countries by the Company's network of partners.

Circassia's broad-based development pipeline includes a range of respiratory medicines. The Company's lead asthma treatment, Fliveo®, targets substitution of GSK's Flixotide® pMDI and is approved in the UK and Sweden. Circassia is also developing a direct substitute for Seretide® pMDI, Seriveo®. In addition, the Company's pipeline includes a number of inhaled medicines for chronic obstructive pulmonary disease, including single and combination dose products. For more information on Circassia please visit www.circassia.com.

CIRCASSIA

Introduction from the Chief Executive

While the first half of 2016 was dominated by June's unexpected and disappointing phase III cat allergy results, we have made good progress in our wider business and are capitalising on a number of strategic opportunities. During the last three months we have taken a prudent approach to our allergy investment and rationalised our cost base. We have also focused on strengthening our existing business and taking initial steps to broaden our pipeline. As a result, we have completed early work on a number of new product opportunities giving us additional pipeline options while we await the results of our house dust mite allergy field study that will inform our wider portfolio strategy. We have also initiated negotiations for the return of EU rights to Fliveo®, our recently approved Flixotide® pMDI substitute, and significantly expanded our direct sales presence to boost our NIOX® revenues and establish ourselves as an attractive commercialisation partner.

Our ambition to build a world-class specialty biopharmaceutical business remains undimmed and we believe the combination of our marketed products, broad pipeline and robust commercial platform gives us the foundation we need to achieve this goal.

Steve Harris
Chief Executive

Operational and financial highlights

NIOX® performing strongly

- Sales increased 21% (14% at CER[1]) to £11.1 million (H1 2015 CER: £9.7 million – £0.6 million under Circassia ownership and £9.1 million under previous ownership)
- Direct clinical sales (ie non-research[2]) increased 35% (26% CER) compared with H1 2015
- Study to extend US label down to four year olds on track to report H2 2016

Respiratory portfolio progressing

- Seriveo® (Seretide® pMDI substitute) filing on track for H2 2017
- Triple combination study shows no significant safety concerns; all three components bioavailable

Prudent approach to allergy portfolio

- No major confounding factors identified in cat allergy phase III dataset
- Allergy investment curtailed following cat allergy phase III results
- Portfolio review to follow results from house dust mite allergy study (n=715) anticipated Spring 2017

Commercial platform expanded as strategic asset for product in-licensing, partnering & acquisition

- Global commercial group expanded to 200
- US sales force increased to approximately 100; managed markets and key accounts teams in place
- Commercial presence strengthened in Germany and China
- UK direct sales force recruitment underway

Portfolio strengthened

- Negotiations initiated with partner for EU rights to Fliveo® (Flixotide® pMDI substitute)
- Particle-engineered Spiriva® DPI substitute progressed into development
- Two new product opportunities initiated leveraging respiratory expertise
- Non-specialty, non-substitutable products to be partnered (including triple combination)
- R&D reorganised; allergy team and R&D facilities rationalised; device group strengthened
- Evaluation of further specialty product opportunities underway

Financial highlights

- Revenues increased to £11.1 million (H1 2015: £0.6 million)
- R&D expenditure £25.1 million (H1 2015: £18.4 million) including £13.8 million on allergy
- Underlying loss for period £25.4 million (H1 2015: £21.7 million)
- Provisions against and impairment of allergy portfolio[3] £76.4 million
- Strong balance sheet with £138.0 million cash[4] at 30 June 2016; one-off payments of £33.2 million relating to 2015 acquisitions paid H1 2016 (cash[4] at 31 December 2015: £203.8 million)

[1] Constant exchange rates (see note 3 in the Notes to the condensed interim consolidated financial statements)

[2] Direct clinical sales include those to clinicians, hospitals and distributors; research sales include those to pharmaceutical companies for use in clinical studies

[3] Includes impairment of goodwill (£74.5 million), other intangible assets (£0.3 million) and provision for termination of certain contracts (£1.6 million)

[4] Cash, cash equivalents and short-term deposits

Operating and strategy review

This year has been a period of both challenges and new opportunities for Circassia. We have substantially increased revenues from our market-leading asthma management products, advanced our respiratory portfolio and expanded our commercial presence. However, we also received disappointing results from our cat allergy phase III study. The subsequent review by both internal and external experts shows the study was well conducted and the design robust, but despite a dramatic decrease in subjects' symptoms and rescue medication use in the active treatment groups the placebo response was extremely high. In light of these unexpected results we acted quickly to rationalise our R&D costs, and we now await results from our house dust mite allergy field study, due in Spring 2017, to finalise the approach to our allergy portfolio.

Following receipt of the phase III results we have reviewed our wider strategy to ensure we deploy our resources effectively to build shareholder value. As a result of this review the Board has concluded that our specialty product focus and direct sales model continue to provide significant opportunities. By expanding our commercial infrastructure we have the opportunity to create an attractive platform to commercialise our own and third-party specialty products. By leveraging our in-house technology we have the opportunity to broaden our pipeline and balance our risk profile. Importantly, by committing only modest investment for early-stage new product development in the short-term we can conserve resources, position our pipeline for expansion and retain the opportunity to revisit our portfolio strategy if we receive compelling house dust mite allergy results in Spring next year.

In recent weeks we have advanced each area of this approach. We have continued to grow our commercial infrastructure and have initiated our pipeline expansion plans. We have initiated discussions for the return of EU commercialisation rights to our lead asthma therapy and have advanced early development work for three new chronic obstructive pulmonary disease products. We remain committed to our goal of building a world-class, self-sustaining specialty biopharmaceutical business and with a strong commercial platform and growing specialty portfolio we are continuing to make progress towards achieving our objective.

NIOX® franchise progress

Strong sales growth

Clinicians in over 40 countries use our NIOX® products to improve asthma diagnosis and management by accurately monitoring patients' fractional exhaled nitric oxide (FeNO). NIOX® is the only point-of-care FeNO device available across all major markets and our current generation VERO® model is now launched in many key territories, including the US, Europe, Japan and China. During H1 2016 NIOX® sales continued to grow strongly, with revenues increasing 21% to £11.1 million (14% at constant exchange rates [CER]) compared with the same period the previous year (H1 2015 CER: £9.7 million – £0.6 million under Circassia ownership and £9.1 million under previous ownership).

Importantly, NIOX® direct clinical sales increased 35% compared with the year before (26% CER) reflecting strong growth in the underlying business. In contrast, revenues from more unpredictable pharmaceutical company use decreased during the period by 12% (17% CER).

During 2016 we developed a number of initiatives to introduce potential customers to NIOX® and convert those using the previous MINO® generation to VERO®. In particular, we rolled out 'experience programmes' that give clinicians the opportunity to use the product in their clinical practise and in the US we have placed over 80% more devices in the year to date than in the whole of last year. This has helped drive VERO® uptake and with the US market now converted to the new device we will continue to expand placement of experience programmes in the coming months.

Registration extension studies on track

During the first half of 2016 we initiated two clinical studies to support label extensions for NIOX VERO®. The first is designed to demonstrate the accuracy of the device in children aged four to six years old using both six- and 10-second test functions. This use is already included in our European registration and we plan to use the study to seek a label extension in the US. Recruitment for the trial is well underway and the study is on track to report in H2 2016 with a subsequent filing planned for H1 2017.

The second study aims to demonstrate the utility of NIOX VERO® in diagnosing primary ciliary dyskinesia (PCD). People with PCD have unusually low levels of nasal nitric oxide and we have adapted the VERO® to measure this exhaled gas. PCD affects roughly 50,000 people in the EU and currently diagnosis can be complex, involving genetic testing or ciliary biopsy. Our clinical study aims to identify diagnostic levels of exhaled nitric oxide for PCD and recruitment is nearing completion. The study results are expected in H2 2016 and we anticipate adding this expanded usage to our European registration in 2017.

Next generation product

With NIOX VERO® increasingly established in key markets, we have initiated concept development for a further generation device to ensure we retain our dominant position in the FeNO field. The new device has the opportunity to leverage ongoing developments in wireless connectivity and further improve the clinician and patient experience.

Respiratory portfolio advancing

Seriveo® (Seretide® pMDI substitute) on track

Our fluticasone / salmeterol combination asthma therapy Seriveo® targets direct substitution of GSK's Seretide® pMDI. This wholly-owned product has a major market opportunity with originator sales in pMDI format accounting for approximately $1.5 billion worldwide in 2015.

In Q1 2016 the treatment completed an initial clinical pharmacokinetic study. Based on the results we have optimised two formulations of the product and both have performed as hoped in in vitro studies. We have now initiated clinical testing of the formulations, and based on the results we aim to move the best performing into a final pharmacokinetic study. We remain on track to file an initial Marketing Authorisation Application for the product in H2 2017.

Triple fixed dose combination study complete

Our fixed dose combination treatment for moderate-to-severe chronic obstructive pulmonary disease (COPD) contains an inhaled corticosteroid (ICS), long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA). Currently, COPD patients require multiple devices to receive these medications and consequently 'triple' products have significant market potential with sales of nearly $8 billion predicted for 2025.

In H2 2015 we progressed our particle-engineered triple combination into a first-in-human clinical study (n=38). The crossover study assessed the safety and pharmacokinetics of single, double and triple combination formulations. In a limited number of subjects the study also compared the formulations' LABA component with the marketed LABA Serevent®.

The results show there were no significant safety or tolerability concerns and no serious adverse events. The data also show each of the product components were bioavailable following inhalation. For those formulations that were compared to the marketed product, including the triple combination, the overall relative bioavailability of the LABA component was similar to Serevent®. Although the study did not compare the relative bioavailability of the other components with marketed products, the triple combination formulation showed increased ICS relative bioavailability compared with the single corticosteroid formulation. As a result, the study provides an important clinical foundation to inform future development plans.

Prudent allergy approach

Phase III data mirror top-line results

Following the announcement of our cat allergy phase III results in June we have now completed an extensive analysis of the full dataset and reviewed the outcome with international experts. The full results are similar to the top-line data with a powerful placebo response eliminating the ability to meet the primary, secondary and exploratory endpoints. This was also the case for a large number of sub-populations, including countries, baseline symptom levels, number of allergies, year of enrolment and a range of demographic characteristics. When pooled by geographical region the data showed a trend towards a treatment effect in European subjects who received two courses of immunotherapy, but this was not statistically significant and did not meet regulators' requirements. The analysis also confirmed subjects received the correct treatment or placebo. Consequently, the review concluded the study's design and conduct were robust and no significant confounding factors were identified.

Broader allergy investment curtailed

Following receipt of the phase III results we halted significant investments in the allergy portfolio and have stopped development activities in our grass and ragweed allergy programmes. Our large-scale house dust mite field study has enrolled over 700 subjects and is well advanced requiring only limited further expenditure. Consequently, the study will continue to completion in Spring 2017, when we will have the opportunity to reassess our wider portfolio strategy if this large-scale phase IIb study delivers compelling results.

Birch allergy phase IIa study complete

We recently received results from our birch allergy phase IIa study (n=64). The data show the treatment was well tolerated with a favourable safety profile. While the study was primarily focused on safety it also included a number of efficacy and pharmacodynamic measures. Overall, the results show improvements compared to placebo in both skin responses and the amount of allergen required to trigger ocular symptoms when subjects were challenged with birch pollen. During natural exposure subjects' symptoms did not improve significantly but the season's pollen levels were modest. While the data from this early-stage, small-scale study are encouraging overall, we will continue to pursue the allergy investment approach outlined above while we await the outcome of our large house dust mite allergy field study.

Commercial infrastructure established as growth platform

Commercial team expansion

During the last six months we have significantly strengthened our commercial capabilities, particularly in the key US market. We have doubled our US NIOX® sales territories to approximately 100 and capitalised on recent retrenchment in 'big pharma' respiratory teams to complete the recruitment and training of our expanded sales force. In addition, we have strengthened our medical affairs, managed markets and key accounts teams and our US field-based resources now total approximately 140.

With limited competition currently, and no competitors in the US, our NIOX® products have a major commercial opportunity. The US specialist segment alone is estimated at $190 million and we have captured only a modest portion of this market to date. With our enlarged sales forces now targeting a substantially greater proportion of specialists across the United States we plan to significantly increase uptake of our novel products and accelerate revenue growth.

Expanding geographical presence

As well as growing our capabilities in the US we have begun the process of boosting our commercial presence in a number of other key territories. In the EU's largest market, Germany, we have appointed a new Commercial Director, while in the UK, France and Italy we have terminated our distributor agreements. We are currently building a direct sales team in the UK with a new Commercial Director now in place and we are evaluating the optimal approach to establish our presence in France and Italy. In parallel, we have strengthened our presence in China where NIOX® sales have grown significantly during 2016. Our Beijing-based team manages a network of distributors and we have recently added market access and medical support to help local partners increase revenues in this significant market.

Building partner-of-choice platform

As a result of our major investment our global commercial team now totals approximately 200. With a growing presence in the US, Germany, UK and China, and plans to expand into further key countries, we are rapidly becoming an attractive commercialisation partner offering expertise that is rare in the specialty market. With our NIOX® franchise supporting our infrastructure expansion we intend to capitalise on the opportunity to complement our in-house portfolio through partnering, in-licensing or acquisition.

Portfolio expansion underway

With our allergy investment curtailed following June's disappointing phase III results we have accelerated plans to broaden and balance our portfolio and during the last three months we have made good progress.

Negotiations for return of EU rights to Fliveo® (Flixotide® pMDI substitute) initiated

Fliveo®, our particle-engineered product targeting substitution of GlaxoSmithKline's Flixotide® pMDI, was recently approved in the UK and Sweden. Under previous ownership the product was out-licensed in key territories and we have now initiated negotiations for the return of the rights in the EU. While the United States is the main market for the product, these smaller territories represent an important commercial opportunity for Circassia.

Development initiated for Spiriva® DPI substitute

We have completed early technical work on a particle-engineered formulation of tiotropium bromide targeting direct substitution of Spiriva® DPI. Spiriva® is approved for use in the treatment of COPD and currently generates revenues of $3.9 billion. Following this initial success we have now progressed the product into development and intend to pursue an abbreviated regulatory route. As a result, we anticipate initiating a pharmacokinetic clinical study next year.

Operating and strategy review continued

Out-licensing non-specialty non-substitutable products
With our strategy firmly focused on building a specialty product business, we plan to out-license primary care treatments if they are not potential direct substitutes for marketed originators. This will allow us to concentrate our resources on products we can sell to specialists and direct substitutes we can commercialise using our existing infrastructure without significant promotion. Consequently, we will not undertake further in-house development of our triple fixed dose combination treatment for COPD and will seek to partner the programme. Similarly we plan to out-license our glycopyrronium bromide COPD therapy, which is already partnered in China, Taiwan, Hong Kong and Macau.

Early work initiated on two new respiratory products
As part of the strategy to broaden our portfolio we are leveraging our respiratory expertise to deliver additional in-house development programmes. We are undertaking early development work on two novel formulations of currently approved drugs for an underserved segment of the specialist moderate-to-severe COPD market and we have successfully completed initial technical and market assessments for both.

- The first contains a LABA/LAMA fixed dose combination. Third-party research suggests the product targets a patient population of up to 350,000 in the US and EU5 with a potential peak sales opportunity of up to $700 million.
- The second targets reductions in COPD exacerbations. The US/EU5 target patient population totals up to 200,000 and market research indicates the product has a potential peak sales opportunity of up to $250 million.

R&D refocused
Since the receipt of our cat allergy phase III results in June we have refocused our R&D organisation to reflect the halting of clinical activities in our grass and ragweed allergy programmes and our focus on a broader portfolio.

- We acted rapidly to reduce the size of our R&D team cutting positions by approximately 25% through a mixture of natural wastage, halted recruitment and redundancy. Subsequently this reduction has allowed us to vacate a portion of our R&D facilities on the Oxford Science Park.
- We have refocused R&D capacity onto our respiratory programmes while maintaining the capability to advance our allergy portfolio if justified by compelling results from our ongoing large-scale house dust mite allergy study. We are also strengthening our device development capabilities and recently appointed a highly experienced head for our in-house team who previously held senior positions at Mundipharma and Pfizer as well as working on GSK's portfolio of inhaled respiratory products.
- We plan to further broaden our pipeline by leveraging our R&D, device and commercialisation capabilities. We are making good progress and are currently assessing a number of product and technology opportunities that fit our specialty product focus.

Summary and outlook

This year has seen both significant challenges and opportunities for Circassia. While our NIOX® products and respiratory portfolio have progressed, the first half of 2016 culminated in unexpected and disappointing phase III cat allergy results. Despite compelling data from previous studies and impressive improvements in allergy symptoms and rescue medication use an exceptional placebo effect eliminated the ability to meet the study endpoints. As a result we took rapid action to curtail investment in our allergy programmes, rationalise our cost base, strengthen our existing business and accelerate our strategy to build a broad and balanced portfolio.

In the last three months we have made significant progress across each of these areas. We have greatly expanded our commercial infrastructure, both to increase our NIOX® revenues and establish Circassia as a partner-of-choice for specialty product commercialisation. We have also continued to advance our in-house development programmes and have broadened our portfolio by leveraging our respiratory expertise to advance a potential substitute for Spiriva® and initiate early development work on two further new products.

In the coming months we plan to continue this progress. We hope to conclude our negotiations and regain EU rights to Fliveo®. The product is already approved in the UK and Sweden, and in parallel we plan to complete our regulatory and launch strategy, leveraging our growing commercialisation capabilities in Europe. We also intend to progress the development of Seriveo® our Seretide® pMDI substitute in preparation for an initial regulatory filing at the end of next year. We plan to complete the ongoing registration extension studies for our market-leading NIOX® products, advance the development of our Spiriva® DPI substitute and complete the evaluation of product and technology opportunities to further broaden our pipeline. In addition, we plan to accelerate NIOX® revenue growth as our expanded sales team becomes established in the market and our promotional initiatives come to fruition. We also intend to complete the large-scale house dust mite allergy field study and finalise our investment strategy for our allergy and broader portfolio.

Our ambition to build a world-class specialty biopharmaceutical business remains undimmed, and despite recent setbacks our strategy to achieve this remains in place. With an established franchise of market-leading products, strong commercial infrastructure and growing portfolio of development programmes we are well positioned to achieve our goal of building a successful company, serving patients around the world and creating significant value for our shareholders.

Financial review

The financial results for the six months to 30 June 2016 are dominated by two main factors that differentiate the first half of this year from the same period in 2015. The first is the impairment of goodwill that was allocated to the allergy franchise to reflect the future benefit of the acquired Aerocrine commercial infrastructure in the commercialisation of the Company's allergy portfolio. Following the disappointing results from the cat allergy phase III study, this goodwill has been fully impaired. The second factor is the full six months' contribution in H1 2016 from the NIOX® and Prosonix respiratory businesses compared with a limited contribution in H1 2015. Aerocrine and Prosonix were acquired on 18 June 2015 and 15 June 2015 respectively and the H1 2015 figures include sales and costs from these businesses from the date of acquisition only.

The financial results for the six months to 30 June 2016 are set out in the table on page 7.

Revenue

Sales of £11.1 million reflect a full six months' contribution from the NIOX® business that accounts for nearly all the Group's turnover for the period. These revenues include sales of NIOX VERO® and NIOX MINO® for use in the management of asthma by clinicians in the US, Europe and Asia Pacific, and for research use in pharmaceutical companies' clinical studies.

Included in total sales of £11.1 million are clinical sales of £8.8 million and research sales of £2.0 million and other revenues of £0.3 million, which include freight.

Gross profit

Gross profit on NIOX® sales was £7.5 million, with a gross margin of 68%. This reflects the continuous growth of NIOX® test kit sales across the globe with favourable pricing options to drive conversion from the earlier NIOX MINO® model to NIOX VERO® in the US.

Sales and marketing

During the period, sales and marketing expenditure was £13.1 million (H1 2015: £2.2 million). This reflects a significant strengthening of the Company's commercial presence in the US, both as a result of the acquisition of Aerocrine and subsequently. In particular, the US sales force increased substantially, and the managed markets, key accounts and medical affairs teams have also expanded in support of the Company's sales effort.

Goodwill arising on the acquisition of Aerocrine last year was allocated to Circassia to reflect the benefit provided by the acquired commercial infrastructure in the future commercialisation of the allergy franchise. The goodwill has now been fully impaired following the disappointing outcome of the cat allergy phase III study resulting in a charge of £74.5 million to sales and marketing expenses.

Research and development activities

Underlying investment in research and development activities increased to £23.2 million (H1 2015: £18.4 million). Of this, £13.8 million (H1 2015: £15.3 million) relates to Circassia's portfolio of allergy candidates, £3.2 million (H1 2015: £0.1 million) to the development of the respiratory portfolio and £2.3 million (H1 2015: £0.3 million) to the NIOX® franchise, of which £1.0 million relates to amortisation charge for acquired R&D technology. Costs not specific to R&D projects were £3.9 million (H1 2015: £2.7 million).

Following the results from the cat allergy phase III study, expenditure on the allergy portfolio has been halted except for the following activities:

- Limited costs that have already been committed.
- Completion of the house dust mite allergy field study (TH005).
- Expenditure required to maintain drug product and drug stability programmes.

Overall, investment in the allergy portfolio during the period was lower than the prior half year. The grass allergy programme moved into the final phase of clinical testing with the start of a registration field study (TG005). Consequently, costs for this programme were higher than for the same period in 2015. This increase was offset by decreases in expenditure on the cat, ragweed and house dust mite allergy programmes. Expenditure on these was lower this year because enrolment in clinical trials was completed in 2015. We anticipate remaining costs to the end of the year in respect of these activities will be considerably less than those incurred in H1 2016.

Investment in the respiratory portfolio mainly relates to the Seretide®/ Advair® pMDI substitute development programme and the triple fixed dose combination clinical study.

In addition, a charge of £1.9 million has been recorded as non-underlying expenditure. Of this, £1.6 million relates to an onerous contract provision for the manufacture of trial batches for the cat and grass allergy programmes and an impairment of £0.3 million for allergy licences and patents following the disappointing result of the cat allergy phase III study.

	Underlying operations £m	Non-underlying items[1] £m	Total Group 2016 £m	Total Group 2015 £m
Revenue	11.1	–	**11.1**	0.6
Gross profit	7.5	–	**7.5**	0.4
Sales and marketing costs	(13.1)	(74.5)	**(87.6)**	(2.2)
Research and development costs	(23.2)	(1.9)	**(25.1)**	(18.4)
Administrative expenditure	(9.5)	–	**(9.5)**	(7.2)
Other gains	–	–	**–**	1.1
Operating loss	(38.3)	(76.4)	**(114.7)**	(26.3)
Finance income – net	6.3	–	**6.3**	–
Share of profit of joint venture	0.8	–	**0.8**	0.3
Loss before tax	(31.2)	(76.4)	**(107.6)**	(26.0)
Taxation	5.8	–	**5.8**	4.3
Loss for the financial period	(25.4)	(76.4)	**(101.8)**	(21.7)
Cash[2]	138.0	–	**138.0**	238.9

[1] Includes impairment of goodwill (£74.5 million) and other intangible assets (£0.3 million), and onerous contract costs provision (£1.6 million).

[2] Includes cash and cash equivalents and short-term deposits.

Administrative expenditure

Underlying administrative expenses, which include overheads specific to corporate functions, centrally managed support functions and corporate costs, increased to £9.5 million (H1 2015: £7.2 million). The increase in H1 2016 reflects the full six months' operation of the two businesses acquired in June 2015.

Finance income – net

Net finance income increased to £6.3 million (H1 2015: £Nil). This includes a foreign exchange gain of £5.8 million (H1 2015: foreign exchange loss £0.8 million) that arose as a result of weakening sterling during the period. The gain was mainly made on US dollar and Swedish krona bank balances.

R&D tax credits on qualifying expenditure

Included within £5.8 million tax for the period is a tax credit of £5.7 million for the current period (H1 2015: £4.3 million) which is recoverable under current legislation relating to R&D expenditure. The increase over the previous year reflects greater R&D expenditure during H1 2016 and an increase in tax relief from 225% to 230% from 1 April 2015.

Loss after tax and loss per share

Basic loss per share for the period was 36p (H1 2015: 11p) reflecting a loss for the financial period of £101.8 million (H1 2015: £21.7 million). This includes impairment charges of £74.8 million. The loss per share for the underlying operations was 9p (H1 2015: 11p), which reflects the positive contribution of the NIOX® business.

Statement of financial position

The Group's net assets at 30 June 2016 were £312.7 million (31 December 2015: £409.7 million). The decrease mainly reflects impairment charges of £74.5 million and £0.3 million to goodwill and intangible assets respectively. Further detail can be found in notes 7 and 8. Other factors are commented on below.

The weakening of sterling against the US dollar and Swedish krona resulted in a credit of £7.6 million to Other Comprehensive Income and Expense due to the retranslation of the Group's overseas operations.

Current liabilities were £23.2 million (31 December 2015: £48.3 million). The decrease is mainly due to the payment in January 2016 of contingent consideration of £30.0 million for the purchase of Prosonix.

Current tax assets were £17.5 million (31 December 2015: £11.8 million), representing an R&D tax credit due from H M Revenue and Customs. Of the £17.5 million, £13.8 million relates to expenditure on allergy programmes and £3.7 million on the respiratory programmes. Receipt of last year's claim is anticipated before the end of the year pending review by HMRC.

Cash flow

The Group's cash position (including short-term deposits) decreased from £203.8 million at 31 December 2015 to £138.0 million at 30 June 2016. Main cash outflows were:

- £30.0 million deferred consideration paid to the former shareholders of Prosonix in January 2016 following receipt of UK marketing authorisation for its lead product in December 2015.
- £37.4 million cash used in operations (HY1 2015: £24.6 million) reflecting the full six months of operations of the two businesses acquired in June 2015 as well as R&D investment in the allergy programmes and the expansion of the US sales and marketing infrastructure.
- £3.2 million payment to acquire the remaining 2.1% of issued shares of Aerocrine AB under the Swedish formal 'squeeze out' procedure. Please see note 13 for further details of the transaction.

The exchange gain on cash and cash equivalents for the period was £5.4 million (H1 2015: exchange loss of £1.7 million).

Summary and outlook

Following the disappointing cat allergy phase III results in June 2016, Circassia moved quickly to minimise expenditure on the allergy portfolio with costs in H2 2016 expected to be considerably less than those incurred in H1 2016. In addition, the Company is expanding its commercial platform with an anticipated increase in investment in sales and marketing in H2 2016 of approximately 50% compared to H1 2016 to further strengthen this key strategic asset and to maximise the opportunity for NIOX® sales growth. The Company will also continue to invest in its broader respiratory portfolio, which includes a Seretide® pMDI substitute that is targeting an initial regulatory filing at the end of next year.

Principal risks and uncertainties

Management of risks is a key responsibility of the Board of Directors of the Company. The Board ensures that the risks taken by the Group are understood, and are appropriate in the light of the Group's strategy and objectives, and that internal controls are in place to effectively identify, assess, and manage important risks.

A risk register is updated periodically by those individuals in the business who manage risks on a day to day basis. This process is coordinated by the Chief Financial Officer. The register is reviewed by the Board of Directors and the Senior Management Team, with a particular emphasis on ensuring that the risk appetite of the Board is fully understood by the relevant employees. The register also sets out activities that are designed to mitigate the identified risks, and the Board and the Senior Management Team analyse these mitigation strategies and ensure that the approach taken is consistent with the nature and degree of risks which are considered acceptable by the Board.

Risk owners across the business are also responsible for reporting any significant issues to the Senior Management Team and for ensuring that other members of their teams are aware of the risk management process. The Senior Management Team will, in turn, update the Board on a timely basis where important developments occur. Within the R&D function, project team meetings take place at least once a month at which the progress and risks associated with each individual project are discussed. These discussions are then set out in detailed reports which are circulated to the Senior Management Team.

The risk management system is designed to manage risks, rather than eliminate them at the expense of achieving corporate objectives. Accordingly, it can only provide a reasonable and not an absolute assurance against material misstatement or loss.

Principal Risks

The main risks relevant to the Group have been identified below, together with an explanation of how they are managed and controlled. Some risks are common across the pharmaceutical industry, while others reflect the Group's specific strategy. The Board considers all of these risks relevant to any decision to invest in the Company.

Regulatory approvals

The Company may not obtain regulatory approval for its products. 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 Company expects.

The pharmaceutical and medical device industries are highly regulated. Regulatory authorities across the world enforce a range of laws and regulations which govern the testing, approval, manufacturing, labelling and marketing of pharmaceuticals and medical devices. Stringent standards are imposed which relate to the quality, safety and efficacy of these products. These requirements are a major determinant of whether it is commercially feasible to develop a drug substance or drug device combination or a medical device, given the time, expertise, and expense which must be invested. Moreover, approval in one territory offers no guarantee that regulatory approval will be obtained in any other territory.

In order to obtain regulatory approval for the products being developed by the Company, it will be necessary to successfully complete the required supporting clinical studies. Clinical studies are typically expensive, complex and time-consuming, and have uncertain outcomes. Conditions in which clinical studies are conducted differ, and results achieved in one set of conditions could be different from the results achieved in different conditions or with different subject populations. Regulatory authorities or institutional review boards may suspend or terminate clinical studies at any time if the subjects participating in such studies are being exposed to unacceptable health risks or may require additional studies to be performed. Difficulties or delays in the enrolment of subjects could result in significant delays in the completion of those studies and even in their abandonment.

This risk is demonstrated by the recent failure of the Company's trial of its cat allergy treatment to achieve its primary or secondary endpoints in a Phase III study. An analysis of the reasons for this failure – including the very substantial placebo effect – found no significant confounding factors and therefore these risks may be relevant to the Company's other allergy programs. These programmes may not successfully complete their own clinical studies and supporting studies; it may not be possible to successfully move to field studies from chamber studies; and problems may arise in validating the manufacturing process for the active pharmaceutical ingredients in the products.

The Company is also developing other drugs and drug device combinations which form part of its respiratory franchise and is seeking to expand the approved indications for its marketed NIOX devices, but these outcomes too are dependent upon the successful conclusion of clinical trials.

The Company relies on third party sub-contractors and service providers for the execution of most aspects of its development programmes. Failure of these third parties to provide services of a suitable quality within acceptable timeframes – for example due to technical reasons or bankruptcy of the provider - may cause the failure or delay of these development programmes.

Even where approval is obtained, regulatory authorities may still impose significant restrictions on the indicated uses or marketing of the product or impose costly, ongoing requirements for post-marketing surveillance or post-approval studies.

Mitigating activities

The Group manages its regulatory risk by employing highly experienced clinical managers and regulatory affairs professionals who, where appropriate, will commission advice from external advisers and consult with the regulatory authorities on the design of the Group's pre-clinical and clinical programs. These in-house experts ensure that high quality protocols and other documentation are submitted during the regulatory process, and that well-reputed contract research organisations with global capabilities are retained to manage the trials. An experienced Medical Advisory Board also advises on the design of the clinical trials which the Company undertakes.

Principal risks and uncertainties continued

Unforeseen side effects

Unforeseen side effects may result from the use of the Company's marketed products or product under development.

There is a risk of adverse reactions with all drugs and drug device combinations. If any of the Company's products that are in trials are found to cause adverse reactions or unacceptable side effects, then product development may be delayed, additional expenses may be incurred if further studies are required, and, in extreme circumstances, it may prove necessary to suspend or terminate development. This may occur even after regulatory approval has been obtained, in which case additional trials may be required or the approval may be suspended or withdrawn or additional safety warnings may have to be included on the label.

There is also a risk that the Company's marketed devices might have to be withdrawn if some unforeseen problem affecting patient health or safety arises due to their use.

Adverse events or unforeseen side effects may also potentially lead to product liability claims being raised against the Company as the manufacturer and developer of marketed products and as the sponsor of clinical trials.

Mitigating activities

The Company conducts extensive pre-clinical and clinical trials which test for and identify adverse side effects associated with its pharmaceutical products. A robust pharmacovigilance plan administered by the in-house pharmacovigilance team is in place to ensure any safety issues that arise affecting the marketed devices, or the drugs and drug/device combinations which are in trials, are identified and reported. Insurance is in place to cover product liability claims that may arise during the conduct of clinical trials, or from the sale and use of NIOX® devices.

Commercial success

The Company's products may not be commercially successful.

The Company may not be able to sell its products profitably if reimbursement from third party payers such as private health insurers and government health authorities is restricted or not available because for example it proves difficult to build a strong enough economic case based on the burden of illness and population impact. Third party payers are increasingly attempting to curtail healthcare costs by challenging the prices that are charged for pharmaceutical products and denying or limiting coverage and the level of reimbursement. Moreover, even if the products can be sold profitably, they may not be accepted by patients and the medical community.

Alternatively, the Company'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 Company. New companies may enter these markets and novel products and technologies may become available that are more commercially successful than those being developed or sold by the Company.

The Group's NIOX MINO® and NIOX VERO® devices currently compete with products made by Bedfont Limited and Medisoft SA. Neither of these competing products are currently available in the US. Outside the US, Germany, and (recently) the UK, the Group relies on distributors to sell its NIOX® devices and such relationships must be carefully managed in order to ensure the services provided are of a sufficiently high quality.

The successful commercialisation of the Group's fluticasone propionate product in the US will, once approved and launched, be largely dependent upon its partner which has the exclusive rights to sell the product in that territory. Moreover, this product and certain other drug products being developed by the Group for treatment of asthma, such as its Seretide substitute, are generic products and so will compete with the innovator products as well as potentially with generics from other third parties.

Other factors that may undermine the Company's efforts to commercialise its products include: the inability to train and retain effective sales and marketing personnel; a failure to persuade prescribers to prescribe products; and higher costs of marketing and promotion than are anticipated by the Company.

Mitigating activities

The Company monitors competitor activity relevant to its marketed NIOX® devices and to its development programmes and ensures it has robust intellectual property protection that would prevent copying. With respect to NIOX®, the Company continues to support trials that would expand usage of the product, and is progressing concept development activities for a next-generation device. The sales force in the largest market (the US) has increased significantly since the acquisition of the NIOX® franchise in June 2015, and a dedicated in-house market access team has been formed and is developing strategies to maximise reimbursement.

Compliance with healthcare regulations

The Group must comply with complex regulations in relation to the marketing of its device products (and in the future will need to comply with such regulations in relation to its drug products once approved). 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.

Mitigating activities

The Group has an in-house Compliance function headed by an experienced compliance professional as Vice President, Global Compliance Officer. The Global Compliance Officer reports to the General Counsel and also has a direct reporting line to the Chair of the Audit and Risk Committee. A Compliance Committee has been formed to oversee activities in this area. The Compliance function works with a network of external advisers in the relevant territories to ensure the appropriate regulations are understood and that strategies are in place to support products in development and those already approved and sold. Processes are in place to ensure that sales compliance requirements are met and any failures or allegations of failure are swiftly investigated and addressed. This includes training of employees and audits of distributors and suppliers. In August 2016 a new Code of Conduct applicable to the whole Group was launched and on-line training has been carried out which will be supplemented in the future by face to face training.

Principal risks and uncertainties continued

Supply Chain

The Company relies on third party contractors for the supply of key materials and services. Problems at 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. Some materials may only be available from one source, as is currently the case for the electrochemical sensor contained in the Company's NIOX devices and the allergy peptides contained in the Company's potential House Dust Mite allergy treatment.

Mitigating activities

Audits of sub-contractors are routinely conducted according to procedures set out in the Company's Quality system. Dual sourcing is put in place where this is practicable. Manufacturing sites for active pharmaceutical ingredients are well established FDA-approved facilities.

Research and development risks

The Company may not be successful in its efforts to build a pipeline of allergy treatments and develop them into marketable products. The failure of the Company's Phase III trial of its candidate cat allergy treatment to meet its primary or secondary endpoints highlights this risk.

Research and development risks will apply to the development programmes that the Company is undertaking or intends to undertake in respect of the products that make up its respiratory franchise. These risks may manifest themselves as a failure to progress pre-clinical or clinical trials.

Mitigating activities

The Company has recruited highly experienced R&D executives. Projects are closely monitored against goals and regularly reported to the Senior Management Team and the Board, and external resources are retained where this is deemed appropriate. In addition, the Company will seek, through business development activity, to identify opportunities that would expand and diversify its portfolio.

Intellectual property, know how, and trade secrets

The Company may be subject to challenges relating to the validity of its patents. If these challenges are successful then the Company may be exposed to generic competition. Two of the Company's granted European patents (one relevant to its cat allergy treatment and a second relevant to its particle engineering technology) are currently the subject of opposition proceedings at the European Patent Office although neither of these oppositions affect currently marketed products, or products that the Company expects to market in the near term.

Alternatively, the Company may be sued for infringement of third party patent rights. If these actions are successful then it would have to pay substantial damages and potentially remove its products from the market.

Such litigation, particularly in the US, involves significant costs and uncertainties.

It is possible that the Company will not be able to secure intellectual property protection, or sufficient protection, in relation to products that are acquired or in development. Similarly, a failure by the Company to maintain or renew key patents would lead to the loss of such protection. In both cases the potential of the Company to earn revenue from its products could be compromised as it would be less difficult for third parties to copy the products.

The Company may rely upon know how and trade secrets to protect its products and maintain a competitive advantage. This may be especially important where patent protection is limited or lacking. Conversely, the Company may be subject to claims that its employees or agents have wrongfully used or disclosed the confidential information of third parties, which could lead to damages or injunctions that affect particular products.

The Company licenses certain intellectual property rights from third parties. If the Company fails to comply with its obligations under these agreements it may enable the other party to terminate the agreement. This could impair the Company's freedom to operate and potentially lead to third parties preventing it from selling certain of its products.

Mitigating activities

Important products are covered by more than one patent family and challenges to patents are defended using carefully selected external patent attorneys and lawyers. The NIOX device, for example, is protected by numerous patents that relate to different aspects of its form and mode of operation. A robust system is in place that ensures patents are renewed on time. Third party patent filings are monitored to ensure the Company continues to have freedom to operate and oppositions are filed where this is considered expedient. Confidential information (both of the Company and belonging to third parties) is protected through use of confidential disclosure agreements with third parties, and suitable provisions relating to confidentiality and intellectual property exist in the Company's employment contracts. Licences are monitored for compliance with their terms.

Organisational capabilities and capacity

The Company may be unable to successfully implement its plans if it does not attract and retain employees with the requisite capabilities and experience, in appropriate numbers. Setbacks in development programmes may mean that the Company finds it difficult to attract sufficient talented new employees and loses existing employees. The Company depends on the skills and experience of its current management team and employees, and is generally subject to competition for, and may fail to retain, skilled personnel.

Existing employees, investigators, consultants and commercial partners may engage in misconduct or improper activities, including non-compliance with regulatory standards and laws.

Where the Company acquires complementary technologies, products, or businesses it may not be able to integrate those acquisitions effectively or realise their expected benefits.

The Company may be vulnerable to disruption and damage as a result of failures of its computer systems.

Mitigating activities

The Company believes its remuneration packages are competitive, and incentive plans based on the contingent award of shares, are in place to attract, motivate and retain staff.

Disciplinary and whistleblowing policies exist to address misconduct by employees and officers, and committee structures have been established with the Contract Research Organisations instructed by the Group to monitor and manage the conduct of the Group's clinical trials. To address IT risks, a disaster recovery plan has been developed. Data is backed up daily on off-site servers and the Group operates from a number of physically separate sites.

The Senior Management Team has considerable experience of integrating acquired businesses and assets, and will assess opportunities using conservative assumptions.

Principal risks and uncertainties continued

Free Float

The UK Listing Authority requires listing issuers to maintain at least 25% free float in their listed shares. At 31 August 2016 the Company had a free float of approximately 14%. If the level of free float cannot be increased to 25% then the UKLA can ultimately require the Company to delist from the Official List. This would adversely affect the ability of new and existing shareholders to buy Ordinary shares and of holders to sell them.

Mitigating activities

The Company will keep the free float under review, and if it remains below 25% will: (i) discuss with Shareholders who own more than 5% of the issue share capital of the Company whether any of their holdings can be disaggregated because decisions are being taken by independent investment managers within that Shareholder's organisation; (ii) discuss with such Shareholders the prospect of reducing their holding below 5%; (iii) seek a derogation from the UKLA while such measures are being implemented.

Financial Operations

The Company has incurred significant losses since its inception and anticipates that it will continue to do so, at least until it is able to launch some of the products that are currently under development or in-license, partner or acquire commercial stage products.

Foreign exchange fluctuations may adversely affect the Company's results and financial condition. The Company records its transactions and prepares its financial statements in pounds sterling, but a significant proportion of its expenditure is in US dollars, Swedish Krona, or Euros.

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 Company, and its joint venture Adiga Life Sciences Inc. currently receive in the United Kingdom and Canada respectively.

Mitigating activities

The Directors assess the viability of the Group over a three year period on a rolling annual basis. The most recent viability statement is set out in the report and accounts for the year ending 31 December 2015. Forward purchases of foreign currencies are made when exchange rates are favourable to provide for expenditure in those currencies. Markets are constantly monitored and an external commentary is provided by Investec on a daily basis. If tax credits are lost in the future then action would be taken to reduce discretionary expenditure.

Condensed interim consolidated statement of comprehensive income

For the six months ended 30 June 2016

	Notes	Underlying operations £m Unaudited 30 June 2016	Non-underlying items* £m Unaudited 30 June 2016	Total £m Unaudited 30 June 2016	Total £m Unaudited 30 June 2015
Revenue		11.1	–	11.1	0.6
Cost of sales		(3.6)	–	(3.6)	(0.2)
Gross profit		7.5	–	7.5	0.4
Research and development costs		(23.2)	(1.9)	(25.1)	(18.4)
Sales and marketing		(13.1)	(74.5)	(87.6)	(2.2)
Administrative expenses		(9.5)	–	(9.5)	(7.2)
Other gains		–	–	–	1.1
Operating loss	4	(38.3)	(76.4)	(114.7)	(26.3)
Finance costs		(0.1)	–	(0.1)	(1.0)
Finance income		6.4	–	6.4	1.0
Finance income - net	5	6.3	–	6.3	–
Share of profit of joint venture	9	0.8	–	0.8	0.3
Loss before tax		(31.2)	(76.4)	(107.6)	(26.0)
Taxation		5.8	–	5.8	4.3
Loss for the financial period		(25.4)	(76.4)	(101.8)	(21.7)
Loss attributable to:					
Owners of Circassia Pharmaceuticals plc		(25.3)	(76.4)	(101.7)	(21.6)
Non-controlling interests		(0.1)	–	(0.1)	(0.1)
Loss for the financial period		(25.4)	(76.4)	(101.8)	(21.7)
Other comprehensive income/(expense)					
Items that may be subsequently reclassified to profit or loss:					
Share of other comprehensive expense of joint venture	9	(0.1)	–	(0.1)	–
Currency translation differences		7.6	–	7.6	(2.5)
Total comprehensive expense for the period		(17.9)	(76.4)	(94.3)	(24.2)
Total comprehensive expense attributable to:					
Owners of Circassia Pharmaceuticals plc		(17.8)	(76.4)	(94.2)	(24.1)
Non-controlling interests		(0.1)	–	(0.1)	(0.1)
Total comprehensive expense for the period		(17.9)	(76.4)	(94.3)	(24.2)
Loss per share					
Loss per share from continuing operations attributable to the equity holders of the parent during the period	10			(£0.36)	(£0.11)

* Non-underlying items comprise impairment of goodwill (£74.5 million) and other intangible assets (£0.3m million), please refer to note 7 and 8, and onerous contract costs provision (£1.6 million)

The notes on pages 16 to 21 are an integral part of these condensed interim consolidated financial statements.

Condensed interim consolidated statement of financial position

As at 30 June 2016

	Notes	30 June 2016 £m Unaudited	31 December 2015 £m Audited
Assets			
Non-current assets			
Property, plant and equipment		**1.3**	1.3
Goodwill	7	**9.6**	81.2
Intangible assets	8	**168.8**	165.6
Deferred tax assets	6	**18.7**	17.2
Investment in joint venture	9	**0.9**	0.2
		199.3	265.5
Current assets			
Inventory		**3.4**	3.0
Trade and other receivables		**10.2**	5.1
Current tax assets	6	**17.5**	11.8
Short-term bank deposits		**34.7**	37.8
Cash and cash equivalents		**103.3**	166.0
		169.1	223.7
Total assets		**368.4**	489.2
Equity and liabilities			
Equity attributable to the owners of the parent company			
Ordinary shares	12	**0.2**	0.2
Share premium	12	**564.0**	564.0
Other reserves	13	**8.7**	2.8
Accumulated losses		**(260.2)**	(158.5)
		312.7	408.5
Non-controlling interests		**–**	1.2
Total equity		**312.7**	409.7
Liabilities			
Non-current liabilities			
Deferred income tax liabilities	6	**32.5**	31.2
		32.5	31.2
Current liabilities			
Trade and other payables		**23.2**	48.3
		23.2	48.3
Total liabilities		**55.7**	79.5
Total equity and liabilities		**368.4**	489.2

The notes on pages 16 to 21 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 2016

	Notes	30 June 2016 £m Unaudited	30 June 2015 £m Unaudited
Cash flows from operating activities			
Cash used in operations	11	**(37.4)**	(24.6)
Interest paid		**(0.1)**	–
Tax credit (paid)/received		**(0.2)**	0.2
Net cash used in operating activities		**(37.7)**	(24.4)
Cash flows from investing activities			
Interest received		**0.3**	2.0
Acquisition of subsidiaries, net of cash acquired		**–**	(190.0)
Contingent consideration payment		**(30.0)**	–
Purchase of property, plant and equipment		**(0.3)**	–
Purchase of intangible assets		**–**	(0.2)
Decrease in short term bank deposits		**3.2**	54.2
Net cash used in investing activities		**(26.8)**	(134.0)
Cash flows from financing activities			
Purchase of treasury shares	13	**(0.4)**	(0.3)
Proceeds from issue of ordinary shares		**–**	266.9
Transactions with non-controlling interests	13	**(3.2)**	–
Net cash (used in)/from financing activities		**(3.6)**	266.6
Net (decrease)/increase in cash and cash equivalents		**(68.1)**	108.2
Cash and cash equivalents at beginning of period		**166.0**	29.7
Exchange gain/(loss) on cash and cash equivalents		**5.4**	(1.7)
Cash and cash equivalents at 30 June		**103.3**	136.2

The notes on pages 16 to 21 are an integral part of these condensed interim consolidated financial statements.

Condensed interim consolidated statement of changes in equity

	Notes	Share capital £m	Share premium £m	Other[1] reserves £m	Accumulated losses £m	Total £m	Non-controlling interests £m	Total equity £m
		Attributable to owners of the parent						
At 1 January 2016 (audited)		0.2	564.0	2.8	(158.5)	408.5	1.2	409.7
Comprehensive expense:								
Loss for the year		–	–	–	(101.7)	(101.7)	(0.1)	(101.8)
Other comprehensive income/(expense):								
Share of other comprehensive expense of joint venture	9	–	–	(0.1)	–	(0.1)	–	(0.1)
Currency translation differences		–	–	7.6	–	7.6	–	7.6
Total comprehensive expense		–	–	7.5	(101.7)	(94.2)	(0.1)	(94.3)
Transactions with owners:								
Purchase of own shares	13	–	–	(0.4)	–	(0.4)	–	(0.4)
Employee share option scheme		–	–	0.9	–	0.9	–	0.9
Transactions with non-controlling interests	13	–	–	(2.1)	–	(2.1)	(1.1)	(3.2)
At 30 June 2016 (unaudited)		**0.2**	**564.0**	**8.7**	**(260.2)**	**312.7**	**–**	**312.7**
At 1 January 2015 (audited)		0.2	297.9	1.3	(108.6)	190.8	–	190.8
Comprehensive expense:								
Loss for the year		–	–	–	(21.6)	(21.6)	(0.1)	(21.7)
Other comprehensive expense:								
Currency translation differences		–	–	(2.5)	–	(2.5)	–	(2.5)
Total comprehensive expense		–	–	(2.5)	(21.6)	(24.1)	(0.1)	(24.2)
Transactions with owners:								
Purchase of own shares	13	–	–	(0.3)	–	(0.3)	–	(0.3)
Issue of Ordinary shares		–	266.1	–	–	266.1	–	266.1
Employee share option scheme		–	–	1.4	–	1.4	–	1.4
Total contributions by owners of the parent, recognized directly in equity	12, 13	0.2	564.0	–	(130.2)	433.9	(0.1)	433.8
Acquisition of subsidiary							3.1	3.1
Total changes in ownership interests that do not result in a change in control recognized directly in equity							3.1	3.1
At 30 June 2015 (unaudited)		**0.2**	**564.0**	**–**	**(130.2)**	**433.9**	**3.0**	**436.9**

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

The notes on pages 16 to 21 are an integral part of these condensed interim consolidated financial statements.

Notes to the condensed interim consolidated financial statements

1. General information

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

The condensed consolidated interim financial statements were approved for issue on 27 September 2016.

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 2015 were approved by the Board of Directors on 11 March 2016 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 been reviewed, but not audited, and the independent review report is set out on page 23 of this document.

Basis of preparation

The condensed consolidated interim financial statements for the six months ended 30 June 2016 have been prepared in accordance with the Disclosure and Transparency Rules of the Financial Conduct Authority (previously the Financial Services Authority) and IAS 34 'Interim financial reporting', as adopted by the European Union.

The condensed consolidated interim financial statements should be read in conjunction with the annual financial statements for the year ended 31 December 2015, which have been prepared in accordance with IFRSs as adopted by the European Union.

Going concern

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

Accounting policies

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

Non-underlying items

The Group presents certain items of income and expense as non-underlying in the Statement of Comprehensive Income and Expense. The determination that an item should be presented as non-underlying is a judgement of the management. The management considers whether providing separate disclosure is helpful in understanding the underlying performance of the business, based on the nature and size of the items and infrequency of the events giving rise to them.

There are not considered to be any new standards, amendments to IFRS's and interpretations effective for the financial year ending 31 December 2016 that would have a material impact on the Group.

Use of estimates and assumptions

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

In preparing these condensed interim financial statements, the significant judgements made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the annual financial statements for the year ended 31 December 2015 except as disclosed below.

Goodwill and other intangible assets

Goodwill and other intangible assets impairment reviews are undertaken annually or more frequently if events or changes in circumstances indicate a potential impairment. Judgements and estimates are made in respect of the carrying value of the CGU containing the goodwill taking into account key assumptions about the product candidates. If the Group is unable to obtain regulatory approval or to commercialise its product candidates, or experiences significant delays in doing so, this could result in an impairment of the related goodwill and intellectual property rights.

2. Financial and capital risk management

Financial risk factors

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 2015. The viability consideration has been disclosed in the last annual report and the Directors believe that the year-end position remains unchanged.

The nature or level of risk that the Group is exposed to has changed in the first half of 2016 as a result of the UK referendum decision to leave the European Union. It is considered that it is too early to quantify the exact impact for the Group and the Directors will keep the situation under review and act to mitigate any increased risks accordingly. There have been no changes in the risk management process or in any risk management policies since the year end except for those disclosed below.

The majority of operating costs are denominated in Sterling, United States dollars, Canadian dollars, Euro, Swiss francs or Swedish krona. Foreign exchange risk arises from future commercial transactions and recognised assets and liabilities.

The foreign exchange risk is considered to have been amplified by the recent EU referendum result in the UK. The Directors expect foreign exchange volatility to affect the Group's results and the resulting impact will be assessed in the annual report.

3. Operating segments

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

The table presents revenue from external customers and profit/loss information regarding the Group's operating segments for the six months ended 30 June 2016 and 30 June 2015. There have been no sales between segments in either reporting period.

Notes to the condensed interim consolidated financial statements continued

	Allergy £m	NIOX® £m	Respiratory £m	Total £m
Six months to 30 June 2016				
Revenue	**–**	**11.1**	**–**	**11.1**
Operating loss	**(104.1)**	**(6.9)**	**(3.7)**	**(114.7)**
Six months to 30 June 2015				
Revenue	–	0.6	–	0.6
Operating loss	(25.4)	(0.7)	(0.2)	(26.3)

There have been no material changes in total assets or total liabilities from the amounts disclosed in the last annual financial statements except for Circassia goodwill impairment disclosed in note 7 that is allocated to the Allergy segment.

NIOX® performance

Constant exchange rates numbers for H1 2015 represent reported H1 2015 numbers re-stated using average exchange rates in H1 2016. Management believes constant currency numbers better represent the underlying performance of the businesses within the Group that have a functional currency that is subject to significant fluctuations against the Sterling. H1 2015 reported revenue is £9.1 million at actual exchange rates in H1 2015 (£0.6 million revenues recorded by Circassia for 19 – 30 June 2015 period and £8.5 million under previous ownership).

4. Operating loss

Included within the operating loss to 30 June 2016 is a goodwill impairment charge of £74.5 million (H1 2015: acquisition-related costs of £4.0 million).

5. Finance income and costs

	Six months ended 30 June 2016 £m	Six months ended 30 June 2015 £m
Finance costs:		
Interest payable	**(0.1)**	(0.2)
Loss on foreign exchange	**–**	(0.8)
Total finance costs	**(0.1)**	(1.0)
Finance income:		
Bank interest receivable	**0.6**	1.0
Gain on foreign exchange	**5.8**	–
Total finance income	**6.4**	1.0
Net finance income	**6.3**	–

6. Taxation

R&D tax credit

The amount included in the interim financial statements for the six months ended 30 June 2016 and 2015 represents the credit receivable by the Group for the period and adjustments to prior years. The amounts are not currently agreed with the relevant tax authorities and have been calculated at a rate of 14.5% for qualifying expenditure, being the prevailing R&D tax credit rate at the time. An uplift of 130% has been applied to all qualifying expenditure in line with R&D tax rules.

Deferred taxation

	Intangibles £m	Tax losses £m	Net deferred tax liability £m
At 1 January 2016	31.2	(17.2)	14.0
(Credit)/charge to the income statement	(0.4)	0.2	(0.2)
Exchange differences	1.7	(1.7)	–
At 30 June 2016	**32.5**	**(18.7)**	**13.8**

	30 June 2016 £m	31 December 2015 £m
Deferred tax liabilities	**32.5**	31.2
Deferred tax assets	**(18.7)**	(17.2)
Total deferred tax position	**13.8**	14.0

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

	30 June 2016 £m	31 December 2015 £m
Losses	**45.1**	40.2
Accelerated capital allowances	**0.4**	0.5
Share based payments and provisions	**1.7**	1.7
Total unrecognised deferred tax asset	**47.2**	42.4

7. Goodwill

	£m
At 31 December 2015	
Cost	81.2
Accumulated impairment	–
Net book amount	**81.2**
Six months ended 30 June 2016	
Opening net book amount	81.2
Foreign exchange movement	2.9
Impairment	(74.5)
Closing net book amount	**9.6**
At 30 June 2016	
Cost	84.1
Accumulated impairment	(74.5)
Net book amount	**9.6**

The negative result of the investigational cat allergy immunotherapy phase III study is considered to be an indicator of impairment in the Circassia CGU as at 30 June 2016.

The Group revised its forecasts to current expectations of the future performance of its CGUs based on the current development plans. The recoverable amount of CGUs was determined based on value in use calculations using a consistent methodology to that disclosed in the 2015 annual report except as described below.

Following the cat allergy immunotherapy phase III study results, the Allergy portfolio value has been fully discounted resulting in the impairment charge for the Circassia CGU of £74.5 million.

There has been no key assumption change for Aerocrine and Prosonix CGUs.

The carrying value of goodwill, translated at period end exchange rates, is allocated to the following CGUs:

Cash generating unit	30 June 2016 £m	31 December 2015 £m
Circassia	**–**	72.1
Aerocrine	**5.2**	4.7
Prosonix	**4.4**	4.4
	9.6	81.2

Notes to the condensed interim consolidated financial statements continued

8. Intangible assets

Group	IPR&D £m	Customer relationships £m	Technology £m	Other £m	Total intangible assets £m
At 31 December 2015					
Cost	88.9	30.8	46.8	1.8	168.3
Accumulated amortisation and impairment	–	(0.9)	(0.9)	(0.9)	(2.7)
Net book amount	**88.9**	**29.9**	**45.9**	**0.9**	**165.6**
Six months ended 30 June 2016					
Opening net book amount	88.9	29.9	45.9	0.9	165.6
Amortisation charge	(0.1)	(0.9)	(1.0)	(0.1)	(2.1)
Impairment	–	–	–	(0.3)	(0.3)
Exchange differences	–	3.0	2.6	–	5.6
Closing net book amount	**88.8**	**32.0**	**47.5**	**0.5**	**168.8**
At 30 June 2016					
Cost	88.9	33.8	49.4	1.8	173.9
Accumulated amortisation and impairment	(0.1)	(1.8)	(1.9)	(1.3)	(5.1)
Net book amount	**88.8**	**32.0**	**47.5**	**0.5**	**168.8**

Due to the negative result of the investigational cat allergy immunotherapy phase III study and the subsequent impact on a wider Allergy product portfolio, related licences and patents have been fully impaired.

9. Investment in joint venture

	Six months ended 30 June 2016 £m	Year ended 31 Dec 2015 £m	Six months ended 30 June 2015 £m
At 1 January	**0.2**	0.1	0.1
Share of profit	**0.8**	0.1	0.3
Foreign exchange difference on consolidation	**(0.1)**	–	–
At period end	**0.9**	0.2	0.4

10. Net loss per Ordinary share

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

		6 months ended 30 June		
		2016 Total	2016 Underlying operations	2015
Loss from continuing operations for the period attributable to ordinary equity owners of the parent company	£m	**(101.7)**	(25.3)	(21.6)
Weighted average number of Ordinary shares in issue	Number	**284,889,171**	284,889,171	199,496,974
Loss per share		**(£0.36)**	(£0.09)	(£0.11)

As net losses from continuing operations were recorded in 2016 and 2015, the dilutive potential shares are anti-dilutive for the earnings per share calculation.

Underlying operations loss per share is calculated in order to provide information about underlying performance and is based on the loss attributable to ordinary equity holders of the parent company excluding non-underlying items.

Notes to the condensed interim consolidated financial statements continued

11. Cash used in operations

Reconciliation of loss before tax to net cash used in operations

	For the six months ended 30 June 2016 £m	2015 £m
Continuing operations		
Loss before tax	**(107.6)**	(26.0)
Adjustment for:		
Finance income	**(0.6)**	(1.0)
Finance costs	**0.1**	0.2
Depreciation	**0.4**	0.1
Impairment	**74.8**	–
Amortisation (note 8)	**2.1**	0.1
Share of joint venture profit (note 9)	**(0.8)**	(0.3)
Fair value gain on derivative	**–**	(1.1)
Share based payment charge	**0.9**	1.4
Foreign exchange (loss)/gain on non-operating cash flows	**(7.4)**	2.2
(Increase)/decrease in trade and other receivables	**(4.1)**	0.2
Decrease/(increase) in inventories	**0.5**	(0.3)
Increase/(decrease) in trade and other payables	**4.3**	(0.1)
Net cash used in operations	**(37.4)**	(24.6)

12. Share capital and share premium

	Number of shares (millions)	Share capital £m	Share premium £m
Balance as at 1 January 2016 and 30 June 2016	**284.9**	**0.2**	**564.0**

	Number of shares (millions)	Share capital £m	Share premium £m
Opening balance as at 1 January 2015	189.4	0.2	297.9
Issue of new shares	95.5	-	266.1
At 31 December 2015	**284.9**	**0.2**	**564.0**

13. Other reserves

	Share option reserve £m	Translation reserve £m	Treasury reserve £m	Transactions with non-controlling interests £m	Total other reserves £m
At 1 January 2016	4.0	3.1	(0.3)	(4.0)	2.8
Employee share option scheme	0.9	–	–	–	0.9
Currency translation differences	–	7.5	–	–	7.5
Purchase of own shares	–	–	(0.4)	–	(0.4)
Transactions with non–controlling interests	–	–	–	(2.1)	(2.1)
At 30 June 2016	**4.9**	**10.6**	**(0.7)**	**(6.1)**	**8.7**
At January 2015	1.3	–	–	–	1.3
Employee share option scheme	2.7	–	–	–	2.7
Currency translation differences	–	3.1	–	–	3.1
Purchase of own shares	–	–	(0.3)	–	(0.3)
Transactions with non–controlling interests	–	–	–	(4.0)	(4.0)
At 31 December 2015	**4.0**	**3.1**	**(0.3)**	**(4.0)**	**2.8**

Notes to the condensed interim consolidated financial statements continued

On 13 May 2016, the group acquired the remaining 2.1% of the issued shares of Aerocrine AB for SEK37.6 million (£3.2 million) to become the owner of 100% of the shares in Aerocrine AB. Immediately prior to the purchase, the carrying amount of the existing 2.1% non-controlling interests in Aerocrine AB was £1.1 million. The group recognised a decrease in non-controlling interests of £1.1 million and a decrease in equity attributable to owners of the parent of £2.1 million. The effect on the equity attributable to the owners of Circassia Pharmaceuticals plc during the year is summarised as follows:

	2016 £m
Carrying amount of non-controlling interests	1.1
Consideration paid to non-controlling interests	(3.2)
Excess of consideration paid recognised in the transactions with non-controlling interests reserve within equity	(2.1)

The arbitration process with non-controlling interests is ongoing, however no further payments have been provided in the interim financial statements.

14. Related party transactions

There have been no new related party transactions that have taken place in the first six months of the current financial year.

15. Events occurring after the reporting period

Following the negative result from the cat allergy phase III study, management has reassessed R&D expenditure in line with the updated strategy resulting in the below detailed provisions recognised after 30 June 2016.

Onerous contract provision
£0.9 million provision relates to the termination of a trial batch manufacturing contract.

Reorganisation provision
£0.5 million provision relates to redundancy payments to staff in the research and development team.

Statement of directors' responsibilities

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

- an indication of important events that have occurred during the first six months and their impact on the condensed set of financial statements, and a description of the principal risks and uncertainties for the remaining six months of the financial year; and
- material related-party transactions in the first six months and any material changes in the related-party transactions described in the last annual report. The Directors of Circassia Pharmaceuticals plc are listed on page 24.

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

Julien Cotta
Chief Financial Officer

27 September 2016

Independent review report to Circassia Pharmaceuticals plc

Report on the condensed consolidated interim financial statements

Our conclusion

We have reviewed the condensed consolidated interim financial statements, defined below, in the Interim Report of Circassia Pharmaceuticals plc for the six months ended 30 June 2016. Based on our review, nothing has come to our attention that causes us to believe that the condensed consolidated interim financial statements are not prepared, in all material respects, in accordance with International Accounting Standard 34 as adopted by the European Union and the Disclosure and Transparency Rules of the United Kingdom's Financial Conduct Authority.

This conclusion is to be read in the context of what we say in the remainder of this report.

What we have reviewed

The condensed consolidated interim financial statements, which are prepared by Circassia Pharmaceutical plc, comprise:

- the condensed consolidated statement of financial position as at 30 June 2016;
- the condensed consolidated income statement and statement of comprehensive income for the period then ended;
- the condensed consolidated statement of cash flows for the period then ended;
- the condensed consolidated statement of changes in equity for the period then ended; and
- the explanatory notes to the condensed consolidated interim financial statements.

As disclosed in note 1, the financial reporting framework that has been applied in the preparation of the full annual financial statements of the group is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union.

The condensed consolidated interim financial statements included in the Interim report have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and the Disclosure and Transparency Rules of the United Kingdom's Financial Conduct Authority.

What a review of condensed consolidated financial statements involves

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, 'Review of Interim Financial Information Performed by the Independent Auditor of the Entity' issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures.

A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and, consequently, does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

We have read the other information contained in the Interim report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed consolidated interim financial statements.

Responsibilities for the interim financial statements and the review

Our responsibilities and those of the directors

The Interim report, including the condensed consolidated interim financial statements, is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the Interim report in accordance with the Disclosure and Transparency Rules of the United Kingdom's Financial Conduct Authority.

Our responsibility is to express to the company a conclusion on the condensed consolidated interim financial statements in the Interim report based on our review. This report, including the conclusion, has been prepared for and only for the company for the purpose of complying with the Disclosure and Transparency Rules of the Financial Conduct Authority and for no other purpose. We do not, in giving this conclusion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

PricewaterhouseCoopers LLP
Chartered Accountants
London

27 September 2016

Shareholder information

Financial calendar
Preliminary results for the 12 months ending 31 December 2016: Q1 2017
Annual General Meeting: H1 2017

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 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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Directors
Dr Francesco Granata (Chairman)
Steven Harris (Chief Executive Officer and co-founder)
Julien Cotta (Chief Financial Officer)
Dr Rod Hafner (Senior Vice President Research and Development)
Dr Jean-Jacques Garaud (Independent Non-Executive Director and Senior Independent Director)
Dr Tim Corn (Independent Non-Executive Director)
Russell Cummings (Non-Executive Director)
Cathrin Petty (Non-Executive Director)
Marvin Samson (Independent Non-Executive Director)
Charles Swingland (Non-Executive Director and co-founder)
Lota Zoth (Independent Non-Executive Director)

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.

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