



Building a world-class specialty biopharmaceutical business

Interim report and accounts 2015

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#### Circassia

Circassia is a world-class specialty biopharmaceutical business focused on allergy and asthma. The Company has an established commercial infrastructure, marketed products, a pipeline of near-term therapies and a portfolio of next generation treatments targeting multi-\$billion market opportunities. Circassia sells its novel, market-leading products for asthma diagnosis and management directly to allergy/asthma specialists in the United States and Germany. Its products are also promoted in a number of other countries by the Company's international network of partners.

Circassia's broad-based development pipeline includes a range of treatments for allergy and asthma. Circassia's most advanced next-generation immunotherapy is currently in phase III testing for cat allergy, and is the first in a new class of treatments, Synthetic Peptide Immuno-Regulatory Epitopes (SPIREs). Three other SPIREs, targeting house dust mite, ragweed and grass allergies, have completed clinical proof-of-concept phase IIb studies. Circassia's lead asthma product targets substitution of GSK's Flixotide® pMDI, and was filed for regulatory approval in H2 2014. The Company anticipates two further product filings by the end of H1 2016, targeting direct substitution of Serevent® pMDI and Seretide® pMDI. Circassia is also developing a number of novel treatments, including a fixed dose 'triple' combination containing an inhaled corticosteroid, long-acting beta agonist and long-acting muscarinic antagonist.

For further information on Circassia please visit: www.circassia.com



## Introduction from the Chief Executive



Following Circassia's successful IPO in March 2014, the first half of 2015 has proved equally transformational for the Company.

We have continued to deliver our pipeline of next generation allergy immunotherapies, and our late-stage programs and phase III studies are on track. At the same time, we have significantly accelerated our strategy to independently commercialize our products and build a broad and balanced portfolio, through the acquisitions of Aerocrine and Prosonix. We now have an established commercial infrastructure selling novel products directly to allergy/asthma specialists in the US and Germany, who are the core customers for our allergy treatments.

In addition, we have complemented our late-stage allergy pipeline with a number of near-term asthma products and high value novel candidates. In the coming year, we intend to expand our commercial presence in preparation for the launch of our cat allergy treatment, which we also expect to boost sales of our current asthma products. As a result, we are ideally positioned to achieve our ambition of becoming a self-sustaining specialty biopharmaceutical business.

Steve Harris
Chief Executive

## Operational and financial highlights

£275.0m

Successful placing and open offer raised £275.0 million (gross) to fund acquisitions

£18.4m

Research and development investment increased to £18.4 million (H1 2014: £16.4 million)

£21.7m

Loss for the period increased to £21.7 million (H1 2014: £16.2 million)

£238.9m

Fully funded to deliver portfolio; £238.9 million cash at 30 June 2015 (30 December 2014: £186.6 million)

Cash, cash equivalents and short-term deposits

#### Allergy immunotherapy clinical programs on track

- Cat allergy phase III registration study (CATALYST) on track to report results H1 2016
- Cat allergy two-to-five year follow-up (CP007A) ongoing;
   329 subjects enrolled to date
- Cat allergy pediatric safety study (CP009) on track to complete H2 2015
- House dust mite allergy phase IIb field study (TH005) targeting recruitment completion H2 2015; 334 subjects enrolled to date (target n=660)
- Grass allergy recruitment campaign for phase III on track to start H1 2016
- Grass allergy safety study (TG004) positive results enable inclusion of controlled asthmatics in phase III
- Grass allergy observational study (TG003) results informing phase III design
- Ragweed allergy phase Ilb follow-up (TR006A) on track to complete H2 2015; 249 subjects enrolled
- Ragweed allergy recruitment campaign for phase Ilb dose-ranging study on track to start in 2016 season
- Birch allergy first-in-human clinical study initiated

#### First allergy product launch preparations underway

- Regional Medical Affairs Directors appointed in US and EU to work with allergy experts
- Analytics, marketing and distribution management established in US
- Cat allergy product preferred brand names submitted to EU regulators for review
- Market research completed to inform launch positioning

#### Aerocrine acquisition accelerates commercialization strategy

- Brings novel market-leading NIOX® products for asthma diagnosis & management; strong growth potential with 28% sales increase in first six months (H1 2015 £ 9.1 million; H1 2014 £ 7.1 million)\*
  - \*Acquisition of Aerocrine completed on 18 June; revenues recorded by Circassia from 19–30 June 2015
- Direct sales in US and Germany targeting allergy/asthma specialists
- Infrastructure highly complementary with Circassia's commercial team
- Opportunity to expand EU presence and US organization
- Infrastructure scalable well in advance of first allergy launch to target steeper and higher sales curve
- Broad international distribution network covers additional territories

#### Prosonix acquisition broadens portfolio

- Brings near-term pipeline targeting direct substitution of leading asthma therapies, and high-value novel product candidates that fit focused commercialization strategy
- Lead product targeting substitution of GSK's Flixotide® pMDI filed H2 2014; UK approval anticipated H2 2015
- Two further product filings planned by end H1 2016
- Novel 'triple' fixed combination therapy to enter clinic H2 2015
- Potential for eight product launches by 2021 (including four lead allergy products)

## Operating review

During the last six months, Circassia has made good progress in advancing its innovative allergy treatments towards the market, and the Company's late-stage development programs are on track. In parallel, we completed a successful £275 million Placing and Open Offer to fund the acquisitions of Aerocrine and Prosonix, which significantly accelerated our strategy, establishing commercial infrastructure to launch and promote our products in key markets and broadening our pipeline of specialty products. With a strong balance sheet and ongoing revenues from the sale of our newly-acquired products, we are fully funded to deliver our portfolio of specialty products and complete our transition into a world-class, self-sustaining specialty biopharmaceutical business.

# Phase III on track

Our cat allergy pivotal phase III study is on track to report in H1 2016

#### Allergy portfolio clinical progress

#### Cat allergy

The Company's most advanced immunotherapy targets cat allergy and is currently in phase III testing. In phase II studies, the treatment achieved highly positive results with a short-course of four doses over 12 weeks reducing allergy symptoms for two years, despite no additional dosing. The ongoing pivotal phase III study (CATALYST) is fully recruited in centers across North America, Europe and Russia. The primary endpoint will assess the combined improvement in allergy symptoms and rescue medication use one year after the start of treatment, and the study is on track to report in H1 2016.

To confirm the product's longer-term efficacy, Circassia is conducting a two-to-five year follow-up study (CP007A) in subjects who have completed the CATALYST trial. Recruitment is well underway, with 329 subjects now enrolled. In addition, we are undertaking a pediatric safety study (CP009) to support our European marketing authorization application, which is on track to complete by the end of this year.

#### House dust mite allergy

Our product candidate targeting house dust mite allergy has also achieved positive phase II results. In a long-term follow-up study, a short-course of therapy maintained symptom improvements two years after the start of treatment, despite subjects not receiving any further doses. In addition, the product demonstrated a stronger effect in those with more severe symptoms, which is the patient group more inclined to seek treatment.

Following these results, in H2 2014 Circassia initiated a large phase IIb field trial (TH005). The randomized, double-blind, placebo-controlled study is ongoing in North America, Europe and South Africa, and will recruit 660 subjects with house dust mite allergy. Currently, 334 subjects have been enrolled, and the study is targeting recruitment completion by the end of 2015.

#### **Grass allergy**

Grass pollen is the most common cause of seasonal allergy. Circassia's novel treatment has successfully completed phase IIb clinical proof-of-concept testing, and in long-term follow-up, symptom improvements continued three pollen seasons after subjects had completed short-course treatment.

Following these encouraging results, we are planning to initiate a pivotal phase III field study, with a recruitment campaign for the trial planned to begin in H1 2016. In the first half of 2015, we received positive results from a safety study (TG004) conducted in controlled asthmatics, which will allow this group to be included in the phase III trial. During H1 2015, we also concluded an observational study in North and South America that included 102 subjects with grass allergy. The study recorded symptoms and rescue medication usage, and despite modest pollen levels, the results provide insights into the natural history of subjects' allergy through the season that are informing the phase III design.

#### Ragweed allergy

Allergy to ragweed pollen is common in North America, and is a growing health issue in Europe. Circassia's treatment is currently in a long-term follow-up study (TR006A) in subjects who completed an earlier phase Ilb single-season trial (TR006). The ongoing study is following subjects over a further pollen season, with no additional treatment, and has now completed recruitment with 249 enrolled. The results will help inform the design of a phase Ilb dose-ranging field study, which will investigate the effect of higher dosing, following results from previous studies that suggest the optimal dose may not yet have been reached. Preparations for the field study are progressing as planned, with a recruitment campaign for the trial anticipated to start in the 2016 pollen season.

## Operating review continued

As we approach the completion of our cat allergy phase III study, we have initiated launch preparations to ensure successful product uptake

In June 2015, we acquired Aerocrine AB, significantly accelerating our strategy to independently commercialize our allergy treatments in key markets

#### Birch & Japanese cedar allergies

Pollen from Birch and Japanese cedar trees can cause allergic reactions in those that are sensitized. Circassia is developing therapies for both these allergies and these earlier stage development programs are progressing on track. Recently, our Birch allergy product advanced into the clinic in a first-in-human study and our treatment for Japanese cedar allergy is anticipated to move into clinical testing in H1 2016.

### Preparations for first allergy product launch

#### Building a successful launch platform

As we approach the completion of our cat allergy phase III study, we have initiated launch preparations to ensure successful product uptake. In the US and Europe, we have appointed Regional Medical Affairs Directors who are educating allergy opinion leaders and specialists to facilitate deep understanding of our novel technology. In addition, we have recruited business analytics, marketing and distribution management in the US to begin to build the capabilities we require to support our launch. This team strongly complements the Aerocrine commercial organization we acquired at the end of the period (see below). With little overlap between the businesses, integration activities have been rapidly established and we anticipate completing the process in the next few months.

During the first half of 2015, we also completed the brand name selection process for our cat allergy treatment and have submitted our preferences to the European Medicines Agency for review. In addition, we completed patient journey research in a number of countries, which will inform our positioning and message development for launch.

#### **Accelerating our commercial strategy**

#### Aerocrine acquisition

In June 2015, we acquired Aerocrine AB, significantly accelerating our strategy to independently commercialize our allergy treatments in key markets. The acquisition includes two market-leading products, which are sold to our core customers of allergy/asthma specialists by an established commercial infrastructure in the US and Germany (Europe's largest allergy market), and by a broad network of partners in additional territories. The products, NIOX® MINO® and the next generation NIOX® VERO®, are used to improve asthma diagnosis and management by measuring fractional exhaled nitric oxide (FeNO), and are the only device available across major markets. Consequently, the products are an ideal strategic fit with our commercialization approach, with sales forces targeting specialists in key markets, partners undertaking promotion in other countries and the potential for primary care sales through partnering.

Asthma represents a significant healthcare burden, with 25 million asthmatics in the US alone resulting in medical costs of over \$50 billion in 2007. Clinical evidence shows that the use of FeNO measurement can improve asthma management through improved diagnosis, determination of inhaled steroid responsiveness, tailoring of inhaled steroid use and monitoring treatment compliance, with the potential to reduce exacerbations. As a result, the approach is included in American Thoracic Society treatment guidelines, which are endorsed by the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology. NIOX is also recommended by the National Institute for Health and Care Excellence (NICE) to help guide asthma diagnosis and management. Consequently, the NIOX products are well positioned for growth, and sales increased by 28% in the first half of 2015 to £9.1 million (H1 2014; £7.1 million)¹.

# >\$500m pa

We aim to accelerate uptake of our cat allergy treatment and achieve higher peak sales, which research suggests have the potential to reach over \$500 million per annum

# Broadening pipeline

We advanced our strategy of broadening and deepening our pipeline of specialty products through the acquisition of Prosonix Ltd, which includes a portfolio of late-stage asthma products and high-value novel product candidates that fit our commercialization approach

With a strong commercial infrastructure already established, with reimbursement, market access, supply chain and marketing expertise in place, we have the opportunity to scale-up this presence in the near-term as well as expanding into other EU territories. We plan to increase the existing field forces, complete training on our cat allergy product, map out key accounts and build customer relationships well in advance of the expected launch of our first allergy treatment. As a result, we aim to accelerate uptake of the product and achieve higher peak sales, which research suggests have the potential to reach over \$500 million per annum. In addition, this commercial investment can help drive greater NIOX sales, which are targeting a market opportunity of approximately \$190 million in the US allergy/asthma specialist segment alone.

#### Building a broad and balanced portfolio

#### Prosonix acquisition

During the first half of 2015, we also advanced our strategy of broadening and deepening our pipeline of specialty products through the acquisition of Prosonix Ltd. This includes a portfolio of late-stage asthma products and high-value novel product candidates that fit our commercialization approach, offering the potential of near-term revenues and longer-term significant returns. Following the completion of the acquisition in June, we are now targeting eight potential product launches by the end of 2021 across our broader pipeline, including our four most advanced allergy product candidates.

The newly-acquired Prosonix portfolio is based on proprietary ultrasonic technologies that provide sophisticated control of active pharmaceutical ingredients, allowing the development of two distinct product types. The first targets direct substitution of leading asthma treatments and exploits regulatory guidelines that provide a rapid route to market, requiring limited or no clinical studies. These products have the potential to be first to market with a unique combination of features, providing therapeutic equivalence, the same formulation in similar devices and a full range of strengths. Consequently, they require limited commercialization investment, while also having the opportunity for robust pricing.

The second group of products comprises novel combinations and optimized formulations offering the potential of improved performance. These target major market opportunities and require more extensive development. These products are a strong fit with Circassia's commercialization strategy, with the potential for direct sales in specialist markets, and partnering to target primary care.

The most advanced product in the portfolio targets substitution of GSK's Flixotide®/Flovent® pMDI, which generated sales estimated at over \$900 million in 2014. The product is partnered with Mylan in a number of major territories, and is currently undergoing regulatory review by the UK's Medicines and Healthcare products Regulatory Agency (MHRA) under the European decentralized procedure, with the outcome anticipated in H2 2015. Following rapidly behind are two further products, targeting direct substitution for GSK's Seretide®/Advair® pMDI and Serevent® pMDI, which achieved estimated global sales of approximately \$1.8 billion and \$60 million in 2014 respectively. Both products are scheduled for filing with the MHRA under the European decentralized procedure within the next 12 months.

During the second half of 2015, we also anticipate progressing the most advanced novel candidate into the clinic. This 'triple' fixed dose combination incorporates an inhaled corticosteroid, longacting beta agonist and long-acting muscarinic antagonist, and targets a market segment forecast to be worth nearly \$8 billion in the next 10 years.

## Outlook

Over the coming year,
 we plan to continue to grow
 NIOX revenues, with the market
 well positioned for expansion

#### **Outlook**

#### Fully funded and well positioned to deliver our strategy

During the second half of 2015, and throughout 2016, we plan to ramp up preparations for the launch of our next generation cat allergy treatment. The allergy market has long been underserved, but has recently come into renewed focus with the launch of new sublingual immunotherapies in the US. We intend to exploit the opportunity presented by the market opening up to new approaches and we believe our novel products have the potential to revolutionize treatment, representing a major commercial opportunity for the Company. By leveraging our newly-acquired commercial infrastructure we aim to increase the penetration of our allergy products, targeting stronger sales growth with higher peak revenues than would otherwise be achievable. Indeed, a 5% penetration uplift for our cat allergy treatment in the US and Germany could generate additional sales significantly greater than the £138 million cost of the Aerocrine business that provides the foundations of this infrastructure.

We are on track to deliver phase III results for our cat allergy treatment in H1 2016, and in preparation for a successful launch, we intend to scale up the existing sales team in the US and Germany and explore the potential for expanding our direct presence in additional EU markets. In the second half of 2015, we plan to expand the US field force from 28 to 50 and to increase this further to an optimal 100-strong organization by Q1 2017, ensuring the team is in place and trained in advance of the anticipated launch later that year. During 2015, we also plan to recruit additional medical affairs experts to work with allergy opinion leaders and specialists in the US and key EU markets.

We also anticipate that our commercial infrastructure investment will boost NIOX sales. Over the last five years, NIOX revenues increased by 18% on a CAGR basis, and during the first six months of 2015 sales grew by 28% compared with the same period in 2014, to £9.1 million¹. Over the coming year, we plan to continue to grow NIOX revenues, with the market well positioned for expansion. The NIOX technology is now covered by a number of important clinical guidelines and reimbursement coverage is increasing. In H1 2015, the next generation NIOX VERO was launched in the US and Japanese markets, and the Chinese launch is planned for the coming weeks. The VERO's improved usability, life span and test speed has the potential to significantly increase uptake while also improving margins.

During the coming months we also anticipate strong progress across our development portfolio. We plan to complete phase II studies of our ragweed and birch pollen allergy treatments, and to complete recruitment into our house dust mite allergy field study. In addition, we expect the outcome of the MHRA's review of our Flixotide pMDI substitute filing and the progression of our novel triple fixed dose combination into the clinic.

In summary, during the first half of 2015, we have made significant strides in advancing our strategy to bring our innovative allergy products to market and establishing the capabilities to independently commercialize them in key territories. In the coming months, we intend to fully integrate the recent acquisitions that provide this infrastructure and broader product base, to prepare for the successful launch of our next generation immunotherapies, while also growing our existing product sales. With a sales force now in place targeting our core allergy/asthma customers, we are well placed to capture the significant value of our innovative products, as we progress towards meeting our goal of becoming a self-sustaining specialty biopharmaceutical business.

<sup>1</sup> Acquisition of Aerocrine completed on 18 June; revenues recorded by Circassia from 19–30 June 2015

### Financial review

	Circassia £m	Acquisitions £m	Acquisition costs £m	Group 2015 £m	Circassia 2014 £m
Turnover	_	0.6	_	0.6	_
Gross profit	_	0.4	_	0.4	_
Sales and marketing	(1.5)	(0.7)	_	(2.2)	_
Research & development costs	(18.0)	(0.4)	_	(18.4)	(16.4)
Administrative expenditure	(3.0)	(0.2)	(4.0)	(7.2)	(3.1)
Other gains	1.1	` _	· -	1.1	· _
Operating loss	(21.4)	(0.9)	(4.0)	(26.3)	(19.5)
Finance income/(costs) net	0.1	(0.1)	` _	<u> </u>	0.1
Share of profit/(loss) of joint venture	0.3	· <u>-</u>	_	0.3	(0.2)
Loss before tax	(21.0)	(1.0)	(4.0)	(26.0)	(19.6)
Taxation	4.3	` _	` _	4.3	3.4
Loss for the financial period	(16.7)	(1.0)	(4.0)	(21.7)	(16.2)
Cash¹	231.8	7.1	_	238.9	186.6

<sup>&</sup>lt;sup>1</sup> Includes cash and cash equivalents and short-term deposits as at 30 June 2015.

Financially, the most significant event during the last six months was the completion of a successful £275 million Placing and Open Offer to fund two acquisitions, both of which completed in June. The acquisition of Prosonix Limited completed on 15 June and Aerocrine AB on 18 June.

The table above sets out the results for the Circassia Group, including the contribution from the acquired companies during the period of ownership and acquisition costs.

#### **Turnover**

Sales of  $\mathfrak{L}0.6$  million recorded by Aerocrine from 19 to 30 June account for the Group's turnover for the period. These revenues include sales of NIOX VERO and NIOX MINO for clinical use in the US, Europe and Asia Pacific, and for use in pharmaceutical companies' clinical studies.

#### **Gross profit**

Gross profit on the Aerocrine sales was £0.4 million, with a gross margin of 63%. This reflects the introduction of the NIOX VERO in the US with pricing options to drive conversion from the previous MINO model.

#### Sales and marketing

During the period, sales and marketing expenditure was £2.2 million (H1 2014: £Nil). Of this, £0.7 million related to Aerocrine and the remainder reflects the build of Circassia's commercial management in the US, and in particular recruitment of nine medical affairs specialists of which six are based in the United States. Their role will include educating specialists in preparation for the launch of the Company's first allergy treatment. Total headcount in Circassia sales and marketing was 14 at the end of the period (H1 2014: Nil).

#### Research and development activities

Investment in research and development activities increased to  $\mathfrak{L}18.4$  million (H1 2014:  $\mathfrak{L}16.4$  million). Of this,  $\mathfrak{L}18.0$  million relates to Circassia's portfolio of allergy candidates. This is mainly due to increases in the following:

- Recruitment of subjects into the house dust mite allergy phase Ilb field trial (TH005)
- Manufacture of active pharmaceutical ingredients and other CMC related activity in preparation for the grass allergy phase Ill clinical trial, for which the recruitment campaign is planned to begin in H1 2016
- Manufacture of active pharmaceutical ingredients for the Japanese cedar allergy and birch allergy products for use in clinical trials
- Increase in R&D headcount to 49 at the end of the period (H1 2014: 31)
- A £0.6 million charge in respect of new share options (H1 2014: £0.4 million)

These increases were offset to some degree by decreases in expenditure in the cat allergy phase III trial (CP007), which completed recruitment at the end of last year.

## Financial review continued

On 11 June 2015, the Company issued 95,469,537 Ordinary shares which funded the acquisitions of Aerocrine and Prosonix

#### **Administrative expenditure**

Administrative expenses, which include overheads specific to corporate functions, centrally managed support functions and corporate costs, increased to  $\mathfrak{L}7.2$  million (H1 2014:  $\mathfrak{L}3.1$  million). The increase reflects one-off deal costs of  $\mathfrak{L}4.0$  million relating to the Aerocrine and Prosonix acquisitions (total deal costs for the acquisitions were  $\mathfrak{L}12.8$  million, with the remaining  $\mathfrak{L}8.8$  million offset against the Share Premium Account). Underlying administrative expenditure decreased by  $\mathfrak{L}0.1$  million, which includes a charge for option awards of  $\mathfrak{L}0.5$  million (H1 2014:  $\mathfrak{L}0.4$  million). Total headcount in Circassia  $\mathfrak{L}8.4$  was 15 at the end of the period (H1 2014: 15).

#### Other gains

A net gain of £1.1 million was made on forward contracts for Swedish krona and US dollars that were taken out to hedge against the purchase of Aerocrine and the associated repayment of a USD35 million loan that became due on change of control. The gain reflects the weakening of GBP Sterling against Swedish krona during the term of the contracts.

#### Net finance income/costs

Net finance income/costs decreased to £Nil (H1 2014: net finance income £0.1 million). Excluding net finance costs of £0.1 million from Aerocrine, underlying net income of £0.1 million remains unchanged compared to the previous year.

#### R&D tax credits on qualifying expenditure

A tax credit of £4.3 million (H1 2014: £3.4 million) is recoverable under current legislation relating to R&D expenditure. The increase over the previous year reflects greater R&D expenditure during H1 2015 and a lower tax credit rate for part of the 2014 period, when it increased from 11% to 14.5% on 1 April 2014.

#### Loss after tax and loss per share

Basic loss per share was 11p (H1 2014: 11p) reflecting a loss for the financial period of £21.7 million (H1 2014: £16.2 million). Although there has been an increase in the Company's Ordinary Share capital following the issue of 95.5 million shares under the Placing and Open Offer in June 2015, there has been no change in the basic loss per share because the loss for the financial period has increased proportionately. Note 14 to the interim financial statements provides a full explanation of the change in share capital.

#### **Acquisition of Aerocrine and Prosonix**

On 11 June 2015, the Company issued 95,469,537 Ordinary shares which funded the acquisitions of Aerocrine and Prosonix. The shares were offered at 288.05p each, raising gross proceeds of £275.0 million.

The consideration for Aerocrine's entire outstanding ordinary share capital of 698,767,052 shares, and employee share options that vested on change of control, is £138.3 million. At 30 June, 92.6% of the share capital had been purchased, and by 2 July 2015, following an extension of the initial offer period, this increased to 97.2%. The remaining 2.8% of the share capital will be purchased as part of the formal compulsory acquisition process. Advance title to these shares is expected to be granted to Circassia within approximately six to nine months, which will provide 100% effective ownership. On 29 June 2015, Circassia paid USD45.1 million (£28.7 million) to OrbiMed and Novo in settlement of Aerocrine's USD35 million loan that became due on change of control together with repayment costs and interest.

The purchase price for Prosonix' entire outstanding share capital was £100 million. Of this, £30 million is deferred and contingent upon receipt of UK marketing authorization for Prosonix' lead product, which is expected in H2 2015.

 ...we are fully funded to bring our cat allergy product to market, deliver our wider portfolio and attain our goal of reaching profitability

Deal costs relating to the acquisitions and the share issue were £12.8 million, of which £8.8 million was offset against the Share Premium Account and £4.0 million of indirect Admission costs were included in the income statement. Of the £8.8 million, £0.8 million was included in trade payables at 30 June 2015 and of the £4.0 million, £0.2 million was included in trade payables and £3.5 million in accruals at 30 June 2015.

#### Statement of financial position

The Group's net assets at 30 June 2015 were £436.9 million (31 December 2014: £190.8 million). The increase reflects the acquisition of Aerocrine and Prosonix, which has been included in the balance sheet at fair value. The detailed preliminary fair values for each company together with goodwill arising are set out in note 4. Deferred consideration of £30.0 million for the purchase of Prosonix has also been recorded and is contingent on receipt of UK marketing authorization for its lead product.

Current tax assets were £13.9 million (2014: £8.8 million), representing the R&D tax credit due from H M Revenue and Customs. Of this, £12.9 million related to the underlying Circassia business and £1.0 million to Prosonix. Of the £12.9 million, £8.6 million was due at 31 December 2014 and £4.3 million arose during H1 2015. Receipt of last year's claim is anticipated before the end of the year.

The tax credit of  $\mathfrak{L}1.0$  million due to Prosonix is for expenditure incurred in the period 1 April 2014 – 30 June 2015.

#### Cash flow

The Group's cash position (including short-term deposits) increased from £186.6 million at 31 December 2014 to £238.9 million at 30 June 2015. Main cash flows were:

- Gross proceeds of £275.0 million from the Placing and Open Offer (H1 2014: gross proceeds of £202.0 million from the IPO). Of the £8.8 million deal costs offset against the Share Premium Account, £8.0 million has been paid.
- Loan repayment of USD45.1 million that became due on the acquisition of Aerocrine. This comprises the USD35 million (£22.3 million) principal, repayment costs of USD9.0 million (£5.7 million), pre-acquisition interest of USD1.0 million (£0.6 million) and post-acquisition interest of USD0.1 million (£64,000).
- Cash paid for the acquisitions of Aerocrine and Prosonix was £199.6 million. This includes a payment of £70.0 million in respect of Prosonix and £129.6 million in respect of Aerocrine. Of the £129.6 million, £0.9 million was paid in respect of settlement of share options, which vested on change of control. Cash received on the acquisition of Aerocrine and Prosonix was £32.4 million and £5.3 million respectively.

#### Summary and outlook

During the next six months, we will continue to ensure our allergy programs remain on track. In addition, we intend to complete the integration of Aerocrine and Prosonix, and to commit significant investment in our commercial infrastructure to prepare for the launch of our first allergy product and boost sales of our existing NIOX products.

We have an extremely robust balance sheet, with cash of £238.9 million as at 30 June 2015. Consequently, we are fully funded to bring our cat allergy product to market, deliver our wider portfolio and attain our goal of reaching profitability.

## Principal risks and uncertainties

The risk information disclosed here is more extensive than usual for an interim announcement in order to reflect the changes in the Group's risk profile as a result of the acquisitions made in the period. 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 has been created and is updated periodically by those individuals in the business who manage risks on a day to day basis. This process is coordinated by the CFO. 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 which are designed to mitigate the identified risks, and again the Board and the Senior Management Team analyze 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 once a month at which progress and risks of each individual project is discussed. These discussions are then documented 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 Company considers all of these risks relevant to any decision to invest in it.

#### Regulatory approvals and compliance

The Group may not obtain regulatory approval for those of its products which are in development. Even where products are approved, subsequent regulatory difficulties may arise, or the conditions relating to the approval may be more onerous or restrictive than the Group expects, or existing approvals might be withdrawn.

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

The Group's lead product candidate is in development for the treatment of cat allergy. Failure to obtain regulatory approval for this lead product, or significant delays in obtaining approval, would have a material adverse effect on the Group's business. This risk can be further divided into a number of component risks, each of which require distinct mitigation strategies. These include a failure to complete the phase III registration study and supporting studies; inability to demonstrate efficacy of the product after moving to field studies from chamber studies; and any problems which might arise in validating the manufacturing process for the active pharmaceutical ingredient in the product.

The Group already holds regulatory approvals for the NIOX MINO and NIOX VERO devices in certain key countries such as the United States, Japan, and Germany but approvals are still pending in a number of other countries. In addition, the Group has applied for approval of its fluticasone propionate product on the basis of in vitro equivalence data only – in accordance with European Guidelines – but it is possible that further studies will be required by the regulator before approval is granted. Delays or complications in any of these regulatory applications could adversely affect the Group's business.

In order to obtain regulatory approval for the Group's products, it will be necessary to successfully complete 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.

The Group relies on third party sub-contractors and service providers for the execution of most aspects of its development programs. 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 programs.

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.

With regard to the risks specifically identified in relation to the cat allergy product candidate, it is of note that recruitment for the phase III study has now been successfully completed; allergen levels used in the exposure chamber have been shown to be comparable to those experienced with an indoor cat; and three validation batches have now been manufactured, giving comfort that the manufacturing process is robust.

#### Unforeseen side effects

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

There is a risk of adverse reactions with all drugs and there is a risk that the malfunction of a medical diagnostic may have an adverse impact on patients. If any of the Group's products are found to cause adverse reactions or unacceptable side effects or risk of misdiagnosis, then product development may be delayed, additional expenses may be incurred if further studies or product development work 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.

Adverse events or unforeseen side effects or device malfunction may also potentially lead to product liability claims being raised against the Group as the developer of the products and sponsor of the relevant clinical trials.

Mitigating activities: The Group conducts extensive pre-clinical and clinical trials which test for and identify any adverse side effects of its novel drug candidates. Its medical diagnostic products are subject to rigorous testing procedures. A robust pharmacovigilance plan is in place to ensure any safety issues are identified and reported. A Risk Evaluation and Mitigation Strategy (REMS) has also been developed to ensure that the benefits of the cat allergy product are balanced against any risks. Insurance is in place to cover product liability claims which may arise during the conduct of clinical trials or sales of the Group's NIOX MINO and NIOX VERO products.

#### Commercial success

The Group may not be able to sell its products profitably if reimbursement from third party payers such as private health insurers and government health authorities is restricted or not available 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 Group's competitors – many of whom have considerably greater financial and human resources – may develop safer or more effective products or be able to compete more effectively in the markets targeted by the Group. New companies may enter these markets and novel products and technologies may become available which are more commercially successful than those being developed by the Group.

The Group's NIOX MINO and NIOX VERO devices compete with products made by Bedfont Limited and Medisoft SA. Neither of these competing products are currently available in the US. Outside the US and Germany 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 will, when launched, be largely dependent upon its partner Mylan who has the rights to sell the product in most major markets. Moreover, this product and certain other drug products being developed by the Group for treatment of asthma, are generic products and so will compete with the innovator products as well as potentially generics from other third parties.

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

Mitigating activities: In the context of the cat allergy product, thorough market research will be carried out prior to product launch and the findings will be used to generate effective and appropriately resourced marketing campaigns. This will emphasize the attributes which differentiate the product from its competitors, for example its short dosing regimen and lack of side effects. A disease awareness campaign will be developed and implemented. Pricing and reimbursement studies and health economic data will be used to support the value proposition which will be presented to payers. The Group has recently launched the NIOX VERO in the US and Japan and launch in China is expected shortly. This device offers advantages over the NIOX MINO (in terms of portability, enhanced life, and better interface). There are courses of action available in the event that insufficient diligence is applied to the marketing of the prospective fluticasone propionate product.

## Principal risks and uncertainties continued

#### Sales and data privacy compliance

The Group must comply with complex regulations in relation to the marketing of its device products (and in the future will need to comply with such regulations in relation to its drug products). These regulations are strictly enforced, particularly in the US. 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) may result in criminal and civil proceedings against the Group.

Mitigating activities: The Group has an internal compliance function which currently reports to the Chief Medical Officer of Aerocrine AB. This 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. Robust processes are in place to ensure that sales compliance requirements are met and any failures or allegations of failure are swiftly investigated.

#### Supply chain

The Group relies on third party contractors 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. Some materials may only be available from one source, as is currently the case for the peptides contained in the cat allergy product, and the sensors for the NIOX MINO and NIOX VERO devices and regulatory requirements may make substitution costly and time-consuming, particularly where the product is regulated as a biologic as is the case for the Group's allergy immunotherapy products in the US.

Mitigating activities: Audits of sub-contractors are routinely conducted according to procedures set out in the Group's Quality system. Dual sourcing is being investigated where this is practicable. Manufacturing sites are well established FDA-approved facilities.

#### Research and development risks

The Group may not be successful in its efforts to use and expand its allergy immunotherapy technology platform, Toleromune®, to build a pipeline of products and develop marketable products. This would have a material impact on the long term success of the business. Failure of programs could result from lack of internal resources or capabilities, or from not obtaining the desired preclinical and clinical results.

In addition, the Group is dependent upon external collaborators for the development of certain of its products. The Group relies upon its collaborations with Panasonic for the development of the NIOX devices and the potential home use device and upon IHG for the development of the sensors contained in those devices.

Mitigating activities: The Group 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. The development collaboration with Panasonic is managed by a steering committee with representatives from the Group. In addition, the Group will seek, through business development activity, to identify opportunities which would expand and diversify its portfolio.

#### Intellectual property, know how, and trade secrets

The Group may be subject to challenges relating to the validity of its patents. If these challenges are successful then the Group may be exposed to generic competition. Four of the Group's granted European patents (three patents relevant to the cat allergy product and a fourth relevant to the SAX process) are currently the subject of opposition proceedings at the European Patent Office. If the opponents are successful then the patent protection for these products in Europe will be reduced or even eliminated.

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

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

The Group licenses certain intellectual property rights from third parties. If the Group fails to comply with its obligations under these agreements it may enable the other party to terminate the agreement. This could impair the Group'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 attacks on patents are defended using expert external patent attorneys and lawyers. A robust system is in place which ensures patents are renewed on time. Third party patent filings are monitored to ensure the Group continues to have freedom to operate and oppositions are filed where this is considered expedient. Confidential information (both of the Group 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 Group's employment contracts. Licences are monitored for compliance with their terms.

With regard to the oppositions against the three cat allergy product patents, detailed submissions have been filed in response to the submissions of the anonymous opponents. A robust defence will also be filed in response of the opposition to the SAX patent which has been brought by Vectura.

#### 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. More particularly, the rapid development which is envisaged may place unsupportable demands on the Group's current managers and employees, particularly if it cannot attract sufficient new employees. The Group depends on the skills and experience of its current management team and employees, and is generally subject to competition for, and may fail to retain, skilled personnel.

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

Where the Group acquires complementary technologies, products, or businesses it may not be able to integrate those acquisitions effectively or realize their expected benefits. The Group is currently integrating the operations of Aerocrine AB and Prosonix Limited which it acquired on 18 June and 15 June respectively.

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

Mitigating activities: The Group has budgeted for substantial growth in headcount over the next 3 years. The management team has already been strengthened in the course of 2014 by the recruitment of a Chief Commercial Officer, General Counsel and Vice President of Human Resources and in 2015 by the appointment of a Chief Business Officer. 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.

#### Free float

The UK Listing Authority requires listing issuers to maintain at least 25% free float in their listed shares. Following the acquisitions of Aerocrine AB and Prosonix Limited in June 2015 the Company had a free float of approximately 19% at 30 June 2015. If the level of free float cannot be increased to 25% then the UKLA may 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 Group has incurred significant losses since the inception of its various businesses (including those of its recently acquired companies Aerocrine AB and Prosonix Limited) and anticipates that it will continue to do so, at least until it is able to launch its allergy immunotherapy products.

Foreign exchange fluctuations may adversely affect the Group's results and financial condition. The Group records its transactions and prepares its financial statements in pounds sterling, but a significant proportion of its expenditure is in US dollars, Swedish krona, Canadian dollars, Swiss Francs, 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 Group, and its joint venture Adiga Life Sciences Inc. currently receive in the United Kingdom and Canada respectively.

Mitigating activities: The Group has prepared a detailed forecast for the next 10 years and, if it achieves its objectives, this shows that the current business plan is sufficient to take the Group through to profitability. 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 in order to ensure there remained sufficient cash to support the business through to profitability.

The changes in the Group's financial risk management policies are detailed in Note 2 to the condensed interim financial statements.

## Condensed interim consolidated statement of comprehensive income

For the six months ended 30 June 2015

	Notes	30 June 2015 £'000 Unaudited	30 June 2014 £'000 Unaudited
Revenue		574	
Cost of sales		(213)	
Gross profit		361	_
Research and development costs		(18,386)	(16,452)
Sales and marketing Administrative expenses		(2,144) (7,215)	(3,092)
Other gains		1,065	(0,002)
Operating loss	5	(26,319)	(19,544)
Finance costs		(990)	(476)
Finance income		1,035	566
Finance income - net	6	45	90
Share of profit/(loss) of joint venture	11	294	(166)
Loss before tax		(25,980)	(19,620)
Taxation	7	4,246	3,378
Loss for the financial period		(21,734)	(16,242)
Loss attributable to:		(21,670)	(16,242)
Owners of Circassia Pharmaceuticals plc		(64)	<del>-</del>
Non-controlling interest		(21,734)	(16,242)
Loss for the financial period			
Other comprehensive expense			
Items that may be subsequently reclassified to profit or loss:		(4.7)	<b>(→</b> )
Share of other comprehensive expense of joint venture Currency translation differences	11	(17) (2,416)	(7)
Total other comprehensive expense for the period		(24,167)	(16,249)
Total comprehensive synamos attributable to			
Total comprehensive expense attributable to: Owners of Circassia Pharmaceuticals plc		(24,110)	(16,249)
Non-controlling interest		(57)	(10,210)
Total other comprehensive expense for the period		(24,167)	(16,249)
Loss per share			
Loss per share from continuing operations attributable to			
the equity holders of the parent during the period	12	(£0.11)	(£0.11)

## Condensed interim consolidated statement of financial position

As at 30 June 2015

Assets   Non-current assets   Property, plant & equipment   8		Notes	30 June 2015 £'000	30 June 2014 £'000
Non-current assets		Notes	Unaudited	Unaudited
Property, plant & equipment   8				
Goodwill         10         101,665         1,835           Other intangible assets         9         165,287         215           Investment in joint venture         11         380         103           Livestment in joint venture         11         380         103           Current assets         11         380         103           Inventory         2,609         -           Trade and other receivables         6,071         2,649           Current assets         7         13,665         8,824           Corrent bank deposits         102,717         156,874           Cash and cash equivalents         102,717         156,874           Cash and cash equivalents         530,373         200,525           Equity and liabilities         261,439         198,063           Total assets         530,373         200,525           Equity and liabilities         228         15           Equity attributable to the owners of the parent company         14         228         15           Ordinary shares         14         228         15           Share option reserve         1,2,811         (6           Other reserves         15         (2,881)         (6		0	1 476	200
Other intangible assets Investments         9         165,287         215           Investment in joint venture         11         380         133           Investment in joint venture         11         380         133           Current assets         26,699		_		
Investment is   1				
Investment in joint venture		9	·	210
Current assets         2,609		11		103
Current assets         1         2,609         1           Trade and other receivables         6,071         2,649           Current tax assets         7         13,865         8,824           Short term bank deposits         102,717         156,874           Cash and cash equivalents         136,177         29,716           Total assets         530,373         200,525           Equity and liabilities         Equity and liabilities         Equity and liabilities           Equity attributable to the owners of the parent company         1         28         15           Ordinary shares         14         228         152           Share premium         14         564,028         297,938           Share option reserve         2,687         1,305           Translation reserve         15         (289)         1-           Other reserves         15         (289)         1-           Accumulated losses         130,000         (108,630           Non-controlling interests         2,961         -           Total equity         436,934         190,759           Liabilities         1         41,028         -           Total liabilities         7         41,028         -<	,		268,934	2,462
Inventory   2,609   -1   -1   -1   -1   -1   -1   -1   -	Current assets		<u> </u>	
Trade and other receivables         6,071         2,649           Current tax assets         7         13,865         8,824           Short term bank deposits         102,717         156,874           Cash and cash equivalents         136,177         29,716           261,439         198,063           Total assets         530,373         200,525           Equity and liabilities           Equity attributable to the owners of the parent company           Ordinary shares         14         228         152           Share premium         14         564,028         297,938           Share option reserve         2,687         1,305           Share option reserve         15         (2,89)         -           Other reserves         15         (2,89)         -           Accumulated losses         (130,300)         (108,630           Non-controlling interests         2,961         -           Total equity         436,934         190,759           Liabilities         7         41,028         -           Deferred income tax liabilities         7         41,028         -           Trade and other payables         22,411         9,766			2.609	_
Current tax assets         7         13,865         8,824           Short term bank deposits         102,717         156,874           Cash and cash equivalents         261,439         198,063           Total assets         530,373         200,525           Total assets         530,373         200,525           Equity and liabilities           Equity and liabilities         Equity attributable to the owners of the parent company           Ordinary shares         14         228         152           Share option reserve         14         564,028         297,938           Share option reserve         2,687         1,305           Translation reserve         (2,381)         6           Other reserves         15         (289)         -           Accumulated losses         (130,300)         (108,630           Accumulated losses         433,973         190,759           Non-controlling interests         2,961         -           Total equity         436,934         190,759           Liabilities         7         41,028         -           Deferred income tax liabilities         7         41,028         -           Current liabiliti			•	2,649
Short term bank deposits         102,717         156,874           Cash and cash equivalents         136,177         29,716           261,439         198,063           Total assets         530,373         200,525           Equity and liabilities         Equity attributable to the owners of the parent company         Value         Value         152         152         152         152         153         152         153<		7		8,824
Cash and cash equivalents         136,177         29,716           261,439         198,063           Total assets         530,373         200,525           Equity and liabilities         Equity attributable to the owners of the parent company         14         228         152           Chair premium         14         564,028         297,938 <th< td=""><td>Short term bank deposits</td><td></td><td>102,717</td><td>156,874</td></th<>	Short term bank deposits		102,717	156,874
Total assets         530,373         200,525           Equity and liabilities         Equity attributable to the owners of the parent company           Ordinary shares         14         228         152           Share permium         14         564,028         297,938           Share option reserve         2,687         1,305           Translation reserve         (2,381)         (6           Other reserves         15         (289)           Accumulated losses         (130,300)         (108,630           Non-controlling interests         2,961         -           Total equity         436,934         190,759           Liabilities         Non-Current liabilities         -           Non-Current liabilities         7         41,028         -           Total liabilities         41,028         -           Current liabilities         22,411         9,766           Contingent consideration         4         30,000         -           52,411         9,766				29,716
Equity and liabilities           Equity attributable to the owners of the parent company         14         228         152           Ordinary shares         14         564,028         297,938           Share permium         14         564,028         297,938           Share option reserve         2,687         1,305           Translation reserve         (2,381)         (6           Other reserves         15         (289)         -           Accumulated losses         (130,300)         (108,630           Non-controlling interests         2,961         -           Total equity         436,934         190,759           Liabilities         Non-Current liabilities         7         41,028         -           Total liabilities         7         41,028         -           Current liabilities         7         41,028         -           Contingent consideration         4         30,000         -           Contingent consideration         4         30,000         -			261,439	198,063
Equity attributable to the owners of the parent company           Ordinary shares         14         228         152           Share premium         14         564,028         297,938           Share option reserve         2,687         1,305           Translation reserve         (2,381)         (6           Other reserves         15         (289)         -           Accumulated losses         (130,300)         (108,630           Non-controlling interests         2,961         -           Total equity         436,934         190,759           Liabilities         Non-Current liabilities         7         41,028         -           Deferred income tax liabilities         7         41,028         -           Total liabilities         41,028         -           Current liabilities         22,411         9,766           Contingent consideration         4         30,000         -           -         52,411         9,766	Total assets		530,373	200,525
Share premium       14       564,028       297,938         Share option reserve       2,687       1,305         Translation reserve       (2,381)       (6         Other reserves       15       (289)       -         Accumulated losses       (130,300)       (108,630         Non-controlling interests       2,961       -         Total equity       436,934       190,759         Liabilities       Non-Current liabilities       7       41,028       -         Non-Current liabilities       7       41,028       -         Total liabilities       7       41,028       -         Current liabilities       22,411       9,766         Contingent consideration       4       30,000       -         52,411       9,766         52,411       9,766	Equity attributable to the owners of the parent company			
Share option reserve       2,687       1,305         Translation reserve       (2,381)       (6         Other reserves       15       (289)       -         Accumulated losses       (130,300)       (108,630         Non-controlling interests       2,961       -         Total equity       436,934       190,759         Liabilities       Non-Current liabilities       7       41,028       -         Non-Current liabilities       7       41,028       -         Total liabilities       41,028       -         Current liabilities       22,411       9,766         Contingent consideration       4       30,000       -         52,411       9,766         52,411       9,766		14		152
Translation reserve         (2,381)         (6           Other reserves         15         (289)         -           Accumulated losses         (130,300)         (108,630)           Non-controlling interests         2,961         -           Total equity         436,934         190,759           Liabilities         Non-Current liabilities           Deferred income tax liabilities         7         41,028         -           Total liabilities         41,028         -           Current liabilities         22,411         9,766           Contingent consideration         4         30,000         -           52,411         9,766	·	14		
Other reserves       15       (289)       -         Accumulated losses       (130,300)       (108,630)         Non-controlling interests         10tal equity       436,934       190,759         Liabilities         Non-Current liabilities         Deferred income tax liabilities       7       41,028       -         Total liabilities       41,028       -         Current liabilities       22,411       9,766         Contingent consideration       4       30,000       -         52,411       9,766	·			1,305
Accumulated losses         (130,300)         (108,630)           Non-controlling interests         433,973         190,759           Non-controlling interests         2,961         —           Total equity         436,934         190,759           Liabilities         Non-Current liabilities         7         41,028         —           Deferred income tax liabilities         7         41,028         —         —           Total liabilities         41,028         —         —         —           Current liabilities         22,411         9,766         —         —           Contingent consideration         4         30,000         —         —           52,411         9,766         —         —         —         —         —				(6)
Non-controlling interests   2,961		15	· · ·	<del>-</del>
Non-controlling interests         2,961         —           Total equity         436,934         190,759           Liabilities         Non-Current liabilities           Deferred income tax liabilities         7         41,028         —           Total liabilities         41,028         —           Current liabilities         22,411         9,766           Contingent consideration         4         30,000         —           52,411         9,766	Accumulated losses		(130,300)	(108,630)
Total equity 436,934 190,759  Liabilities  Non-Current liabilities  Deferred income tax liabilities 7 41,028 -  Total liabilities  Current liabilities  Trade and other payables Contingent consideration 4 30,000 -  52,411 9,766			433,973	190,759
Liabilities Non-Current liabilities Deferred income tax liabilities 7 41,028 -  Total liabilities 41,028 -  Current liabilities Trade and other payables Contingent consideration 4 30,000 -  52,411 9,766	Non-controlling interests		2,961	
Non-Current liabilities  Deferred income tax liabilities  7 41,028  - Total liabilities  Current liabilities  Trade and other payables Contingent consideration  4 30,000  - 52,411 9,766	Total equity		436,934	190,759
Deferred income tax liabilities 7 41,028 —  Total liabilities 41,028 —  Current liabilities  Trade and other payables 22,411 9,766 Contingent consideration 4 30,000 —  52,411 9,766	Liabilities			
Total liabilities 41,028 —  Current liabilities  Trade and other payables Contingent consideration 4 30,000 —  52,411 9,766				
Current liabilities Trade and other payables Contingent consideration  4  22,411  9,766  2000  52,411  9,766	Deferred income tax liabilities	7	41,028	
Trade and other payables         22,411         9,766           Contingent consideration         4         30,000         -           52,411         9,766	Total liabilities		41,028	
Contingent consideration         4         30,000         -           52,411         9,766				
<b>52,411</b> 9,766	· ·			9,766
	Contingent consideration	4	30,000	
<b>Total liabilities</b> 93,439 9,766			52,411	9,766
	Total liabilities		93,439	9,766
Total equity and liabilities 530,373 200,525	Total equity and liabilities		530,373	200,525

## Condensed interim consolidated statement of cash flows

For the six months ended 30 June 2015

		30 June 2015 £'000	30 June 2014 £'000
	Notes	Unaudited	Unaudited
Cash flows from operating activities			
Cash used in operations	13	(24,640)	(21,480)
Interest received		2,022	160
Interest paid		(25)	(7)
Tax credit received		190	
Net cash used in operating activities		(22,453)	(21,327)
Cash flows from investing activities			
Acquisition of subsidiaries, net of cash acquired		(189,975)	-
Purchase of intangibles	9	(163)	-
Decrease /(increase) in short term bank deposits		54,157	(143,354)
Net cash used in investing activities		(135,981)	(143,354)
Cash flows from financing activities			
Purchase of treasury shares	15	(289)	-
Proceeds from issue of ordinary shares		266,912	193,172
Net cash from financing activities		266,623	193,172
Net increase in cash and cash equivalents		108,189	28,491
Cash and cash equivalents at beginning of period		29,716	23,568
Exchange loss on cash and cash equivalents		(1,728)	(578)
Cash and cash equivalents at 30 June		136,177	51,481

## Condensed interim consolidated statement of changes in equity

	_			Attribu	table to owners	of the parent	Non-	
Group	Notes	Share capital £'000	Share premium £'000	Other reserves¹ £'000	Accumulated losses £'000	Total £'000	controlling interest £'000	Total equity £'000
At 1 January 2015 (audited)		152	297,938	1,299	(108,630)	190,759	_	190,759
Comprehensive expense: Loss for the year		_	_	-	(21,670)	(21,670)	(64)	(21,734)
Other comprehensive expense: Share of other comprehensive expense of joint venture	11	_	_	(17)	_	(17)	_	(17)
Currency translation differences	• •	_	_	(2,359)	_	(2,359)	(57)	(2,416)
Total comprehensive expense		_	_	(2,376)	(21,670)	(24,046)	(121)	(24,167)
Transactions with owners: Purchase of own shares Issue of Ordinary shares Employee share option scheme	15	- 76 -	266,090 -	(289) - 1,382	- - -	(289) 266,166 1,382	- - 19	(289) 266,166 1,401
Total contributions by				1,002		1,002	10	1,101
owners of the parent, recognized directly in equity	14	228	564,028	17	(130,300)	433,973	(102)	433,871
Acquisition of subsidiary							3,063	3,063
Total changes in ownership interests that do not result in a change in control recognized directly in equity							3,063	3,063
At 30 June 2015 (unaudited)		228	564,028	17	(130,300)	433,973	2,961	436,934
At 1 January 2014 (audited) Comprehensive expense: Loss for the year		65 -	103,403	56 -	(73,479) (16,242)	30,045 (16,242)	_ _	30,045 (16,242)
Other comprehensive expense: Share of other comprehensive expense of joint venture	11	_	_	_	(7)	(7)	_	(7)
Total comprehensive expense		-	_	_	(16,249)	(16,249)	-	(16,249)
Transactions with owners: Issue of Ordinary shares Capitalized reserves re bonus		54	194,528	-	-	194,582	-	194,582
shares at IPO Employee share option scheme		33	_	- 780	(33)	- 780	_	- 780
At 30 June 2014 (unaudited)	14	152	297,931	836	(89,761)	209,158		209,158
						<u> </u>		

 $<sup>^{\</sup>mbox{\tiny 1}}$  Other reserves includes the share option reserve, translation reserve and other reserves.

## 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 the UK. The address of its registered office is The Magdalen Centre, Robert Robinson Avenue, Oxford Science Park, Oxford, Oxfordshire, England, OX4 4GA.

These condensed interim financial statements were approved for issue on 28 July 2015.

These condensed 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 2014 were approved by the Board of Directors on 26 February 2015 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.

These condensed interim consolidated financial statements have been reviewed, but not audited.

#### **Basis of preparation**

These condensed interim consolidated financial statements for the six months ended 30 June 2015 have been prepared in accordance with the Disclosure and Transparency Rules of the Financial Conduct Authority (previously the Financial Services Authority) and with IAS 34, 'Interim financial reporting', as adopted by the European Union. The condensed interim financial statements should be read in conjunction with the annual financial statements for the year ended 31 December 2014, 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 believe it is appropriate to prepare the financial information on the going concern basis. This is because the Group's research into new products continues to progress according to plan and the additional funding secured following Admission in 2014, will allow the Group 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.

There are not considered to be any amendments to IFRS's effective for the financial year ending 31 December 2015 that would have a material impact on the Group.

#### Revenue

Revenue comprises the fair value of consideration received or receivable for the sale of goods and services in the ordinary course of the Group's activities. Revenue is shown net of value added tax and trade discounts and after elimination of intra-Group sales. Income is reported as follows:

#### Sale of goods

The Group sells medical technology equipment that enables inflammation of the airways to be measured as well as consumable items and spare parts. As the Group provides 12-month guarantees for these products, sales are reported as income when the significant risks and benefits have transferred to the buyer and the seller no longer has any significant control over the goods. Where a sale also includes an installation period, income is reported in full after the installation is completed.

#### Sale of services

The sale of services includes installation and training as well as the servicing of sold products. Services are sold at a fixed price and income is reported successively as the service is provided.

#### Licence income

Technology and product licensing revenue represents amounts earned for licences granted under licensing agreements, including up-front payments, milestone payments and technology access fees. Revenues are recognized when these are non-refundable, the Group's obligations related to the revenues have been completed and their payment is reasonably assured. Refundable licensing revenue is treated as deferred until such time that it is no longer refundable. In general, up-front payments are deferred and amortized in line with the period of development. Milestone payments relating to defined project achievements are recognized as income when the milestone is accomplished.

Royalty revenue is recognized on an accrued basis and represents income earned as a percentage of product sales in accordance with the relevant agreement net of any amounts payable to others.

#### Inventory

Inventories are valued at the lower of the acquisition cost and the net realisable value. The FIFO (first in, first out) principle is used to calculate the acquisition value for inventories mainly comprise products for sale and stocks of components for the service activities in Sweden and the US. The acquisition value comprises all expenses for purchases. The net realisable value is the expected sale price less expected costs for preparation and selling.

#### Intangible assets

Intangible fixed assets, relating to goodwill and intellectual property rights acquired through licensing or assigning patents and know how are carried at historic cost, less accumulated amortization, where the useful economic life of the asset is finite and the asset will probably generate economic benefits exceeding costs.

Goodwill arising on the acquisition of subsidiaries represents the excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition-date fair value of any previous equity interest in the acquiree over the fair value of the identifiable net assets acquired.

For the purpose of impairment testing, goodwill acquired in a business combination is allocated to each of the cash generating units (CGUs), or groups of CGUs, that is expected to benefit from the synergies of the combination. Each unit or group of units to which the goodwill is allocated represents the lowest level within the entity at which the goodwill is monitored for internal management purposes. Goodwill is monitored at the operating segment level.

Goodwill impairment reviews are undertaken annually or more frequently if events or changes in circumstances indicate a potential impairment. The carrying value of the CGU containing the goodwill is compared to the recoverable amount, which is the higher of value in use and the fair value less costs of disposal. Any impairment is recognized immediately as an expense and is not subsequently reversed.

Where a finite useful life of the acquired intangible asset cannot be determined, the asset is tested annually for impairment by allocating the assets to the cash generating units to which they relate. Amortization would commence when product candidates underpinned by the intellectual property rights become available for commercial use. Amortization would be calculated on a straight line basis over the shorter of the remaining useful life of the intellectual property or the estimated sales life of the product candidates. No amortization has been charged to date, as the product candidates underpinned by the intellectual property rights are not yet available for commercial use.

Expenditure on product development is capitalized as an intangible asset and amortized over the expected useful economic life of the product candidate concerned. Capitalization commences from the point at which technical feasibility and commercial viability of the product candidate can be demonstrated and the Group is satisfied that it is probable that future economic benefits will result from the product candidate once completed. Capitalization ceases when the product candidate receives regulatory approval for launch. No such costs have been capitalized to date.

Expenditure on research and development activities that do not meet the above criteria, including ongoing costs associated with acquired intellectual property rights and intellectual property rights generated internally by the Group, is charged to the statement of comprehensive income as incurred. Intellectual property and in-process research and development from acquisitions are recognized as intangible assets at fair value. Any residual excess of consideration over the fair value of net assets in an acquisition is recognized as goodwill in the financial statements.

#### Computer Software

Expenditure on software costs are capitalized as an intangible asset and amortized over the expected useful economic life of the software. Until such an asset is fully developed, the costs are capitalized and classified within intangibles assets as 'Software in development'. These costs are not amortized until the software has been fully developed and operational, at which point the total cost of the software development is amortized over its estimated useful life.

#### 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 2014 except as disclosed below.

#### Business combinations

The Group accounts for all business combinations under the acquisition method. Under the acquisition method, the identifiable assets acquired and liabilities and contingent liabilities assumed are measured at their fair value at the acquisition date. Judgements and estimates are made in respect of the measurement of the fair values of assets and liabilities acquired and consideration transferred. The consideration includes contingent consideration, which is measured at fair value taking into account the probability and timing of payment. Where necessary, the Group engages external valuation experts to advise on fair value estimates, or otherwise performs estimates internally.

#### Fair value of acquired assets

#### Intangibles Technology

In estimating the Fair Value of Technology, a variation of the Income Approach called the Relief from Royalty Method is used. This methodology is considered the standard and preferred technique to value assets such as trademark, core technology and patents.

#### Intangibles Customer Relationships and IPR&D

The Customer Relationships have been valued based on the Excess Earnings Method. This valuation method is based on discounting the cash flows that can be attributed to the intangible asset, after taking into account the contribution of other assets.

#### Deferred tax

The Group is subject to income taxes in numerous jurisdictions. Significant judgement is required in determining the worldwide provision for income taxes. There are many transactions and calculations for which the ultimate tax determination is uncertain. Note 7 provides more information on the tax rates assumed.

## Notes to the condensed interim consolidated financial statements continued

#### 2. Financial risk management

#### Financial risk factors

The condensed interim financial statements do not include all financial 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 2014. 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.

#### Fair value estimation

The table below analyzes the Group's financial instruments carried at fair value at 30 June 2015.

Liabilities	£'000
Contingent consideration	30,000
Total liabilities	30,000

The Group had no financial assets or liabilities measured at fair value at 31 December 2014.

Details regarding the contingent consideration are disclosed in note 4. The Group had no contingent consideration financial liabilities at either 1 January 2014 or 31 December 2014 and there were no transactions in contingent consideration during the year ended 31 December 2014. Therefore comparative information is not applicable.

#### 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 operating profit/loss.

The table presents profit information regarding the groups operating segments for the six months ended 30 June 2015. The group had one single operating segment in the period ended 30 June 2014.

	30 June 2015 Operating loss £'000
Circassia	(25,386)
Aerocrine	(749)
Prosonix	(184)
Total	(26,319)

#### 4. Business combinations

#### **Prosonix Limited**

On 15 June 2015, the Group acquired 100% of the share capital of Prosonix Limited, a specialty pharmaceutical company focused on the development of a portfolio of late stage asthma products and high value novel product candidates. The total consideration was £100.0 million. None of the goodwill is expected to be deductible for tax purposes.

The goodwill of £10.2 million arises from unrecognized assets such as the workforce.

The following table summarizes the consideration paid for Prosonix Limited, and the amounts of the assets acquired and liabilities assumed recognized at the acquisition date.

Consideration	£′000
Cash	70,000
Contingent consideration	30,000
Total consideration	100,000

Recognized amounts of identifiable assets acquired and liabilities assumed	£'000
Provisional fair value	
Cash and cash equivalents	5,255
Property, plant and equipment	797
Intangible assets (Technology)	19,179
Intangible assets (IPR&D)	88,700
Trade and other receivables	1,713
Trade and other payables	(4,304)
Deferred tax liabilities	(21,500)
Total identifiable net assets	89,840
Goodwill	10,160
Total consideration	100,000

The fair value of acquired identifiable intangible assets of £107.9 million is provisional pending receipt of the final valuations for those assets. Owing to the proximity of acquisitions to the reporting date, there may be some reclassifications when reporting at year end. A deferred tax asset has not been recognized pending receipt of the final valuations.

The contingent consideration arrangement requires the Group to pay the former owners of Prosonix Limited £30 million in the event that Prosonix receives a product marketing authorisation in respect of Prosonix' lead product in the United Kingdom on or before 31 December 2016 and £15 million on or before 31 December 2017.

The potential undiscounted amount of all future payments that the Group could be required to make under this arrangement is therefore between £nil and £30 million.

The fair value of the contingent consideration is considered to be equal to its book value as payment is anticipated by H2 2015. This is based on the expectation at the date of acquisition and to date there has been no change in this expectation. This is a level 3 fair value measurement.

The fair value of trade and other receivables is £1.7 million and includes trade receivables with a fair value of £0.08 million. The gross contractual amount for trade receivables due is £0.08 million.

The revenue included in the consolidated income statement from 16 June 2015 to 30 June 2015 contributed by Prosonix Limited was £nil. Prosonix Limited contributed a loss of £0.07 million for the same period.

Had Prosonix Limited been consolidated from 1 January 2015, the consolidated income statement for the six months ended 30 June 2015 would show pro-forma revenue in respect of Prosonix Limited of £1.3 million and pro-forma profit of £1.2 million.

#### **Aerocrine AB**

On 18 June 2015, the Group acquired 92.6% of the share capital of Aerocrine AB. The company offers two market-leading products, which are sold to the Group's core customers of allergy/asthma specialists by an established commercial infrastructure in the US and Germany (Europe's largest allergy market), and by a network of partners in additional territories. The products, NIOX MINO and NIOX VERO, are used to improve asthma diagnosis and management by measuring fractional exhaled nitric oxide (FeNO), and are the only device available across major markets.

The products are an ideal strategic fit with the Group's commercialization approach, with sales forces targeting specialists in key markets, partners undertaking promotion in other countries and the potential for primary care sales through partnering.

With a strong commercial infrastructure already established, with reimbursement, market access, supply chain and marketing expertise in place, there is an opportunity to scale-up this presence in the near-term as well as expanding into further EU territories. The Group plans to increase the existing field forces, complete training on the Group's allergy products, map out key accounts and build customer relationships well in advance of the launch of the Group's cat allergy product. As a result, the Group aims to accelerate uptake of its cat allergy product and achieve higher peak sales, which research suggests have the potential to reach over \$500 million per annum. In addition, this commercial investment is expected to drive greater NIOX sales, which are targeting a market opportunity of approximately \$190 million in the US allergy/asthma specialist segment alone.

The consideration paid at acquisition was 1.7 billion SEK, equivalent to £128.7 million. None of the goodwill is expected to be deductible for tax purposes.

The goodwill at acquisition of £90.3 million arises from future customer relationships and sales force synergies.

The following table summarizes the consideration paid for Aerocrine AB, and the amounts of the assets acquired and liabilities assumed recognized at the acquisition date.

£'000
128,675
128,675

# Notes to the condensed interim consolidated financial statements continued

Recognized amounts of identifiable assets acquired and liabilities assumed	£'000
Provisional fair value	
Cash and cash equivalents	32,420
Property, plant and equipment	466
Intangibles (Customer relationships)	29,900
Intangibles (Technology)	28,248
Inventories	2,303
Trade and other receivables	4,160
Trade and other payables	(8,031)
Other financial investments	226
Borrowings	(28,397)
Net deferred tax assets/(liabilities)	(19,900)
Total identifiable net assets	41,395
Non-controlling interest	(3,063)
Goodwill	90,343
Total consideration	128,675

The fair value of acquired identifiable intangible assets of £58.1 million is provisional pending receipt of the final valuations for those assets. Owing to the proximity of acquisitions to the reporting date, there may be some reclassifications when reporting at year end. A deferred tax asset has not been recognized pending receipt of the final valuations.

The non-controlling interest has been recognized as a proportion of net assets acquired.

The revenue included in the consolidated income statement from 19 June 2015 to 30 June 2015 and contributed by Aerocrine AB was £0.6 million. Aerocrine AB also contributed an operating loss of £0.7 million over the same period.

Had Aerocrine AB been consolidated from 1 January 2015, the consolidated income statement for the six months ended 30 June 2015 would show pro-forma revenue in respect of Aerocrine AB of  $\mathfrak{L}9.1$  million and pro-forma operating loss of  $\mathfrak{L}12.4$  million.

#### 5. Operating loss

Included within the operating loss to 30 June 2015 are acquisition-related costs of £4.0 million (H1 2014: £0.2 million relating to costs of Admission), which have been expensed against the income statement. All other costs of acquisition (2014: Admission) have been offset against the Share Premium Account.

#### 6. Finance income and costs

	Six months ended 30 June 2015 £'000	Six months ended 30 June 2014 £'000
Finance costs:		
Bank charges payable	(7)	(9)
Interest payable on loan notes	(194)	_
Loss on foreign exchange	(789)	(467)
Total finance costs	(990)	(476)
Finance income:		
Bank interest receivable	1,035	566
Total finance income	1,035	566
Net finance income	45	90

#### 7. Taxation

#### R&D tax credit

The amount included in the interim financial statements for the six months ended 30 June 2015 and 2014 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 11% for expenditure up to 31 March 2014 and at a rate of 14.5% for qualifying expenditure from 1 April 2014 onwards, being the prevailing R&D tax credit rates at the time. An uplift of 125% has been applied to all qualifying expenditure in line with R&D tax rules.

#### **Deferred tax liability**

A total deferred tax liability of £41.0 million exists at 30 June 2015. The balance is broken down as follows:

	£'000
At 1 January	_
Arising on acquisition of Aerocrine (note 4)	19,900
Arising on acquisition of Prosonix (note 4)	21,500
Exchange differences	(372)
At 30 June	41,028

The deferred tax liability arising upon the acquisition of Aerocrine is equal to approximately 35% of the intangible assets acquired.

The deferred tax liability arising upon the acquisition of Prosonix Limited is equal to 20% of the intangible assets acquired.

#### **Deferred tax asset**

The Group has an unrecognized deferred tax asset in respect of:

	30 June 2015 £'000	31 December 2014 £'000
Losses	53,266	15,323
Accelerated capital allowances	43	43
Other	1,965	1,337
At 30 June	55,274	16,703

In light of the continuing losses, recovery of the deferred tax asset is not sufficiently certain, and therefore no asset has been recognized.

#### 8. Property, plant and equipment

	£'000
Six months ended 30 June 2015:	
Opening net book amount as at 1 January 2015	309
Acquisition of subsidiary (note 4)	1,263
Depreciation and amortization	(96)
Closing net book amount as at 30 June 2015	1,476

The group held no property, plant and equipment at 30 June 2014.

# Notes to the condensed interim consolidated financial statements continued

#### 9. Intangible assets

	IPR&D £'000	Customer relationships £'000	Technology £'000	Other £'000	intangible assets £'000
Six months ended 30 June 2015:					_
Opening net book amount	_	_	_	215	215
Acquisition of subsidiaries (note 4)	88,700	29,900	47,427	_	166,027
Additions	_	_	_	163	163
Depreciation and amortization	-	_	_	(27)	(27)
Foreign exchange loss on intangibles acquired	_	(560)	(531)	_	(1,091)
Closing net book amount as at 30 June 2015	88,700	29,340	46,896	351	165,287
Six months ended 30 June 2014:					
Opening net book amount	_	_	_	437	437
Additions	_	_	_	_	_
Depreciation and amortization	_	_	_	_	_
Impairment	_	_	_	(260)	(260)
Closing net book amount as at 30 June 2014	-	-	_	177	177

Total

#### 10. Goodwill

	Total goodwill £'000
As at 1 January 2015 and 2014	1,835
Acquisition of subsidiaries (note 4)	100,503
Additional consideration transferred post acquisition	918
Foreign exchange difference on goodwill at period end	(1,691)
At 30 June 2015	101,565

The allocation of goodwill to cash generating units, on the acquisition of Aerocrine and Prosonix, will be presented in the Annual report for the year ending 31 December 2015. The group paid £0.9 million to settle the fair value of vested share options. This has been treated as additional consideration paid for Aerocrine, increasing goodwill.

#### 11. Investment in joint venture

	Six months ended 30 June 2015 £'000	Year ended 31 Dec 2014 £'000	Six months ended 30 June 2014 £'000
At 1 January	103	195	195
Share of profit/(loss)	294	(82)	(166)
Foreign exchange difference on consolidation	(17)	(10)	(7)
At period end	380	103	22

#### 12. 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 year.

		2015	2014
Loss from continuing operations attributable to ordinary equity ow	ners		
of the parent company	(£'000)	(21,670)	(16,242)
Weighted average number of Ordinary shares in issue	Number	199,496,974	148,366,886
Loss per share		(£0.11)	(£0.11)

As net losses from continuing operations were recorded in 2015 and 2014, the dilutive potential shares are anti-dilutive for the earnings per share calculation.

#### 13. Cash used in operations

Reconciliation of loss before tax to net cash used in operations

	Six months ended 30 June 2015 £'000	Six months ended 30 June 2014 £'000
Continuing operations Loss before tax	(25,980)	(19,620)
Adjustment for: Finance income Finance costs Depreciation (note 8) Amortization (note 9) Share of joint venture (profit)/loss (note 11) Fair value gain on derivative Share based payment charge Foreign exchange loss on non-operating cashflows	(1,035) 201 96 27 (294) (1,069) 1,401 2,226	(566) 9 - - 166 - 780 578
Changes in working capital:  Decrease / (increase) in trade and other receivables Increase in inventories Decrease in trade and other payables  Net cash used in operations	222 (352) (83) (24,640)	(279) - (2,548) (21,480)

#### 14. Share capital and share premium

	Number of shares (millions)	Share capital £'000	Share premium £'000
Opening balance as at 1 January 2015	189.4	152	297,938
Issue of new shares	95.5	76	274,924
Expenses relating to share issue	_	_	(8,834)
At 30 June 2015	284.9	228	564.028

	Number of shares (millions)	Share capital £'000	Share premium £'000
Opening balance as at 1 January 2014	80.5	65	103,403
Conversion of loan notes into Ordinary shares	0.9	_	2,014
Issue of new shares & conversion of pre-IPO shares	108.0	87	201,911
Expenses relating to share issue	_	_	(9,390)
At 31 December 2014	189.4	152	297,938

#### 15. Other reserves

#### **Treasury shares**

The group acquired 0.1 million of its own shares through purchases on the London Stock Exchange in February 2015. The total amount paid to acquire the shares, net of income tax, was £0.3 million and has been deducted from shareholders' equity. The shares are held as 'Treasury shares'. The company has the right to re-issue these shares at a later date. All shares issued were fully paid.

	Share option reserve £'000	Translation reserve £'000
At 1 January	1,305	(6)
Currency translation differences	_	(2,375)
Share based payment charge	1,382	
At 30 June	2,687	(2,381)

#### 16. Event occurring after the reporting period

On 15 May 2015, Circassia Pharmaceuticals plc ("Circassia") announced a public offer to the shareholders of Aerocrine AB ("Aerocrine") ("the Offer"). During the extended acceptance period of the Offer, acceptances increased such that following settlement Circassia held a total of 679,092,664 shares in Aerocrine, representing approximately 97.2 percent of the total amount of shares and votes in Aerocrine.

During the extended acceptance period, which ended on 26 June 2015, 31,986,367 shares corresponding to 4.6 percent of the outstanding shares and votes in Aerocrine were tendered in the Offer. For shareholders that accepted the Offer during the extended acceptance period, settlement took place on 2 July 2015.

## 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 28.

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
28 July 2015

Julien Cotta Chief Financial Officer

## 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 and accounts" of Circassia Pharmaceuticals plc for the six months ended 30 June 2015. 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 Pharmaceuticals plc, comprise:

- the condensed interim consolidated statement of financial position as at 30 June 2015:
- the condensed interim consolidated statement of comprehensive income for the period then ended;
- the condensed interim consolidated statement of cash flows for the period then ended;
- the condensed interim 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 and accounts" 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 accounts" and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed consolidated interim financial statements.

## Responsibilities for the condensed consolidated interim financial statements and the review

#### Our responsibilities and those of the directors

The "Interim report and accounts", 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 and accounts" 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 and accounts" 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

28 July 2015

## Shareholder information

#### Financial calendar

- Preliminary results for the 12 months ending 31 December 2015: Q1 2016
- Annual General Meeting: H1 2016

#### Registrars

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

#### **Shareview Portfolio**

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

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

#### Addresses for correspondence

#### **Head office**

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

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

General enquiries: info@circassia.com

Investors: IR@circassia.com Website: www.circassia.com

#### Registrars

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

Shareholder support: 0871 384 2030

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

#### Directors

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

Lota Zoth (Independent Non-Executive Director)

#### Forward-looking statements

This Interim report and accounts 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 forwardlooking statements may not actually be achieved. Nothing contained in this Interim report and accounts 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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Tel: +44 (0)1865 405560 www.circassia.com

