#### **2018 Preliminary Results**

- Vectura reports strong 2018 financial and operational performance -

**Chippenham, UK – 26 March 2019**: Vectura Group plc (LSE: VEC) ("Vectura" or "the Group") today announces its preliminary results for the year ended 31 December 2018.

# **Financial highlights**

	2018	2017	% change
Revenue	£160.5m	£148.0m	8.4%
Gross profit	£98.9m	£90.8m	8.9%
R&D	(£55.5m)	(£60.3m)	8.0%
Adjusted EBITDA <sup>1</sup>	£39.0m	£25.8m	51.2%
Operating loss	(£105.4m)	(£96.2m)	(9.6%)
Basic loss per share	(13.2p)	(12.6p)	(4.8%)
Cash from operating activities	£35.1m	£26.9m	30.5%
Cash and cash equivalents	£108.2m	£103.7m	4.3%

- Full year reported revenue of £160.5m, +8.4%
  - o Inhaled portfolio revenues of £131.1m, +15.0%
  - Strong flutiform® performance with Vectura revenues of £79.6m, +13.7%, driven by strong product supply revenues, + 17.0%
  - o Generic Ellipta® deal signed with Hikma, £6.6m revenue recognised in 2018
- R&D costs of £55.5m at the lower end of the guidance range, reflecting refocused portfolio prioritisation and initiatives to transform R&D productivity
- Adjusted EBITDA of £39.0m, up 51.2%, driven by revenue growth, improved gross margin, lower R&D costs and productivity improvements
- Operating loss of £105.4m, after ongoing amortisation and exceptional items, impacted by £39.8m impairment of intangible assets following the discontinuation of the VR475 programme, as previously communicated
- Strong cash generation from operations, up 30.5% to £35.1m. Closing cash and cash equivalents of £108.2m, share buyback of £13.8m also completed in the year

# **Operational highlights**

- Positive progression and expansion of inhaled generics pipeline
  - VR315 repeat clinical trial on track to enable Hikma Pharmaceuticals ("Hikma") to resubmit data in 2019, supporting potential launch in 2020
  - Largest product agreement deal in Vectura's history signed with Hikma for the global development of generic versions of GSK's Ellipta® portfolio, up to \$80m in future milestones plus a share of distributable net profit, up to a mid-teen percentage
  - VR2081 development continues with first clinical trial batches delivered to Sandoz
- Growing clinical evidence supports the expansion of Vectura's enhanced nebulised portfolio
  - As previously reported, the VR475 Phase III study did not meet the challenging primary endpoint of reduction in exacerbations in a severe adolescent and adult asthma population. Secondary data support differentiated performance versus conventional nebuliser and further validates confidence in the platform and symptom relief endpoints for VR647

<sup>&</sup>lt;sup>1</sup> Adjusted EBITDA is a non-IFRS measures which is calculated as operating loss, adding back amortisation and impairment, depreciation, share-based payments and exceptional items. A reconciliation of operating loss to adjusted EBITDA is presented in note 9 to the financial statements.

- Two positive studies for VR647 (US) in children with completed; results support Phase
   III development and partnering progression
- Commenced development of three new nebulised therapies, targeting niche or orphan disease segments
- Operational Excellence driving improved performance and creating additional capacity
  - Significant progress in R&D transformation, focused partner and alliance management and supply chain initiatives contributing to strong adjusted EBITDA performance and creating additional capacity for new nebulised pipeline projects

# Summary guidance and outlook

The Group expects a sustained financial performance in 2019 after a strong 2018, with continued overall revenue growth offset by the gross profit impact from the loss of EXPAREL® revenues and the normalisation of the *flutiform®* gross margin. The Group expects the partnering of VR647 later this year. R&D guidance for the year remains unchanged at £45m to £55m.

Commenting on the preliminary results, James Ward-Lilley, Chief Executive Officer of Vectura, said: "Focused execution of the Group's strategy resulted in strong financial and operational performance in 2018. Our generic portfolio is progressing well with the VR315 repeat clinical trial on track to enable Hikma resubmission in 2019, and the signing of the global agreement with Hikma to develop generic versions of GSK's Ellipta® portfolio being a major catalyst for future value. Despite the disappointment of the VR475 Phase III study, we continue to make good progress with our nebulised programmes, including development of three new specialist opportunities.

"We look forward to sustaining our operational performance and providing an update on a number of important catalysts in 2019 including VR315 resubmission, partnering of VR647, further progress on our new nebulised assets and Phase III study completion for QVM149, our ICS/LAMA/LABA therapy for asthma, partnered with Novartis."

#### **Analyst briefing**

James Ward-Lilley, Chief Executive Officer, and Paul Fry, Chief Financial Officer will present the Preliminary Results for analysts today at 9.30am to 10.30am GMT. The presentation will be held at the offices of Numis, 10 Paternoster Square, London, EC4M 7LT. There will be a simultaneous live conference call.

Dial-in details are:

Participant local dial-in: +44 (0) 207 192 8000 Participant free phone dial-in: +44 (0) 800 376 7922

Participant code: 9974699

A live webcast of the meeting and the presentation slides, will be available on Vectura's website: <a href="https://www.vectura.com/investors/presentations-and-webcasts">https://www.vectura.com/investors/presentations-and-webcasts</a>

- Ends-

#### For more information, please contact:

#### **Vectura Group plc**

David Ginivan - VP Corporate Communications +44 (0)7471 352 720 Elizabeth Knowles - VP Investor Relations +44 (0)7767 160 565

# Consilium Strategic Communications +44 (0)20 3709 5700

Mary-Jane Elliott / Jessica Hodgson / David Daley

# **Forward-looking statements**

This press release contains forward-looking statements, including statements about the discovery, development and commercialisation of products. Various risks may cause Vectura's actual results to differ materially from those expressed or implied by the forward looking statements, including: adverse results in clinical development programmes; failure to obtain patent protection for inventions; commercial limitations imposed by patents owned or controlled by third parties; dependence upon strategic alliance partners to develop and commercialise products and services; difficulties or delays in obtaining regulatory approvals to market products and services resulting from development efforts; the requirement for substantial funding to conduct research and development and to expand commercialisation activities; and product initiatives by competitors. As a result of these factors, prospective investors are cautioned not to rely on any forward-looking statements. We disclaim any intention or obligation to update or revise any forward looking statements, whether as a result of new information, future events or otherwise.

#### **About Vectura**

Vectura is an industry-leading inhaled product formulation, device design and development business offering a uniquely integrated inhaled drug delivery platform. We develop inhalation products to help patients suffering from airways diseases.

Vectura has ten key inhaled and eleven non-inhaled products marketed by partners with global royalty streams, and a diverse partnered portfolio of drugs in clinical development. Our partners include Hikma, Novartis, Sandoz, Mundipharma, Kyorin, Baxter, GSK, UCB, Bayer, Chiesi, Almirall, Dynavax and Tianjin KingYork.

Vectura's strategy is to fully leverage its differentiated technology and skills, maximising value by enhancing the delivery and performance of inhaled products, and through the development of high-quality generic alternatives to branded therapies.

For further information, please visit Vectura's website at www.vectura.com

# **Operational Review**

#### Continued growth of key partnered in-market products

The Group reported full year reported revenue of £160.5m up 8.4% compared to the prior year. Inhaled revenues of £131.1m grew by 15.0%, with overall revenue growth being impacted by the anticipated decline in non-inhaled revenues to £29.4m, a 13.5% decline following the expiry of certain patents for EXPAREL®, ADVATE®, and Xatral®.

# flutiform® (Mundipharma, Europe and Rest of world (excl. North America) / Kyorin, Japan)

flutiform® generated total in-market sales of €221.7m, up 8.5% in value (CER) and up 12.2% in volume², contributing £79.6m revenue for Vectura up 13.7% compared to 2017.

The European ICS/LABA market is a highly competitive and genericised market which declined by 3.3%² in value during 2018. Despite the slowing of in-market sales growth rates, *flutiform*® sales in Europe grew 2.0%, to €114.4m, and grew 2.7% in volume, reaching a market value share of 3.8% of the ICS/LABA market². We expect that the launch of the breath-activated *flutiform*® k-haler® and the addition of the positive opinion for the paediatric indication of *flutiform*® will reinforce the continued differentiation of the product in this challenging market.

The less mature and non-genericised Japanese market grew by 3.3%<sup>2</sup> in value. In-market sales of *flutiform*® grew strongly, up 12.8% in value and 17.4% in volume, to €87.2m<sup>2</sup>, despite price reductions of approximately 5.8% in place since April 2018. *flutiform*® reached a market share of 15.4% in volume and 12.2% in value, up 1.2ppts and 0.7ppts respectively compared to 2017<sup>2</sup>.

<sup>&</sup>lt;sup>2</sup> IQVIA SMART MIDAS constant currency sales. Royalties payable to the Group by partners are based on agreed contractual definitions of net sales, which differ from IQVIA reported sales and may include other adjustments or deductions.

flutiform® remains at an early stage of its lifecycle in rest of world territories and has continued to grow strongly, with in-market sales of €20.1m up 35.1% compared to 2017².

# Ultibro® Breezhaler®, Seebri® Breezhaler®, Utibron™ Neohaler® Inhalation Powder and Seebri™ Neohaler® (Novartis/Sunovion, US)

Ultibro® Breezhaler® continues its class-leadership of the dual bronchodilator LAMA/LABA class (ex. US), with growth of 7.9% compared to 2017², despite increased competition. In-market sales in Europe grew by 6.3% to \$385.4m, and also grew strongly in rest of world, up 23.2% to \$73.4m². Vectura recognised royalties of £17.8m in respect of sales of Ultibro® Breezhaler® and Seebri® Breezhaler® (2017: £17.3m).

Japanese in-market growth remains low at 0.4% with in-market sales of \$45.8m, and limited sales in the US of \$7.4m<sup>2</sup> reflect the challenge for the fourth market entrant in a competitive market and market access restrictions.

Novartis expects QVM149 Phase III study completion in H2 2019 with regulatory submission in Europe and Japan also in H2 2019, triggering a filing milestone to Vectura of \$2.5m. The Group will earn royalties on net sales upon launch of the product. The product has the potential to be one of the first ICS/LAMA/LABA therapies for asthma. Current consensus estimates are for sales of \$238m by 2024<sup>3</sup>.

# **GSK Ellipta® products**

GSK continues to report strong growth of its Ellipta® portfolio which is important for both the short term £9.0m maximum annual royalty received by Vectura and the longer-term potential of the range of Ellipta® AB-rated substitutable generics now being developed by the Group, in partnership with Hikma.

# AirFluSal® Forspiro® (Sandoz, EU & RoW, excl. US)

AirFluSal® Forspiro® continues to grow strongly in the competitive commoditised European generic ICS/LABA market. Vectura recorded total royalty and device sales revenue of £4.4m up 15.8% compared to 2017.

# Breelib<sup>™</sup> (Bayer, EU & RoW, excl. US)

Breelib $^{TM}$ , Vectura's first commercialised FOX $^{\otimes}$  handheld smart nebuliser, continues to receive positive customer feedback and adoption. The product is growing successfully in new markets; now launched in 7 markets and with additional launch roll-outs continuing. Vectura revenue remains limited given the nature of the niche target opportunity for this product.

# Positive progression and expansion of inhaled generics pipeline

# VR315 (Hikma, US)

Recruitment is progressing well on the repeat clinical study for VR315. Hikma anticipates being able to submit data from the study to the US Food and Drug Administration (FDA) during 2019 to support its regulatory application, enabling a potential US launch in 2020.

As expected, Mylan has now launched its version of generic Advair® in the US named Wixela® Inhub®, providing an encouraging precedent for future approvals of complex AB-rated substitutable inhaled generic products. The US market opportunity for such inhaled respiratory generics remains highly attractive, with 2018 reported net sales of \$1.5bn for GSK's Advair® in the US⁴. There are high technical and financial barriers to entry for these assets and few pharmaceutical companies, individually or collaboratively, are able to address these challenges effectively. Given the significant ICS/LABA market volume opportunity, which has continued to grow to more than 36 million units per annum², we continue to forecast significant market volume and value opportunities for VR315 when it reaches the market.

<sup>&</sup>lt;sup>3</sup> Evaluate Pharma Consensus Worldwide Peak Sales extracted March 2019

<sup>&</sup>lt;sup>4</sup> Evaluate Pharma extracted March 2019

# Global agreement signed with Hikma for the development of generic versions of GSK's Ellipta® portfolio

On the 8<sup>th</sup> of November, the Group signed a global agreement with Hikma for the development and commercialisation of an AB-rated substitutable drug-device combination of generic versions of the GSK Ellipta® portfolio, using our proprietary Open-Inhale-Close (OIC) dry powder inhaler device. This deal validates both the assessment of the inhaled generic segment in the US and confidence in the progression of the existing VR315 programme.

Upon signing, the Group received an upfront milestone payment of \$15m and is eligible to receive up to a further \$80m milestone payments dependent upon achieving key pre-defined development milestones. In the event of product approval, Vectura will receive a share of distributable net profit up to a mid-teen percent for each portfolio product. This represents a significant opportunity with consensus analyst projections of global net sales of the Ellipta® products of approximately \$5bn by 2024, of which \$4bn is forecast in the US<sup>5</sup>.

**VR2081 (Sandoz, US)** Vectura is continuing its pMDI development work on VR2081, with the first clinical trial batches delivered to the Group's partner Sandoz.

**VR632 (Sandoz, EU)** was approved in Europe in May 2018, with launches planned throughout 2019. This approval triggered a £0.3m development milestone payment to the Group from Sandoz.

# Growing clinical evidence supports the expansion of our enhanced nebulised portfolio

# VR475 (Severe adult asthma, EU)

As previously reported, the VR475 Phase III study did not meet the challenging primary endpoint of reduction in exacerbations in a severe adolescent and adult asthma population. As a result, the Group will not be pursuing further development of this programme.

Secondary data analysis demonstrated positive trends and clinically meaningful differences between VR475 and placebo and versus conventionally nebulised budesonide, reinforcing the differentiated characteristics of Vectura's guided inhalation system. These data have a positive read across to the ongoing VR647 programme.

# VR647 (Paediatric asthma, US)

Two positive studies were completed (Pharmacokinetic and Usability) during 2018, supporting progression to a Phase III development programme. VR647 has the potential to improve compliance and efficacy in a paediatric patient population that has limited therapy options. VR647 aims to deliver efficacy similar to Pulmicort Respules®, with a lower steroid dose, significantly shorter treatment time and confidence in correct dose delivery. Vectura's goal is to establish VR647 as the treatment of choice for children with mild-moderate asthma in the US. An end of Phase II meeting with the FDA is planned for H1 2019, enabling confirmation of Phase III programme design and partnering progression in H2 2019.

# Three new programmes utilising our differentiated nebulised platform

Given the increased evidence for Vectura's differentiated nebulised platform and aligned to its refocussed R&D investment, the Group initiated three new nebulised development programmes in 2018. The goal of these non-budesonide projects is to enhance existing molecules, by repurposing and reformulating, to be delivered by Vectura's proprietary nebulised platforms. These programmes, which are focussed in niche or orphan disease segments, have the potential to address multi-billion dollar markets with individual peak year sales potential in excess of \$250m.

5

<sup>&</sup>lt;sup>5</sup> Global Data Consensus Forecast accessed March 2019

The three programmes initiated in 2018 focus on the inhaled management of cardiopulmonary vascular disease, cystic fibrosis and infection in post-transplant immunocompromised patients. These programmes could come to market within eight years and have potential for partnering within a three-to-five year period, post-initiation.

Vectura will outline progress on these programmes during 2019, with the Group targeting at least one orphan drug designation by the end of the year.

# VR465 (Ablynx – a Sanofi Company, ALX-0171, Global)

Further validation of the clinical performance of the FOX® device was provided by the positive primary endpoints for the Ablynx ALX-0171 (VR465) anti-RSV Nanobody Phase II programme, with anti-viral efficacy and target exposure achieved. These data were supportive of our technology, however, Sanofi has deprioritised this programme and does not intend to continue with further development.

# Operational Excellence driving improved performance and creating additional capacity

Operational Excellence has been a major area of focus for the business and has been a key driver of the Group's strong EBITDA performance in 2018. Key elements included:

- Implementing an R&D transformation programme including, reprioritisation of projects, use of systematic ways of working and better resource forecasting and allocation, supported by enhanced enterprise wide planning tools. This activity has created capacity to allow our teams to spend more time focusing on scientific project work and to support more programmes including funding the three early-stage new nebulised programmes, within a reduced total R&D spend of £55.5m (2017: £60.3m).
- Effective alliance management, including settlements of the return of specific AirFluSal® Forspiro® territory rights from Sandoz, VR2076 triple therapy project termination with Mundipharma and the settlement of an outstanding intellectual property related agreement with Therabel.
- Supply chain improvements, notably the agreement for transfer of the Holmes Chapel site ownership from Sanofi to Recipharm. These efforts have helped to support a strong *flutiform®* product supply gross profit margin, reaching 39.2% in 2018.
- The Group has taken steps to reduce its facilities footprint in 2018, including announcing closure of its Gauting site in Germany, and planned divestment of surplus buildings in Switzerland.

# Lyon facility

Over the past two years a significant transformation programme has taken place at Vectura's Lyon oral manufacturing site. This has included the development of an end-to-end contract development and manufacturing organisation approach, ranging from early stage development, scale-up, and manufacturing through to bottling and blister line packaging, including serialisation and aggregation. As a result of these initiatives, along with significant operational KPI improvements, the site signed six new manufacturing and development contracts in 2018. These new agreements have enabled the site to increase development revenues by 25% which has largely offset the reduction in Sular® product supply revenue and has mitigated the impact of the expected decline of royalty revenues from legacy products.

# **Board changes**

The Board was pleased to welcome Paul Fry to Vectura as Chief Financial Officer in October 2018. Paul brings significant industry experience and he is already making a positive impact in his role.

In June 2018, Vectura welcomed Anne Whittaker to the Board as a Non-Executive Director. Anne has more than 25 years of experience in the life science industry, including senior leadership roles with large pharmaceutical, biotech, and speciality pharma companies.

The Board extends its thanks to Andrew Derodra and Frank Condella, who stood down as Chief Financial Officer and Non-Executive Director and Vice Chairman respectively, for their support and contribution to the success of Vectura following the merger with Skyepharma PLC.

#### **Brexit**

The Group has closely reviewed the potential risks associated with Brexit. The Board believes Vectura has undertaken a robust approach to ensuring any impact within the Group's control is mitigated as far as possible.

Mitigating activities have included continued close working with our supply chain network and partners, establishing a new EU legal entity and transferring our notified regulatory body for our device assets.

#### **GSK** legal action

In December 2018, the UK High Court ruled in favour of GSK in an action based on certain additional Vectura patents which GSK previously had an option to take a licence to under the patent licence and option agreement with Vectura dated 5<sup>th</sup> August 2010 and which they chose not to exercise. Having taken advice from experienced advisers on the issues covered in the judgement an appeal process has been initiated. The judgment applies only in respect of the UK patents and does not directly affect the proceedings which Vectura commenced against GSK under its US patents. There is no impact on the timing of US litigation; the Group still expects the US jury trial to go ahead in April/May 2019. The Group will provide an update following its conclusion.

# **Capital allocation**

The Group ended the year with a strong cash position of £108.2m, a level which exceeds operational requirements. In the absence of attractive M&A opportunities and given the Board's view of the intrinsic value of the business, it continues to review the Group's capital allocation priorities including the consideration of material shareholder returns.

# Anticipated major newsflow and key catalysts in H2 2019:

- VR315 (US) repeat Phase III study read-out and resubmission
- VR647 (US) partnering post FDA end of Phase II meeting
- Updated disclosure on new nebulised niche portfolio assets, including potential orphan drug designation
- QVM149 Phase III study completion and submission

GSK litigation in the US is scheduled for April/May 2019 and the Group will provide an update following the conclusion of this trial.

#### **Financial review**

Extract from the Consolidated Income Statement for the year ended 31st December 2018

	2018	2017	%
	£m	£m	change
Product supply revenues	85.6	74.7	14.6%
Royalty and other marketed revenues	58.4	63.7	(8.3%)
Development revenues	16.5	9.6	71.9%
Revenue	160.5	148.0	8.4%
Cost of sales	(61.6)	(57.2)	(7.7%)
Gross profit	98.9	90.8	8.9%
Research and development	(55.5)	(60.3)	8.0%
Other operating expenditure and income	(12.8)	(12.5)	(2.4%)
Exceptional items	(9.0)	(4.5)	(100%)
Amortisation and impairment charges	(127.0)	(109.7)	(15.8%)
Operating (loss)/profit	(105.4)	(96.2)	(9.6%)
Adjusted EBITDA	39.0	25.8	51.2%
Adjusted EBITDA margin %	24.3%	17.4%	6.9ppts

#### 1. Revenue

Vectura adopted IFRS 15 "Revenue from contracts with customers" on 1 January 2018. The collaborative agreement with Hikma to develop generic versions of GSK's Ellipta® portfolio is the first agreement that the Group has signed since the implementation of the standard and therefore this is the first agreement that has been accounted for in full in accordance with this standard.

#### 1.1 Product supply revenue

The Group generates significant revenues from the supply of finished or semi-finished products, largely manufactured by third party suppliers, to commercial distribution partners. Costs to deliver these revenues are reported under Cost of sales. These revenues grew by 14.6% in 2018, largely driven by strong volume demand for *flutiform*®.

Total Product supply revenues and gross margin

	2018	2017	%
	£m	£m	change
flutiform®	74.2	63.4	17.0%
Other inhaled products	3.1	2.7	14.8%
Other non-inhaled products	8.3	8.6	(3.5%)
Revenue	85.6	74.7	14.6%
Cost of sales	(61.6)	(57.2)	(7.7%)
Gross profit	24.0	17.5	37.1%
Gross profit margin %	28.0%	23.4%	4.6ppts

#### flutiform®

Vectura earned 46.2% (2017: 42.8%) of total reported revenue from the supply of finished *flutiform®* products to Mundipharma (Europe and Rest of World) and Kyorin (Japan). Strong in-market growth of *flutiform®*, up 8.5% in value and 12.2% in volume<sup>6</sup>, and the normalisation of Mundipharma supply chain requirements resulted in a 17.0% increase in product supply revenue.

<sup>&</sup>lt;sup>6</sup> IQVIA SMART MIDAS constant currency sales. Royalties payable by partners to the Group are based on agreed contractual definitions of net sales, which differ from IQVIA reported sales and may include other adjustments or deductions.

#### flutiform® revenues

In-market flutiform® sales6 (constant currency)	2018	2017	%
in-market julijorm sales (constant currency)			change
Territory			
Europe	€114.4m	€112.2m	2.0%
RoW (ex. North America)	€20.1m	€14.9m	35.1%
Japan	€87.2m	€77.3m	12.8%
Total in-market sales	€221.7m	€204.4m	8.5%

Vactura product cumply rayonyos and grass profit	2018	2017	%
Vectura product supply revenues and gross profit	£m	£m	change
flutiform® product supply revenue	74.2	63.4	17.0%
Cost of sales	(47.4)	(40.1)	(18.2%)
One-off margin credits / (debits)	2.3	(1.1)	>100%
Gross profit	29.1	22.2	31.1%
Gross profit margin %	39.2%	35.0%	4.2 ppts
Gross profit margin % (ex. one-off credits/(debits)	36.1%	36.8%	(0.7) ppts

flutiform® gross margin was up 4.2 percentage points in 2018, benefitting from the release of a supplier provision booked in 2017 and a credit from Sanofi in settlement of historic claims prior to sale of the Holmes Chapel manufacturing facility to Recipharm. Despite market price reductions in Japan partially impacting the Group's supply prices, the gross margin earned for product supply sales, excluding one-off items, was 36.1% (2017: 36.8%).

The Group also earned royalties in 2018 on *flutiform*® sales made by Kyorin in Japan. Including these royalties, total revenues for *flutiform*® were £79.6m (2017: £70.0m).

# Other inhaled products

Vectura also earns revenue from the supply of devices to partners including the GyroHaler® device to Sandoz for the AirFluSal® Forspiro® product and the FOX® device to Bayer for use in their Breelib™ product. In total this revenue stream contributed £3.1m in the year, an increase of 14.8% compared to 2017. Vectura continues to focus on margin improvement initiatives to enhance the profitability of these revenue streams.

# Other non-inhaled products

The Group's oral manufacturing facility in Lyon, France generates product supply revenues from sales of oral tablets to partners.

Product supply revenues from Lyon of £8.3m were lower than the prior year (2017: £8.6m), driven by a reduction in Sular® volumes which were unusually high in 2017 as a result of a competitor failure to supply. Excluding Sular®, non-inhaled product supply revenues grew 23.2%.

The operational focus of the Lyon site continues to be on improving profitability by replacing steady volume declines in mature and off-patent products, with growing new manufacturing volumes, supply revenues and associated development fees through new agreements. Six new such agreements were signed during 2018.

Some of the products manufactured at the Lyon site also earn the Group royalties, reported separately.

# 1.2 Royalty and other marketed revenues

The Group also generates revenues from products marketed by partners which incorporate Vectura's intellectual property. These revenues typically comprise royalties, share of sales arrangements or sales-based milestones, reflecting financial returns on historic R&D investments in partnered programmes. These revenues are earned without further material costs being incurred by the Group.

Total royalty and other marketed revenues

	2018	2017	%
	£m	£m	change
Ultibro® and Seebri®	17.8	17.3	2.9%
Ellipta®	9.0	9.0	-
flutiform®	5.4	6.6	(18.2%)
AirFluSal® Forspiro®	2.9	2.3	26.1%
Other non-inhaled royalties	14.5	17.4	(16.7%)
Royalty revenue	49.6	52.6	(5.7%)
Share of net sales of EXPAREL®	5.1	6.6	(22.7%)
Other inhaled marketed revenues	3.7	4.3	(14.0%)
Other non-inhaled marketed revenues	-	0.2	n/m
Royalty and other marketed revenues	58.4	63.7	(8.3%)

**Ultibro** Breezhaler and Seebri Breezhaler are now established and substantial products in Europe. Ultibro® continues to be the leading LAMA/LABA combination treatment ex-US and continues to grow well in Europe and Rest of World territories.

**Total royalties** 

Ultibro® and Seebri® performance			
Net sales <sup>7</sup>	2018	2017	%
			change
Ultibro® Breezhaler® Seebri® Breezhaler®	\$454m	\$411m	10.5% (2.0%)
	\$148m	\$151m	
Total in-market sales	\$602m	\$562m	7.1%
Vectura royalties	2018	2017	%
vectura royalties	£m	£m	change
Ultibro® Breezhaler®	13.7	12.7	7.9%
Seebri® Breezhaler®	4.1	4.6	(10.9%)

Vectura revenues for Ultibro® and Seebri® Breezhaler® are derived from a royalty percentage of net sales reported by Novartis. Royalties from Ultibro® Breezhaler® increased by 7.9% in 2018 (+11.0% CER) while royalties from Seebri® Breezhaler® declined by 10.9% (-6.5% CER).

17.8

17.3

GSK's Ellipta® products continue to grow. Accordingly, Vectura has recognised the maximum annual royalty of £9.0 million during 2018. The technology licensed to GSK is covered by granted patents with an earliest expiry date for one of the granted patent families in major markets of November 2019.

flutiform® royalties for Europe and most of the RoW territories are subject to the terms of the agreement with Mundipharma which limits the aggregate amount of royalties that can be earned by Vectura where royalties and product supply exceed 35% of Mundipharma's net sales. As a result of this cap, royalties from Mundipharma have reduced to virtually nil in 2018 (2017: £1.9m).

Strong in-market performance by Kyorin drove value and volume growth in Japan, up 12.8% and 17.4% respectively<sup>6</sup>. As a result royalties from Japan grew by 10.4% (CER +12.5%), partially offsetting the reduction in Mundipharma royalties.

Other non-inhaled royalties comprise royalties earned on oral and other non-inhaled products which benefit from the Group's historical intellectual property. Many of these products are manufactured at the Group's production facility in Lyon.

<sup>&</sup>lt;sup>7</sup> As reported by Novartis on 30 January 2019

Non-inhaled royalty and other marketed revenues

	2018	2017	%
	£m	£m	change
RAYOS® / LODOTRA®	7.7	6.7	14.9%
Requip <sup>®</sup>	2.0	2.9	(31.0%)
Solaraze <sup>®</sup>	2.0	2.9	(31.0%)
ADVATE®	-	1.2	(100%)
Xatral®	0.1	0.8	(87.5%)
Other products	2.7	3.1	(12.9%)
Total	14.5	17.6	(17.6%)

Total non-inhaled royalties continued a downward trend as products move towards the end of their lifecycle. Decreases in ADVATE® and Xatral® royalties were due to prior year patent expiry. This underlying decline was partially offset by strong RAYOS®/LODOTRA® royalty growth, up 14.9% to £7.7m, due to increased promotional activity. The Licence Agreement for RAYOS®/LODOTRA® has been amended with effect from 1 January 2019 with a minimum \$8.0m annual royalty now payable to Vectura for RAYOS® for the calendar years 2019 to 2022.

Share of net sales of EXPAREL® is £5.1m, a reduction of £1.5m due to the share of net sales ceasing in September 2018 following expiry of the last expiring patent listed in the relevant agreement with Pacira. The Group remains eligible to receive a non-patent dependent \$32m sales milestone when twelve-month net sales of EXPAREL® reach \$500m on a cash received basis. Pacira reported 2018 net sales of EXPAREL® of \$331m, a 17.0% increase compared to 2017. Current analyst consensus estimates are that Pacira will reach \$500m annual net sales towards the end of 2023.

Other inhaled marketed revenues include a £1.3m milestone received on the anniversary of the first European launch of Breelib<sup>™</sup>. In 2017, Vectura recognised a £4.3m milestone from this launch. Under the terms of its agreement with Bayer, Vectura is eligible to receive a further €4.25m in milestones spread over the next five years, paid annually, and an additional €0.5m following commercial launch in Turkey.

Additionally, as part of an agreement with Sandoz regarding revised territory rights for AirFluSal® Forspiro®, Vectura recognised revenues of £2.4m during the period, of which £2.0m relates to the release of deferred income.

#### 1.3 Development revenues

The Group also earns revenue from agreements with partners which draw on Vectura's device, formulation and development capabilities to deliver commercially attractive inhalation products. Under these agreements, during the development phase Vectura typically receives a series of cash flows in consideration for a variety of activities, which may comprise an upfront fee as consideration for the licence to access intellectual property, milestone payments for specific clinical or other development-based outcomes, or fees billed directly for work performed. Together these revenues have been categorised as Development revenues. Revenues are recognised when contractual performance obligations are deemed to have been met, with the profile of these revenues varying by programme and over time.

Costs to deliver these revenues are reported under Research and Development (R&D) expenditure in the consolidated income statement and tend to be incurred on a more consistent basis over the life of the programme.

These agreements may also include sales-based royalties and commercial milestones post-launch. The economics of each partner agreement is structured differently in terms of the timing and mix of payments.

#### **Development revenues by programme**

	2018	2017	%
	£m	£m	change
Licensing of intellectual property			
Generic Ellipta® portfolio (Hikma)	4.2	-	n/m
Other inhaled programmes	0.4	0.6	(33.3)%
Total licensing revenues	4.6	0.6	>100%
Development services			
flutiform® K-Haler®	2.4	3.2	(25.0%)
Generic Ellipta® portfolio (Hikma)	2.4	-	n/m
VR2081 (Sandoz)	1.3	1.1	18.2%
VR2076	1.7	1.5	13.3%
Other inhaled development services	2.6	2.0	30.0%
Other non-inhaled development services	1.5	1.2	25.0%
Total development services	11.9	9.0	32.2%
Total development revenues	16.5	9.6	71.9%

# Generic Ellipta® portfolio

In November, Vectura signed a global development and commercialisation agreement with Hikma for the development of an AB-rated substitutable drug-device combination of generic versions of the GSK Ellipta® portfolio. Upon signing of the deal, Vectura received an upfront cash payment of \$15m (£11.4m). Of this, £6.6m was recognised in 2018 which comprises £4.2m from the licensing of intellectual property and £2.4m in respect of development services. The remaining income from the upfront payment of £4.8m is expected to be recognised over the next two years.

# Licensing of intellectual property - Other inhaled programmes

In 2018, Vectura recognised £0.4 million from the successful completion of the RESPIRE clinical trial for VR465 which used Vectura's adapted handheld FOX® nebuliser to deliver Ablynx/Sanofi's ALX-0171 medication to infants with Respiratory Syncytial Virus (RSV) infection.

#### K-haler® development

These revenues relate to fees charged for development work related to the *flutiform*® breath-activated k-haler®, launched in September 2018.

#### VR2081 (Sandoz)

A \$5.0m upfront milestone from Sandoz was received in 2017 relating to the VR2081 programme. This milestone, plus the majority of the next two contractual development milestones, are deemed highly probable and therefore are being recognised as development work progresses on a percentage completion basis. Revenues recognised from ongoing development work are expected to be in the range of £1.0m - £2.0m in 2019.

#### **VR2076**

Following the conclusion of termination discussions with Mundipharma, deferred income and provisions amounting to £1.7m have been released in 2018 relating to past development work performed.

#### **QVM149**

Novartis expects the Phase III programme to complete in H2 2019 with regulatory submission in Europe and Japan also in H2 2019, triggering a filing milestone to Vectura of \$2.5m. The Group will earn royalties on net sales upon launch of the product.

#### **VR647 (US)**

An end of Phase II meeting with the FDA is planned for H1 2019, enabling confirmation of Phase III programme design and partnering progression in H2 2019. Typically a partnering agreement will include a payment for a licence to intellectual property developed by Vectura which would be recognised as revenue upon signing, and a level of development fees recognised over time.

#### Other inhaled development services

In 2017 and 2018, other inhaled development services mainly comprise projects partnered with Hikma, with the increase in 2018 driven by development activity on the generic project VR730 (generic Salmeterol).

#### Other non-inhaled development services

The Group earned £1.5m in 2018 (2017: £1.2m) from the provision of development services related to products which are or will be manufactured at its oral tablet production facility in Lyon, France. This increase reflects the success the team is achieving in signing new contracts generating development fees with the prospect of converting these into more substantive product supply volumes once development activity is completed.

# 2. Research and Development (R&D) expenses

The Group's R&D expenditure has been presented under two distinct categories:

- a) **Partnered** this category represents R&D expenditure funded by partners to progress the agreed contracted programmes. This expenditure is principally funded by Development revenues earned from the partner, which may be contingent upon the achievement of certain future milestones;
- b) **Pre-Partnered** this category of R&D spend reflects investments funded by the Group on programmes yet to be partnered, as well as investments in its own innovative proprietary technology platforms. These investments are the basis for generating future partnering and licencing revenue opportunities.

Total R&D expenditure by category

	2018	2017	%
	£m	£m	change
Partnered R&D	20.6	25.7	(19.8%)
Pre-partnered R&D	34.9	34.6	0.9%
Total R&D	55.5	60.3	(8.0%)

#### Partnered R&D

Partnered R&D expenditure in 2018 represented 37.1% of total R&D expenditure (2017: 42.6%). The predominant focus of Partnered R&D spend has been on generic programmes (70%) reflecting the change in the Group's strategic focus towards generic programmes.

#### Pre-partnered R&D

Pre-partnered R&D expenditure in 2018 represented 62.9% of total R&D expenditure (2017: 57.4%). This total expenditure included £6.7m of external R&D expenditure which related to the Phase III programme VR475. Development of VR475 is being wound down following the top-line results from the Phase III clinical study.

In 2018, positive results were achieved from the VR647 Phase II pharmacokinetic and mouthpiece methodology studies, and preparations continue for the Phase III programme. As previously indicated, the Group will seek to partner VR647 for Phase III during 2019.

In 2018, Vectura initiated and is progressing three new pipeline projects based on combining existing proven molecules with our proprietary breath-controlled nebulised technology. Spend on these projects is expected to increase in 2019 as they approach the clinical phases.

R&D guidance for 2019 remains unchanged at £45m - £55m.

#### 3. Other operating expenditure and income

Other operating expenditure comprises a £2.6m non-cash charge for share-based compensation (2017: £2.1m) as well as corporate, administrative and selling and marketing costs of £12.8m (2017: £12.1m).

These costs were partially offset by other operating income of £2.6m, up from £1.7m in 2017 due to partner contributions to new manufacturing equipment and a one-off credit from Sanofi prior to the sale of their Holmes Chapel facility.

#### 4. Amortisation and impairment of intangible assets

As a result of the VR475 Phase III study not meeting its primary endpoint, the Group is not pursuing further development and partnering of the programme. The carrying value of the intangible asset recognised as part of the Activaero GmbH acquisition in March 2014 has been impaired in full, with a resulting £39.8m impairment charge. A further impairment charge of £1.7m has been recognised following the decision by Sanofi to cease development of the VR465 programme.

These impairments, as well as the full amortisation of the EXPAREL® intangible asset in 2018, result in a £17.3m increase in the overall amortisation and impairment charge versus the prior year.

#### 5. Exceptional items

Exceptional items include £7.1m of costs arising from the progression of legal proceedings against GSK in the US and UK relating to enforcement of certain of Vectura's patents in respect of the Ellipta® products. These costs include a provision for reimbursement of GSK's legal costs in the UK following the recent first instance judgment in GSK's favour. Vectura has been granted leave to appeal this judgment. The first instance hearing in the US proceedings is scheduled for April/May 2019.

For a breakdown of exception items by category, please refer to note 4 to consolidated financial statements.

# 6. Adjusted EBITDA

Adjusted EBITDA is a non-IFRS measure which management uses to assess the performance of the business. This has increased by over 50% to £39.0m in 2018 driven mainly by revenue growth, a higher product supply margin and lower R&D expenditure.

As shown in note 6 to the consolidated financial statements, adjusted EBITDA is calculated by adjusting the statutory reported operating loss for non-cash items such as depreciation, amortisation and share-based compensation and for items that are exceptional in nature and do not represent the underlying trends of business performance.

#### 7. Net finance income/expense

Net finance income has arisen from £0.8m of foreign exchange gains. In 2017 foreign exchange losses were £1.4m and other financing expenses were £1.2m

#### 8. Loss before tax

The Group's statutory loss before tax of £104.8m has increased by 2.5% from £102.2m in 2017 as benefits from growth in revenues, an improved product supply margin, lower R&D expenditure and lower amortisation charges have been more than offset by the impairment charge relating to VR475.

#### 9. Taxation

The Group's effective tax rate ("ETR") is a 15.8% credit (2017: 16.2% credit). A net taxation credit of £16.6m (2017: £16.5m credit) has been recognised in the consolidated income statement, being the net effect of a current tax expense in the Group's US and Swiss operations offset by deferred tax credits on the amortisation and impairment of acquisition accounting fair value adjustments and the recognition of a non-current deferred tax asset in respect of non-trade losses.

#### 10. Loss per share

Despite growth in adjusted EBITDA and operating cash flow, basic and diluted loss per share has increased to 13.2 pence (2017: 12.6 pence loss per share) as a result of the VR475 impairment charge and the lower weighted average number of shares following completion of the share buyback in February 2018.

#### 11. Foreign exchange exposure

The Group receives revenue and incurs expenses in a number of foreign currencies and, as such, movements in foreign exchange rates can materially impact the Group's financial results. Had foreign currency rates in 2018 remained constant with those of 2017, the Group's reported adjusted EBITDA would have been approximately £1.0m higher.

As an indication, a 5% strengthening or weakening of sterling against the Euro, US Dollar and Swiss Franc would have had an impact of between £3m-£4m on the Group's adjusted EBITDA in 2018.

# **Balance Sheet**

#### Goodwill

Goodwill is not amortised but is tested annually for impairment. No impairment was recognised following this review during 2018. The increase of £2.0 million in goodwill to £163.4m at 31 December 2018 arises from foreign exchange gains upon revaluation of goodwill denominated in foreign currencies, primarily the Swiss Franc.

#### Intangible assets

The carrying value of intangible assets at 31 December 2018 of £219.9m has decreased by £115.5m during the period. This is primarily due to amortisation of £85.5m and impairment charges of £41.5m for the VR475 and VR465 intangible assets. This negative movement was partially offset by foreign exchange gains of £10.6m upon revaluation of intangibles denominated in foreign currencies, primarily the Swiss Franc, and £0.9m of software additions.

# Property, plant and equipment

The net book value of property, plant and equipment is £57.8m, £4.7m higher than at 31 December 2017 due to additions of £8.5m and foreign exchange gains of £2.0m which were partially offset by depreciation of £5.8m. Additions comprise mainly of manufacturing equipment to support the production of *flutiform®*, the development of oral tablet production in Lyon, and equipment to support the Group's nebuliser platforms.

#### Inventory

Similar to last year, over 91% of inventories of £26.7m held at 31 December 2018, relate to *flutiform®*. The value of inventories has increased by £3.3m compared to 2017, driven by growth in *flutiform®* volumes, a longer stand time for semi-finished product and a foreign exchange uplift from translation of the balance sheet of the Group's Swiss operations into Sterling.

# **Provisions**

Total provisions have increased by £5.5m to £10.9m at 31 December 2018 (31 December 2017: £5.4m). Aside from the movements already discussed under exceptional items and under *flutiform®* gross margin, the principal change has been a reclassification of £5.8m from other payables to provisions due to increased uncertainty as to the timing of settlement.

# Swiss defined benefit retirement liability

The Swiss defined benefit retirement liability has decreased by £0.5m to £3.1m (31 December 2017 £3.6m). This is largely due to curtailment gains of £0.7m arising from redundancies recorded in exceptional items, less £0.2m of other movements.

#### Cash and liquidity

Vectura continues to maintain strong liquidity with cash and cash equivalents of £108.2m, an increase of £4.5m versus 2017. The previously announced £15.0m share buyback programme completed in February 2018 with 2018 cash outflows of £13.8m.

Cash generated from operating activities was £35.1m in 2018 (2017: £26.9m). The difference to Adjusted EBITDA of £39.0m is explained as follows:

	2018
Adinated FRITRA	4m 39.0
Adjusted EBITDA	39.0
Exceptional items cash outflow not in adjusted EBITDA <sup>1</sup>	(4.1)
Deferred income release - AirFluSal® Forspiro® (Sandoz)	(2.0)
Deferred income and provision release - VR2076	(1.7)
Cash milestone received versus revenue recognised - Generic Ellipta* portfolio (Hikma)	4.8
Release of flutiform® supplier provision	(1.1)
Other working capital movements	0.2
Cash generated from operating activities	35.1

 $<sup>^{1}</sup>$  Exceptional costs are mainly driven by cash outflows of £3.7m relating to GSK litigation.

The Group made scheduled corporation tax payments relating to its US and Swiss operations of £6.0m (2017: £2.9m). These were partially offset by research and development tax credits received of £1.0m (2017: £2.1m).

Net cash outflows from capital expenditure were £12.3m, £2.6m higher than 2017. These included investments in manufacturing equipment for *flutiform®* and for the Lyon site, as well as investment in the Group's laboratories and platform technologies.

The Group has access to a £50.0m multicurrency revolving credit facility with Barclays Bank PLC and HSBC Bank PLC. This facility expires in August 2021 and remains undrawn.

By order of the Board

Paul Fry Chief Financial Officer

# **Appendix to the Financial Review**

Breakdown of non-inhaled revenue and gross profit.

	2018	2017	%
	£m	£m	change
Rayos® / Lodotra®	1.6	1.1	45.5%
Sular®	1.4	3.0	(53.3%)
Diclofenac®	1.5	1.4	7.1%
Other	3.8	3.1	22.6%
Product supply revenue	8.3	8.6	(3.5%)

Solaraze®	2.0	2.9	(31.0%)
Rayos® / Lodotra®	7.7	6.7	14.9%
Requip ®	2.0	2.9	(31.0%)
Other royalties	2.8	5.1	(45.1%)
EXPAREL® share of net sales	5.1	6.6	(22.7%)
Royalty and other marketed revenues	19.6	24.2	(19.0%)
Development services	1.5	1.1	36.4%
Licencing – other	-	0.1	n/m
Development revenues	1.5	1.2	25.0%
Total non-inhaled revenue	29.4	34.0	(13.5%)
Cost of sales	(11.2)	(10.9)	(2.8%)
Non-inhaled gross profit	18.2	23.1	(21.2%)

# Consolidated Income Statement

For the year ended 31 December

		2018	2017
	Note	£m	£m
Revenue	2	160.5	148.0
Cost of sales		(61.6)	(57.2)
Gross profit		98.9	90.8
Selling and marketing expenses		(3.4)	(4.0)
Research and development expenses	3	(55.5)	(60.3)
Corporate and administrative expenses		(12.0)	(10.2)
Other operating income		2.6	1.7
Operating profit before exceptional items and amortisation		30.6	18.0
Amortisation and impairment		(127.0)	(109.7)
Exceptional items	4	(9.0)	(4.5)
Operating loss		(105.4)	(96.2)
Loss from associates		(0.2)	(3.4)
Finance income		1.3	0.2
Finance expenses		(0.5)	(2.8)
Loss before taxation		(104.8)	(102.2
Net taxation credit	5	16.6	16.5
Loss after taxation		(88.2)	(85.7)
Adjusted EBITDA*	6	39.0	25.8
Loss per share (basic and diluted)	7	(13.2p)	(12.6p)

All results are attributable to shareholders of Vectura Group plc and are derived from continuing operations.

During the period, the Group transitioned to *IFRS 15 Revenue from contracts with customers*. Owing to transitional relief available, the comparative period has not been restated. Refer to note 18.

The accompanying notes form an integral part of these Consolidated Financial Statements.

<sup>\*</sup>Adjusted EBITDA is a non-IFRS measure comprising operating loss, adding back amortisation and impairment, depreciation, share-based payments and exceptional items. Refer to note 6 "Adjusted EBITDA".

# Consolidated Statement of Other Comprehensive Income

For the year ended 31 December

	2018	2017
	£m	£m
Loss after taxation	(88.2)	(85.7)
Items that may be reclassified to the Income Statement:		
Exchange movements arising on consolidation	14.2	(13.9)
Related impact of taxation	(0.5)	(1.2)
Items that will not be reclassified to the Income Statement:		
Actuarial gain on re-measurement of defined benefit pensions	0.2	1.1
Related impact of taxation	-	(0.2)
Other comprehensive income/(loss)	13.9	(14.2)
Total comprehensive loss	(74.3)	(99.9)

All results are attributable to shareholders of Vectura Group plc and are derived from continuing operations.

The accompanying notes form an integral part of these Consolidated Financial Statements.

# Consolidated Balance Sheet

At 31 December

At 31 December		2018	2017 (*Restated)	2016 (*Restated)
	Note	£m	£m	£m
ASSETS				
Non-current assets				
Goodwill	8	163.4	161.4	162.8
Intangible assets	9	219.9	335.4	456.8
Property, plant and equipment		57.8	53.1	54.8
Other non-current assets		10.1	7.4	4.0
Total non-current assets		451.2	557.3	678.4
Current assets				
Inventories		26.7	23.4	18.4
Trade and other receivables		35.3	34.1	56.6
Cash and cash equivalents		108.2	103.7	92.5
Total current assets		170.2	161.2	167.5
Total assets		621.4	718.5	845.9
LIABILITIES				
<b>Current liabilities</b>				
Trade and other payables		(61.1)	(56.5)	(59.8)
Corporation tax payable		(10.1)	(11.4)	(8.6)
Provisions	10	(1.1)	(2.2)	(1.9)
Total current liabilities		(72.3)	(70.1)	(70.3)
Non-current liabilities				
Other non-current payables		(6.2)	(9.6)	(12.2)
Provisions	10	(9.8)	(3.2)	(3.5)
Retirement benefit obligations	11	(3.1)	(3.6)	(5.9)
Deferred taxation	12	(35.7)	(53.5)	(76.8)
Total non-current liabilities		(54.8)	(69.9)	(98.4)
Total liabilities		(127.1)	(140.0)	(168.7)
Net assets		494.3	578.5	677.2
SHAREHOLDERS' EQUITY				
Share capital	13	0.2	0.2	0.2
Share premium	14	61.6	61.5*	61.0*
Translation reserve		40.0	26.3	41.4
Other reserves	14	447.3	599.1*	598.3*
Retained losses		(54.8)	(108.6)	(23.7)
Total shareholders' equity		494.3	578.5	677.2

<sup>\*</sup>Restated amounts of £41.3m relate to the correction of pre-Skyepharma merger share premium and merger reserves recognised on the acquisition of Activaero in 2014. The restated Merger reserves were subsequently utilised in full, and as a result, no longer remain. Refer to note 14.

The accompanying notes form an integral part of these Consolidated Financial Statements. These Consolidated Financial Statements and accompanying notes were approved by the Board of Directors on 25 March 2019 and were signed on its behalf by:

J Ward-Lilley P Fry
Director Director

# Consolidated Statement of Changes in Equity

For the year ended 31 December

For the year ended 31 December					Other reserve	nc .			
					Other reserve	Share-based			
		Share capital	Share premium	Merger reserve	Own shares reserve		Translation reserve	Retained losses	Total equity
	Note	£m	£m	£m	£m	£m	£m	£m	£m
At 31 December 2016 as previously reported		0.2	102.3	551.9	(0.7)	5.8	41.4	(23.7)	677.2
Share premium restatement*	14	_	(41.3)	41.3	_	_	_	_	_
At 31 December 2016 restated		0.2	61.0	593.2	(0.7)	5.8	41.4	(23.7)	677.2
Loss for the year		_	_	_	_	_	_	(85.7)	(85.7)
Other comprehensive (loss) / income		_	_	_	_	_	(15.1)	0.9	(14.2)
Total comprehensive loss		_	_	_	_	_	(15.1)	(84.8)	(99.9)
Share-based payments		_	_	_	_	3.9	_	_	3.9
Exercise of share awards		_	0.5	_	_	_	_	_	0.5
Employee share trust transactions		_	_	_	(1.8)	_	_	_	(1.8)
Share buyback programme		_	_	_	_	_	_	(1.4)	(1.4)
Transfer between reserves		_	_	_	_	(1.3)	_	1.3	_
At 31 December 2017		0.2	61.5	593.2	(2.5)	8.4	26.3	(108.6)	578.5
Adoption of IFRS 15	18	_	_	_	_	_	_	0.3	0.3
At 1 January 2018 as adjusted		0.2	61.5	593.2	(2.5)	8.4	26.3	(108.3)	578.8
Loss for the year		_	_	_	_	_	_	(88.2)	(88.2)
Other comprehensive income / (loss)		_	_	_	_	_	13.7	0.2	13.9
Total comprehensive income / (loss) for the year		_	_	_	_	_	13.7	(88.0)	(74.3)
Share buyback programme		_	_	_	_	_	_	(13.8)	(13.8)
Share-based payments		_	_	_	_	3.7	_	_	3.7
Employee share schemes		_	0.1	_	0.3	(3.8)	_	3.3	(0.1)
Release of special reserves**		_	_	(8.2)	_	_	_	8.2	_
Merger reserve release		_	_	(143.8)	_	_	_	143.8	_
At 31 December 2018		0.2	61.6	441.2	(2.2)	8.3	40.0	(54.8)	494.3

<sup>\*</sup> Reserves were restated to reduce share premium and increase Merger reserves by £41.3m to correct share premium recognised on the acquisition of Activaero in 2014 in accordance with s610 of the Companies Act. The restated Merger reserves were subsequently utilised in full, and as a result, no longer remain. Refer to note 14.

\*\* A Board resolution in July 2018 confirmed that certain creditor conditions, imposed pursuant to the July 2011 share capital reduction, had been satisfied. Specifically, all specified external creditors had been paid and all intercompany creditors had either been paid or provided their consent. Therefore, non-distributable special reserves of £8.2m, for the protection of these creditors, have been released to distributable retained earnings.

The accompanying notes form an integral part of these Consolidated Financial Statements.

# **Consolidated Cash Flow Statement**

For the year ended 31 December

		2018	2017
	Note	£m	£m
Cash flows from operating activities			
Loss after taxation		(88.2)	(85.7)
Adjustments reconciling loss after tax to operating cash flows	15	123.3	112.6
Cash generated from operating activities		35.1	26.9
Research and development tax credits received		1.0	2.1
Corporation tax paid		(6.0)	(2.9)
Net cash inflow from operating activities		30.1	26.1
Cash flows from investing activities			
Purchase of intangible assets		(0.8)	(0.2)
Purchase of property, plant and equipment		(11.5)	(9.5)
Interest received		0.2	0.2
Net cash outflow from investing activities		(12.1)	(9.5)
Cash flows from financing activities			
Share buyback programme		(13.8)	(1.4)
Funding relating to the issue of shares and share options		(0.2)	(1.3)
Repayment of mortgage borrowings and other finance charges		(0.8)	(0.5)
Net cash outflow from financing activities		(14.8)	(3.2)
Effects of foreign exchange fluctuations on cash held		1.3	(2.2)
Increase in cash and cash equivalents		4.5	11.2
Cash and cash equivalents at the beginning of the year		103.7	92.5
Cash and cash equivalents at the end of the year		108.2	103.7

The accompanying notes form an integral part of these Consolidated Financial Statements.

#### 1. General information

Vectura Group plc (the "Company") is a public limited company incorporated and domiciled in the United Kingdom. The final results have been prepared in accordance with International Financial Reporting Standards ("IFRS") adopted for use in the EU as at 31 December 2018 ("adopted IFRS"), International Financial Reporting Interpretations Committee ("IFRIC") interpretations and those parts of the Companies Act 2006 applicable to companies reporting under IFRS.

Vectura's Group plc 2018 Annual Report will be posted to shareholders on 16 April 2019. The financial information set out in this document does not constitute the company's statutory accounts for the years ended 31 December 2018 or 2017 but is derived from those accounts. Statutory accounts for 2017 have been delivered to the registrar of companies, and those for 2018 will be delivered in due course, following the Company's Annual General Meeting, which will be held at 10.30am on 29 May 2019. The auditor has reported on those accounts; their reports were (i) unqualified, (ii) did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying their report and (iii) did not contain a statement under section 498 (2) or (3) of the Companies Act 2006.

The final statements have been prepared in accordance with the Group's accounting policies approved by the Board. Critical accounting policy and judgment areas can be found in note 17 and details of principal business risks and uncertainties can be found in Note 21.

The Group is managed on the basis of a single reportable segment, being the development and supply of pharmaceutical products and as such no separate segmental information is provided as it would not be different from the Consolidated Income Statement.

Selected explanatory notes which reflect extracts from the full financial statements are included to explain events and transactions that are significant to the understanding of the changes in the Group's financial position and performance since the last annual financial statements.

# 1.1 Alternative performance measures ("APMs")

Alternative performance measures, which are used in these financial statements, are also used by the Board and management for planning and reporting. These measures are also used in discussions with the investment analyst community. APMs are not displayed with more prominence, emphasis or authority than IFRS measures.

**Adjusted EBITDA** is defined as operating loss adding back amortisation and impairment, depreciation, share-based payments and exceptional items. Refer to note 6 "Adjusted EBITDA".

**Exceptional items** are presented whenever significant expenses are incurred or income is received as a result of events considered to be outside the normal course of business, where the unusual nature and expected infrequency merits separate presentation to assist comparisons with previous years. Items which are included within the exceptional category include:

- costs associated with major corporate transactions;
- Board approved spend on the integration of major corporate transactions; and
- other major transformation programmes.

Furthermore, significant and unusual items of litigation (e.g. GSK litigation) and significant and unusual items which individually distort the underlying performance of the business and therefore warrant highlighting separately to the users of the accounts are also included within exceptional items. Refer to note 4 "Exceptional items".

**Underlying** and **non-recurring revenues** were previously presented in the 2017 financial statements in order to separate out revenues which can vary significantly each period. Following stakeholder feedback, this presentation was replaced and revenues have now been disaggregated according to whether they relate to product supply, development stage work or royalty and other marketed revenues. These revised categories are not considered APMs.

# 2. Revenue

Detailed analysis and commentary on revenue is provided in the Finance review.

	2018	2017
	£m	£m
Product supply revenues	85.6	74.7
Royalty and other marketed revenues	58.4	63.7
Development revenues	16.5	9.6
Total revenues	160.5	148.0

Development revenues include £8.5m (2017: £8.5m) for completed development service obligations, £3.7m (2017: £1.1m) for deferred income released on partially completed development service obligations and £4.2m (2017: nil) in respect of granting of a licence related to the new collaborative arrangement with Hikma signed in 2018, being the first arrangement to which IFRS 15 has been applied outside of the standard's transition rules.

Revenue of £6.6m (2017: £nil) has been recognised relating to the collaborative arrangement with Hikma signed in November 2018 to develop generic versions of GSK's Ellipta® portfolio. Of this amount, £4.2m (2017: nil) was recognised when the Group provided Hikma with the right to use intellectual property related to Vectura's Open-Inhale-Close prototype device as it existed on the grant date. The remaining £2.4m has been recognised reflecting the degree of progress made towards completing the second performance obligation being the provision of development services on Vectura's Open-Inhale-Close device.

The Group has determined the transaction price to be \$20.0m being the upfront milestone of \$15.0m and a variable payment of \$5.0m, which is contingent on successful completion of the device development services. The \$5.0m variable payment has been constrained subject to further development progress being made resulting in reduced uncertainty.

In addition, Vectura is obliged to perform future formulation and process development activities for up to five products which will only be committed upon agreement of individual product development plans in the future. The Group has assessed these services to be offered at their standalone selling price such that no material right to discounted services exists.

Revenue by geographical location

	2018 £m	2017
		£m
United Kingdom	55.2	49.2
Japan	35.1	33.0
Switzerland	31.0	27.3
United States of America	15.8	13.8
Rest of Europe	13.3	15.3
Rest of world	10.1	9.4
Total revenues	160.5	148.0

Geographical location is derived from customer invoicing points as opposed to patients receiving treatment.

#### **Revenue from major customers**

Three major customers contributed individually in excess of 10% of total Group revenues: Customer A - £43.9m (2017: 35.2m), Customer B - £35.1m (2017: £33.0m) and Customer C - £22.4m (2017: £17.1m).

#### **Customer contract balances**

The following table details trade receivables, contract assets and contract liabilities with customers:

	2018	2017
	£m	£m
Trade receivables	15.1	11.5
Customer contract assets - accrued royalty revenues	10.2	14.2
Customer contract liabilities - advanced consideration received	(6.5)	(4.6)

Accrued royalty revenues are transferred to trade receivables when the right to payment becomes unconditional upon receipt of royalty statements. Of the £11.4m payment received in respect of the new collaborative arrangement with Hikma, £4.8m has been deferred to be recognised as progress is made towards completing the second performance obligation.

Contract liabilities consists of advance payments from customers being released as performance obligations are satisfied. As part of an agreement with Sandoz regarding revised territory rights for AirFluSal® Forspiro®, Vectura recognised revenues of £2.4m during the period, of which £2.0m relates to the release of deferred income. In respect of VR2081, £1.3m of deferred income was also released and recognised as revenues for the services performed in 2018.

#### 3. Research and development expenses

	2018	2017
	£m	£m
Partnered R&D	20.6	25.7
Pre-partnered R&D	34.9	34.6
Total research and development expenses	55.5	60.3

Partnered research and development expenditure represents expenditure funded by partners to progress agreed contracted programmes. Pre-partnered research and development expenditure reflects investments funded by the Group on programmes yet to be partnered, as well as investments in the Group's own innovative proprietary technology platforms.

#### 4. Exceptional items

Exceptional items are presented whenever significant expenses are incurred or income is received as a result of events considered to be outside the normal course of business, where the unusual nature and expected infrequency merits separate presentation to assist comparisons with previous years.

	2018	2017
	£m	£m
Legal fees (1)	7.1	1.8
Skyepharma merger integration costs (2)	1.4	4.5
Site closure costs (3)	1.3	_
Other exceptional items (4)	0.2	0.4
Research and development accrual release (5)	(1.0)	(2.2)
Total exceptional items	9.0	4.5

Classification if costs were not presented as exceptional:

Legal fees of £7.1m (2017: £1.8m) relate to ongoing legal proceedings against GSK from enforcement of Vectura's patents in respect of the GSK Ellipta® products. In the UK, a judgement was handed down by the High Court on 13 December 2018 ruling in favour of GSK. Reimbursement of GSK's legal costs in the UK following this judgement are included in the exceptional charge. In the US, a jury trial is scheduled in Delaware for April 2019.

Post-merger integration costs of £1.4m (2017: £4.5m) include redundancy and other costs from initiatives to combine the businesses, streamline ways of working and enhance productivity, and £0.9m (2017: £1.8m) of share based payment charges. These arise from retention shares granted to key members of management considered critical to the integration process. The charges are lower than the comparative period primarily because the awards with an 18-month service condition vested on 22 March 2018.

The decision to close one of the Group's four operational sites, Gauting in Germany, by June 2021 was communicated in June 2018. Activities will be transferred to the remaining sites during the closure period. A provision of £1.1m has been recognised for redundancies arising from the closure. The provision assumes the redundancy payments are made at the end of the closure period and is discounted at a rate of one percent (being a proxy for the German risk free rate). The remaining £0.2m relates to share-based payment charges specifically for the retention of staff during the closure period.

Other exceptional items include the final redundancy costs from restructuring of the Group's manufacturing facility in Lyon which commenced in July 2016.

Following a detailed review of the research and development accruals during 2017, a number of individually immaterial historical accruals were identified where it was no longer considered probable that these accruals would result in future cash outflows. The accruals, totalling £2.2m, were released in the 2017 consolidated income statement and a final £1.0m has been released in 2018. These are presented within exceptional items to enable users to understand the impact of the credit on the current year performance. Management has determined that there is no material impact of the accruals on any comparative income statement, balance sheet or cash flow statement.

<sup>(1)</sup> Classified as research and development expenditure

 $<sup>^{(2)}</sup>$  Classified within corporate and administrative expenses and research and development expenditure

<sup>(3)</sup> Classified separately as restructuring costs

<sup>(4)</sup> Classified within cost of sales

<sup>(5)</sup> Classified within cost of sales and research and development expenditure

#### 5. Taxation

	2018	2017
	£m	£m
Current taxation	(4.6)	(5.9)
Adjustments to prior periods recognised	(0.1)	0.4
Total current taxation charge	(4.7)	(5.5)
Deferred taxation	21.3	22.0
Net taxation credit	16.6	16.5

Deferred taxation charges of £0.5m (2017: £1.4m) were recognised in other comprehensive income.

Current taxation arises from trading profits generated in Switzerland and the US. Deferred tax relates predominantly to credits arising on the unwinding of tax liabilities on the intangible assets acquired as a result of the acquisition of Activaero in 2014 and the Skyepharma merger in 2016.

The Group's effective tax rate ("ETR") before other comprehensive income ("OCI") is a 15.8% credit (2017: 16.2% credit). This equates to the applicable UK tax rate of 19%, adjusted for a number of factors discussed below.

#### **UK Taxation**

The UK sub-Group is loss-making and benefits from the R&D Expenditure Credit ("RDEC"). The RDEC is subject to UK corporation tax and therefore is included within the Consolidated Income Statement and presented as Other Operating Income. In addition, certain UK companies are able to participate in the UK Patent Box regime, the benefit of which is expected to increase as new products are approved. The UK corporation tax rate will reduce to 17% from 1 April 2020, which has been substantively enacted. The impact on the group accounts is expected to be immaterial.

#### **US Taxation**

Taxable income arose in respect of the percentage of net sales received from EXPAREL®. This ceased from September 2018.

#### **Swiss Taxation**

The Group continues to be tax-paying in Switzerland and continues to monitor the Swiss Tax Reform, expected to be enacted from 1 January 2020.

#### Effective tax rate ("ETR")

In Switzerland and the US, the Group is profitable and subject to taxation at the local rates (Swiss ETR 9.7% charge (2017: 8.5%), and the US corporate rate applied is 21% (2017: 35%)). The uncertain tax position disclosed has decreased by £0.1m in the year. These charges, along with a significant credit (ETR: 19.8% credit) in respect of deferred tax liabilities relating to intangible assets acquired on the Skyepharma and Activaero acquisitions (refer to note 12 "Deferred tax liabilities"), together drive the Group's ETR credit of 15.8% (2017: 16.15%).

	2018	2017
	£m	£m
Loss before tax	(104.8)	(102.2)
Loss before tax multiplied by standard rate of UK corporation tax of 19% (2017: 19.25%)	19.9	19.7
Effects of:		
UK Patent box benefit	-	0.1
Expenses not deductible for tax purposes	(0.1)	(2.5)
Unrecognised deferred tax*	(8.9)	(5.4)
Prior year deferred tax	0.4	0.5
Recognition of deferred tax on losses	2.0	-
Differences arising from prior period computations	(0.1)	0.4
Differences in effective overseas tax rates	3.4	2.1
Impact of deferred tax rate change	-	1.6
Total tax credit for the year	16.6	16.5

<sup>\*</sup> Unrecognised deferred tax mainly relates to losses incurred for which no deferred tax assets have been recognised as future recovery, or timing of recovery, cannot be supported.

The ETR (excluding the future release of the uncertain tax position) is expected to remain in the range of 10-15% credit for 2019 as a result of both the taxable Swiss profits and the significant credit in respect of deferred tax liabilities on intangibles acquired, which is expected to continue for the remainder of their useful lives. If VR315 US progresses to market as expected, the Group's loss before tax would decrease, and the ETR (before the release of the uncertain tax position) is expected to increase to 20-30% credit ETR as the UK moves into a profitable position and utilises brought forward tax losses. This is subject to change as the impact of Swiss tax reform becomes certain, and the credit is expect to reduce in future years as the Group's intangible assets are amortised in line with their respected useful economic lives.

# 6. Adjusted EBITDA

Adjusted EBITDA is a non-statutory measure used by the Board, the Executive Leadership Team and managers of the business to monitor the Group's performance.

		2018	2017
		£m	£m
Operating loss		(105.4)	(96.2)
Exceptional items	4	9.0	4.5
Amortisation and impairment of intangible assets	9	127.0	109.7
Depreciation of property, plant and equipment		5.8	5.7
Share-based payments		2.6	2.1
Adjusted EBITDA		39.0	25.8

# 7. Loss per share

Basic Loss per share of 13.2 pence per share (2017: 12.6 pps) equals diluted Loss per share of 13.2 pps (2017: 12.6 pps). The following table provides details of the impact as if shares had been considered dilutive.

	2018	2017
Loss after taxation (£m)	(88.2)	(85.7)
Weighted average number of shares (m)	666.1	678.9
Effect of dilutive potential shares (m)	6.3	6.2
Diluted weighted average number of shares (m)	672.4	685.1

# 8. Goodwill

	2018	2017
	£m	£m
At beginning of the year	161.4	162.8
Foreign exchange	2.0	(1.4)
At end of the year	163.4	161.4
Allocation to cash generating units (CGUs)		
UK and Germany	100.1	100.1
Switzerland	63.3	61.3
At end of the year	163.4	161.4

Goodwill has been allocated to cash generating units ("CGUs"), being the Group's geographic locations for operations and intellectual property. The recoverable amounts of each CGU is assessed using a fair value less costs of disposal model. This is calculated using a discounted cash flow approach, with a post-tax discount rate applied to the projected risk-adjusted post-tax cash flows and terminal value. IAS 36 "Impairment of Assets" requires the use of pre-tax cash flows and pre-tax discount rates. However, discounting post-tax cash flows at a post-tax discount rate provides materially the same result when there are neither temporary differences nor available tax losses at the measurement date.

The Group's weighted average cost of capital ("WACC") of 10% (2017: 9%) is used in the calculation to discount the cash flows to reflect the impact of risks relevant to the Group and the time value of money. The Group rate is then adjusted for risks specific to each CGU.

Cash flows relating to the Swiss CGU are discounted at 9% (2017: 8%) and to the UK and Germany CGU at 11% (2017: 9%). Whilst no specific Brexit adjustment is made to the discount rates, market volatility caused by Brexit is incorporated into risk free rates, equity market returns and economic expectations and has contributed to the increase in the Group's WACC.

Cash flows are based on the most recent budget approved by the Board covering 2019 and the 10 Year Plan to 2028. Details relating to the discounted cash flow models used in the impairment tests of the cash generating units are as follows:

Valuation basis	Fair value less cost of disposal		
Key assumptions	Brexit proceeds in an orderly manner with minimal disruption to the <i>flutiform</i> ® supply chain		
	Time to develop and launch pipeline products		
	Net sales forecasts and related royalty inflows		
	Timing of partnering pipeline products and milestone achievement		
	Gross profits margins on product supply		
	Discount rate		
	Taxation rate		
Determination of	Forecast development plans		
assumptions	Net sales forecasts are determined from partner forecasts and external market data		
<b>,</b>	Milestone amounts and royalty rates reflect past experience and forecast sales from market data		
	Margins reflect past experience, adjusted for expected future changes		
Discount rates based on Group WACC, adjusted for country specific risks			
	Taxation rates based on appropriate rates for each region		
Specific projected	10 years (reflecting a longer term planning cycle)		
cash flow year			
Terminal growth	Nil		
rate			
Discount rate	UK and Germany: 11%		
	Switzerland: 9%		

The Group conducted a sensitivity analysis on the impairment test of each CGU's carrying value. The UK and Germany CGU valuation indicates significant headroom such that a plausible change in any key assumption is unlikely to result in an impairment of the related goodwill. The forecast cash flows would need to reduce in excess of 65% (2017: 70%) before impairment arises. This is primarily because this CGU comprises a significant number of internally-generated intangibles.

The Swiss CGU has relatively low headroom primarily because it includes significant acquired intangibles, the largest being *flutiform*®. The sensitivity analysis indicates that either a decline of annual cash flows in excess of 11% or an increase in the discount rate by 1.5% would, all other assumptions being equal, cause impairment. A 1% increase in the discount rate combined with a 3.5% reduction in annual cash flows would likely cause impairment.

The sensitivity of the Swiss CGU to the potential outcomes of the UK exiting the EU ("Brexit") has been considered. Brexit could have a range of potential outcomes, of which the most severe is considered to be the UK exiting the EU on 29 March 2019 without a transition period ("hard Brexit"). In this scenario, the Group believes that there is a reasonable possibility that the Group's *flutiform*® supply chain could be disrupted. *flutiform*® is manufactured in the UK with raw materials imported mainly from the EU into the UK and the Group's partners export finished product from the UK into the EU and Japan.

As the cash flows from <code>flutiform</code>® form part of the recoverable amount of the Swiss CGU, sensitivities have been modelled ranging from minimal disruption to the <code>flutiform</code>® supply chain to severe but still reasonably possible disruption such that partner and patient demand cannot be satisfied. The sensitivities also consider an increase in operating costs from adverse regulatory changes. Details relating to the sensitivities are as follows:

Key assumptions	Severity and duration of border disruption
, ,	Stock levels of finished products and raw materials
	Level of switching in market between flutiform® and other available brands
	Tariff levels and other regulatory or trading costs
	Extent of sharing of incremental costs with the Group's partners
	Changes in batch failure rates following implementation of new release testing process
Determination of	External inputs from professional bodies, trade associations and governmental bodies
assumptions	Internal risk mitigation reviews and those with partners and suppliers
assamptions	The Group's own inventory tracking and supply forecasts
	Potential applicable tariffs and duties from the World Trade Organisation (WTO)
	Internal expertise and experience of regulatory and testing regimes
Specific projected	10 years (reflecting a longer term planning cycle)
cash flow year	
Terminal growth rate	Nil
Discount rate	9%

The impact of these sensitivities range from no impairment to an impairment of goodwill allocated to the Swiss CGU of £57.7m in the most severe but reasonably possible case. There remains a high level of uncertainty as at the date of approval of these financial statements as to how and whether specific risks will materialise. The full implications of Brexit will not be understood until future tariffs, trade, regulatory, tax, and other free trade agreements to be entered into by the United Kingdom are established. Furthermore, Vectura could experience changes to laws and regulations post Brexit, in areas such as intellectual property rights, employment, environment, supply chain logistics, data protection and health and safety, which may be relevant in assessing the Group's assets.

#### 9. Intangible assets

	Non-inhaled				
	Inhaled	Smart nebuliser	in-market		
	in-market assets	technology*	assets	Other	Total
	£m	£m	£m	£m	£m
Cost:					
At 1 January 2017	327.2	132.7	156.8	16.7	633.4
Additions	_	_	_	0.2	0.2
Disposals	(3.5)	_	(74.6)	_	(78.1)
Foreign exchange	(14.6)	5.6	(5.4)	(0.8)	(15.2)
At 31 December 2017	309.1	138.3	76.8	16.1	540.3
Additions	_	_	_	0.9	0.9
Foreign exchange	15.8	1.6	4.2	0.8	22.4
At 31 December 2018	324.9	139.9	81.0	17.8	563.6
Amortisation:					
At 1 January 2017	(31.3)	(48.8)	(91.4)	(5.1)	(176.6)
Amortisation	(49.4)	(20.6)	(29.6)	(1.4)	(101.0)
Impairment	_	_	_	(8.7)	(8.7)
Disposals	3.5	_	74.6	_	78.1
Foreign exchange	3.1	(2.3)	3.0	(0.5)	3.3
At 31 December 2017	(74.1)	(71.7)	(43.4)	(15.7)	(204.9)
Amortisation	(48.0)	(14.5)	(22.8)	(0.2)	(85.5)
Impairment	_	(41.5)	_	_	(41.5)
Foreign exchange	(5.7)	(1.7)	(3.6)	(0.8)	(11.8)
At 31 December 2018	(127.8)	(129.4)	(69.8)	(16.7)	(343.7)
Net book value:					
At 31 December 2018	197.1	10.5	11.2	1.1	219.9
At 31 December 2017	235.0	66.6	33.4	0.4	335.4

<sup>\*</sup>used in pipeline programmes

Inhaled in-market assets comprise the *flutiform*® and GSK's Ellipta® assets recognised on the Skyepharma merger. The Group receives product supply revenue on the *flutiform*® asset and royalties on both assets.

Non-inhaled in-market assets include several near end of life licences, patents, know-how agreements and marketing rights recognised on the Skyepharma merger, which are in use, and from which the Group continues to receive royalties.

The carrying value of the smart nebuliser technology asset at 31 December 2018 represents the amortised cost attributed to technology acquired through the Activaero transaction on 13 March 2014 being leveraged in the VR647 development programmes.

Impairment losses of £39.8m (2017: nil) arose from the decision to discontinue development of VR475 following the Phase III study results and a £1.7m charge (2017: nil) following the decision by Sanofi not to continue with the VR465 development programme despite positive Phase II study results.

Impairment tests on intangible assets are undertaken if events occur which call into question the carrying values of the assets. The assumptions relating to future cash flows, estimated useful lives and discount rates are based on business forecasts and are therefore inherently judgemental. Future events could cause the assumptions used in these impairment tests to change with a consequent adverse effect on the future results of the Group.

For the purposes of impairment testing, a value in use approach is applied. Details relating to the value in use calculations used for the impairment testing are as follows:

Intangible type	Inhaled in-market assets
Specific asset	flutiform®
Key assumptions	<ul> <li>Product supply volume forecast</li> <li>Margin (depending on pricing assumptions, raw material costs and cost of manufacture)</li> <li>Discount rate</li> </ul>
Determination of key assumptions	<ul> <li>Internal forecasts with input from partners and external market data</li> <li>Margins reflect past experience, adjusted for expected changes in pricing, raw material costs and cost of manufacture.</li> <li>Discount rate based on Group WACC, with a 1% risk deduction for being on-market and therefore having no development risk.</li> </ul>
Discount rate	9% (2018: 8%)

The Group has conducted a sensitivity analysis based on a number of reasonably possible downsides scenarios relating to reductions in margin (up to 6% reduction), volumes (up to 30% reduction) and the discount rate. All other assumptions being constant, an increase in the discount rate in excess of 16.5%, a reduction in volumes in excess of 23.0% or a reduction in margin in excess of 9.5% would cause impairment. In addition, the Brexit sensitivities in note 8 would have an impact ranging from no impairment of the *flutiform*® intangible to an impairment of £21.0m in the most severe case. The risk of future impairment of the *flutiform*® intangible is mitigated by further amortisation of the asset in 2019.

The Group's intangibles are amortised on a straight line basis using the following useful economic lives ("UELs"):

	Carrying value £m	Acquisition date	Useful economic life from acquisition date
Inhaled in-market assets	197.1	June 2016	3.5 – 7 years
Smart nebuliser technology	10.5	March 2014	8 years
Non-inhaled in-market assets	11.2	June 2016	3.5 years

The Group's sensitivity analysis shows that, had UELs been extended for 2018 by one year, then the impairment and amortisation charge would be £17.8m lower. Had UELs been reduced for 2018 by one year, then the impairment and amortisation charge would be £27.3m higher.

Following a contract renegotiation, effective from 1 January 2019, the UEL for non-inhaled in-market assets was extended by an additional four years.

#### 10. Provisions

	Employee	Property	Commercial	Total
	£m	£m	£m	£m
At 1 January 2018	2.2	1.9	1.3	5.4
Transfer from other payables	-	-	5.8	5.8
Charged/ (released) during the period	1.4	0.7	(1.8)	0.3
Utilised during the year	(0.4)	(0.2)	-	(0.6)
At 31 December 2018	3.2	2.4	5.3	10.9
Current	0.6	0.2	0.3	1.1
Non-current	2.6	2.2	5.0	9.8

Provisions of £10.9m (2017: £5.4m) have increased as a result of the transfer of a commercial liability of £5.8m, which was previously recognised in other payables. This transfer reflects the uncertainty of the phasing of future payments and the obligation is now considered to be constructive in nature. In this one instance, as the phasing of repayments cannot be reliably measured and owing to immateriality, no discounting has been applied. Of this provision, £0.8m has been released during the period.

A further £1.1m has also been released from commercial provisions in respect of a *flutiform®* supplier provision as payment is no longer considered probable, and this is partially offset by the recognition of a £0.3m provision for reimbursement of GSK's legal costs in the UK, which is expected to be settled in 2019 and is therefore presented as current. Refer to note 4 "Exceptional items".

Employee provisions relate to the Group's Gauting (Germany) and Lyon (France) sites. A provision of £1.2m has been made for redundancy payments following the decision to close the German site by June 2021. A provision of £1.4m for French statutory lump sum payments, payable upon the retirement of employees at the Lyon facility, with payments not expected in the medium term, and £0.6m for French redundancies payable in 2019. Refer to note 4 "Exceptional items".

Property provisions are recognised in respect of an onerous lease in Switzerland and the commitment to restore the Group's leased R&D facilities in Chippenham to their original 2012 condition in 2027.

# 11. Retirement benefit obligations

# Swiss defined benefit pension plan

The amounts recognised in the balance sheet for the Swiss scheme are as follows:

	2018	2017
	£m	£m
Present value of funded obligations	(16.2)	(17.7)
Fair value of plan assets	13.1	14.1
Balance sheet liability	(3.1)	(3.6)

The net decrease in the Swiss defined benefit pension plan primarily relates to the impacts of curtailments as pension plan employees reduced from 78 to 61. The Swiss Federation of Actuaries increase to the discount rate to 0.8% (2017: 0.65%) further reduced the liability, being offset by current service charges and foreign exchange losses. Expected employer contributions to post-employment benefit plans of £0.6m are consistent with the 2018 actual contributions paid in year (2017: £0.7m).

The sensitivity of the defined benefit obligation to changes in the weighted principal assumptions is:

		Monetary effect of	Monetary effect of
		increase in	decrease in
	Change in	assumption	assumption
	assumption	£m	£m
Discount rate	+1%/-0.8%	(1.6)	1.3
Pension increases	+/- 1%	(1.4)	Not applicable
Salary growth	+/- 2%	0.6	(0.5)
Life expectancy	+/- 1 year	(0.5)	0.5

A full IAS 19 disclosure is provided in the Annual Report.

#### 12. Deferred tax liabilities

The principal deferred tax liabilities relate to differences between the tax and accounting base of intangible assets and buildings uplifted as a consequence of fair value accounting requirements. Deferred tax liabilities are as follows:

	Intangible assets £m	Foreign exchange gains fm	Tangible assets £m	Total £m
At 31 December 2016	69.8	5.1	1.9	76.8
Credited to income statement	(22.0)	-	-	(22.0)
Charged to OCI	-	1.2	-	1.2
Foreign exchange	(2.2)	(0.3)	-	(2.5)
At 31 December 2017	45.6	6.0	1.9	53.5
Credited to income statement	(19.1)	-	(0.6)	(19.7)
Charged to OCI	-	0.5	-	0.5
Foreign exchange	1.2	0.2	-	1.4
At 31 December 2018	27.7	6.7	1.3	35.7

Deferred tax liabilities associated with intangible assets unwind to offset the tax distortion that would otherwise occur as the assets are amortised. As a result of the impairment of the carrying value of the smart nebuliser technology intangible asset attributed to VR475 (refer to note 9), the deferred tax liability of €12.7m (£11.1m) has been credited back in the period to the Consolidated Income Statement. In addition, as a result of the impairment and the announcement to close the Gauting site, the deferred tax asset on German tax losses of £5.3m (2017: £5.3m) has been released as a debit against the deferred tax liability release for VR475.

Deferred tax liabilities on Swiss and US unrealised foreign exchange gains arise on permanent funding loans because foreign exchange gains are deferred on the local balance sheet in accordance with Swiss and US laws.

The Group did not recognise deferred tax assets on tax losses amounting to £254.9m (2017: £248.4m). The majority of the losses are unlikely to offset taxable profits as they mostly relate to non-trading losses in investment holding companies. There are no current plans to recover these losses in the foreseeable future.

The future value of deferred tax liabilities in Switzerland are sensitive to the anticipated future Swiss tax reform. The Swiss Corporate Tax and Old Age Insurance Reform Bill will be put to a public vote by Swiss citizens on 19 May 2019. If the vote is successful, the reform will enter into force on 1 January 2020. The Group is monitoring the situation closely and, while the overall tax burden is unlikely to change materially, there are a number of complex provisions in the legislation and a number of areas yet to be finalised and hence once enacted will likely cause an adjustment to the amounts recognised in these Consolidated Financial Statements in the next accounting period.

# 13. Ordinary share capital

		Number
Allotted, called up and fully paid	£m	of shares
Ordinary shares of 0.025p, each at 1 January 2018	0.2	678,508,698
Issued to satisfy Vectura employee share plans	_	1,561,183
Share buyback programme – cancellations	_	(14,682,736)
Ordinary shares of 0.025p, each at 31 December 2018	0.2	665,387,145

On 14 November 2017, the Group announced that the Board had approved a share buyback to return up to £15m of capital to shareholders. On 28 February 2018, the £15.0m share buyback programme was completed with £13.6m (2017: £1.4m) of capital returned to shareholders in 2018 at a weighted average price of 92 pence per share. Directly attributable costs of £0.2m have been expensed to equity.

During the year, the Group allotted 1,561,183 (2017: 1,961,880) ordinary shares of 0.025p each related to employee share option awards.

# 14. Restatement of share premium within reserves

Following completion of the share buy-back programme, a review of the Vectura Group plc's distributable reserves was performed. It was identified that shares issued on 13 March 2014 with a market value of £41.3m, as part consideration for the Activaero acquisition, were incorrectly recorded in non-distributable share premium.

The share premium of £41.3m should have been recognised as a separate reserve, usually referred to as a merger reserve, and therefore this amount has been reclassified in the comparative year. Merger reserves are initially non-distributable, but can in future become distributable and the entire restated amount became distributable and, as such, was released from merger reserves to retained losses in November 2018 following impairment of the German investment. See Statement of Changes in Equity for amounts previously reported.

#### 15. Cash flow information

# Cash generated from operating activities

	2018	2017
	£m	£m
Cash flows from operating activities		
Loss after taxation	(88.2)	(85.7)
Adjustments		
Net taxation credit	(16.6)	(16.5)
Amortisation and impairment	127.0	109.7
Depreciation	5.8	5.7
Net finance (income) / expense	(0.8)	2.6
Share-based payments (including those in exceptional items)	3.7	3.9
Increase in inventories	(2.0)	(5.9)
(Increase) / decrease in trade and other receivables	(1.9)	17.2
Increase / (decrease) in trade and other payables	7.2	(6.9)
Loss from associates	0.2	3.4
Other non-cash items	0.7	(0.6)
Total adjustments	123.3	112.6
Cash generated from operating activities	35.1	26.9

#### Analysis of movement in financial liabilities

	2018	2017
	£m	£m
At the beginning of the year	4.1	4.5
Repayments	(0.3)	(0.3)
Interest expense	0.1	0.1
Foreign exchange movements	0.1	(0.2)
At the end of the period	4.0	4.1

Financial liabilities entirely relate to a Swiss property mortgage secured on the Swiss R&D facility. Repayments include £0.2m (2017: £0.2m) of capital repayments.

# 16. Going concern

The Groups' activities together with the factors likely to affect its future development performance and position are set out in the Business Review. The Group has made a loss for the year, however, it continues to be cash generative. A summary of the Group's financial position, cash generated in the year and accounting loss made after non-cash amortisation charges is included within the Financial Review. The Group has considerable financial resources together with long-term contracts with a number of customers across different geographic areas and jurisdictions. The Directors believe that the Group is well placed to manage its business risks successfully despite the current uncertain economic outlook. The Directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future, and as such, they continue to adopt the going concern basis of accounting in preparing the annual financial statements.

# 17. Critical accounting areas of judgement and estimation

The following critical judgements are those which have the most significant effect on the amounts recognised in the financial statements:

Applying IFRS 15 "Revenue from Contracts with Customers" to long term collaborative agreements

Collaborative development and marketing agreements which licence the Group's technology and intellectual property ("IP") can and do have unique terms. Consequently, the accounting judgments required to apply IFRS 15 to each such agreement can differ significantly.

# (a) Identification of performance obligations

A contract with a customer is in the scope of the standard when it is legally enforceable and all of the following criteria are met:

- the contract is approved and the parties are committed to their obligations;
- rights to goods or services and payment terms can be identified;
- the contract has commercial substance; and
- collection of consideration is probable.

An agreement often provides a customer with an option to acquire additional services. Judgement is required to determine the extent to which the Group or the customer is committed to these services throughout the agreement.

This has been applied to the agreement with Hikma to develop generic versions of GSK's Ellipta® portfolio. It has been judged that the licence to use Vectura's intellectual property and the provision of services for development of Vectura's Open-Inhale-Close device are considered committed as the initial \$15.0m milestone received on signing of the agreement is non-refundable. Hikma also has the option to acquire future formulation and process development services for up to five products on terms specified in the agreement. It has been judged that these services are not committed until product development plans are agreed.

# (b) Whether a licence to the Group's intellectual property is capable of being distinct

A licence granted by the Group usually provides the partner with a right to use, but not to own, the IP related to a development. A licence is capable of being distinct from development services if, regardless of contractual terms, it could be sold separately.

The timing of revenue recognised from a licence of intellectual property depends on whether:

- The licence is capable of being distinct (i.e. could be sold separately as it exists at the point in time
  it was granted). In this case revenue is recognised at the point in time the licence is granted,
  normally at contract inception. This treatment applies to the development of the generic GSK
  Ellipta® portfolio with Hikma.
- The licence is not capable of being distinct and therefore, the customer cannot obtain the value of
  the licence without the provision of additional services from Vectura. In this instance, revenue is
  recognised as those services accrue. This treatment applies to the development of VR2081 with
  Sandoz.

# (c) Allocation of the transaction price based on standalone selling prices at contract inception

For collaborative agreements containing multiple performance obligations, the Group must determine the standalone selling price identified on inception of the contract. Once these have been determined, these are not subsequently amended. The key assumptions used to determine the standalone selling price include forecast revenues, the cost of satisfying the obligation, development timelines and probabilities of technical, regulatory and commercial success.

These prices are considered to be a judgement on inception of the contract as opposed to an estimate, because, unlike an estimate, these are not subsequently amended. Refer to note 2 for details of the judgements applied to the agreement with Hikma to develop generic versions of GSK's Ellipta® portfolio.

# Uncertain tax positions

A provision for an uncertain tax position is recognised within current tax liabilities relating to recent utilisation of historical losses claimed in an overseas jurisdiction. The provision is recognised on the basis of the Group's interpretation of inherently complex tax legislation. The judgement of whether and how much to provide is formed after taking external professional advice, and is based on Management's judgement of the potential tax that could be assessed as due. The tax provision is recognised at £4.9m (2017: £5.0m) in Corporation tax payable. This provision is partially released to the Consolidated Income Statement as each annual Statute of Limitation (the period during which the tax authority can enquire into each return) is closed, with the uncertainty expected to be fully resolved in 2021.

The following critical estimates, if changed in 2019, would materially impact reported performance:

#### Revenue - Variable consideration included in revenue contracts

Variable consideration includes the estimate of payments in the form of contingent development related and regulatory approval milestones. These milestones are included in the transaction price when the most likely outcome is they will be received. Once this established, the entire transaction price is constrained to the extent that it is highly probable that a significant reversal of revenue will not occur in future periods. The estimate is reassessed for each reporting period.

The initial transaction price for the development of the generic GSK Ellipta® portfolio with Hikma has been assessed as \$20.0m, which includes a fixed \$15.0m non-refundable milestone received in 2018 and a second \$5.0m milestone due on Hikma confirming completion of the device development services. The second milestone is being constrained (i.e. not recognised) until further development progress is made and there is greater certainty over the achievement of the second milestone. If this \$5.0m milestone had not been constrained, additional revenue of £2.2m (\$2.9m) would have been recognised in 2018.

Impairment of goodwill and intangible assets acquired through business combinations

Goodwill arising on a business combination is not amortised, but is tested annually for impairment. This testing requires judgement as to the value in use of the cash-generating units ("CGUs") to which goodwill has been allocated. The actual performance of CGUs may differ from the valuations derived through this exercise. Refer to note 8 "Goodwill".

Intangible assets are reviewed for indicators of impairment and where such indicators exist a full impairment test is performed to ensure the recoverable amount is higher than the carrying value. Impairment tests are based on internal risk-adjusted future cash flows discounted to present value. Some of the more significant assumptions include the product supply volume forecast, margin (depending on pricing assumptions, raw material costs and cost of manufacture) and the appropriate discount rate to measure the inherent risks in the cash flows.

These valuations are inherently subjective. The sensitivity of the *flutiform®* intangible, being the Group's largest intangible asset, to downside scenarios is presented within note 9 "*Intangible assets*".

Useful economic lives of intangible assets acquired through business combinations

Intangible assets relating to in-market products are amortised with reference to average patent lives in the most applicable territories. The key estimate is which patent or midpoint of the patents to use, due to the varying strength of the patents and different time periods for different territories. Given the quantum of the intangible assets, any change in assumptions would have a significant impact on the amortisation charge.

Intangible assets relating to smart nebuliser-based technology acquired through the Activaero acquisition and leveraged in various development programmes are amortised in line with the expected consumption of economic benefits. These may change, for example on approval of a product incorporating the technology and in such cases. The useful economic life ("UEL") is reviewed and adjusted accordingly. If the UEL changes, the Group's financial statements would be significantly impacted through changes to amortisation and deferred tax.

Actuarial assumptions applied to the Swiss pension benefits in the application of accounting policies

The Group operates a pension scheme in respect of its employees in Switzerland. As some of the risks of the scheme match the criteria under IAS 19 Employee Benefits for a defined benefit plan, the scheme is accounted for as such. Application of IAS 19 involves estimates about uncertain future events based on independent actuarial valuation reports.

#### 18. Accounting Policies – new standards adopted - Revenue from contracts with customers

The Group has initially applied IFRS 15 from 1 January 2018 using the cumulative effect method. Under this method, the comparative information is not restated, but £0.3m of deferred income from VR2081 was released to retained losses net of related taxes.

The Group's presents revenues as follows:

Revenue is measured at the fair value of the consideration which is expected to be received in exchange for the goods and services provided, net of applicable taxes. In accordance with IFRS 15, the Group recognises revenue through application of the five-step model as follows:

- The Group identifies a contract with a customer;
- The performance obligations within this contract has been identified;
- The transactions price has been determined;
- This transaction price has been allocated to the performance obligations in the contract; and
- Revenue is recognised as or when each performance obligation is satisfied.

#### <u>Product supply revenues</u>

The Group generates revenues from the supply of finished or semi-finished products, largely manufactured by third party suppliers, to commercial distribution partners. Revenue is recognised when the customer gains control of the goods which is when the performance obligation is satisfied.

# Royalties and other marketed revenues

Where a licence of intellectual property is the predominant item to which a royalty relates, then revenues are recognised upon the occurrence of partner net sales.

Other marketed revenues primarily include sales or usage based milestones for which revenue is recognised consistently with royalties as stated above.

#### Development revenues

Revenues related to development stage programmes are allocated to the following performance obligations as applicable:

# (a) Licence to the Group's intellectual property

A licence granted by the Group usually provides the partner with a right to use, but not to own, the IP related to a development that has not yet received regulatory approval as it exists at contract inception. A licence is capable of being distinct from development services if, regardless of contractual terms, it could be sold separately as it exists at the point in time it was granted.

The timing of revenue recognised from a licence of intellectual property depends on whether:

- The licence is capable of being distinct (i.e. could be sold separately as it exists at the point in time it was granted). In this case revenue is recognised when control is transferred, normally at contract inception; or
- The licence is not capable of being distinct and therefore, the customer cannot benefit from the value of purchasing it without the provision if additional services from Vectura. In this instance, revenue is recognised as those services accrue.

#### (b) Development services

Revenue from a contract to provide development services is recognised by reference to the stage of completion of the contract. Stage of completion is estimated by either completion of relevant milestones or proportion of estimated hours for work performed to date, as appropriate.

# 19. Accounting Policies – new standards not currently adopted

The Group is required to apply IFRS 16 "Leases" and IFRIC 23 "Uncertainty over Income tax treatments" from the mandatory transitional date 1 January 2019. Transition notes are included in the full financial statements to be published in April 2019.

# Operating leases and the future Impact of IFRS 16 "Leases" applied from 1 January 2019

IFRS 16 eliminates the classification of either operating leaves or finance leases and introduces a single lessee accounting model where the lessee is required to recognise assets and liabilities for material leases lasting more than one year. Historically, the Group has only entered into material leases relating to commercial properties.

Under the modified retrospective approach, the Group will apply IFRS 16 from the beginning of 2019, calculating lease assets and liabilities as at the beginning of 2019, whilst applying the practical expedients allowed by the standard.

Cumulative adjustment to retained earnings as at 1 January 2019

The Group will not restate 2018 financial information and will recognise the cumulative effect adjustment in equity on transition using the modified retrospective approach as detailed following the table below:

Transitional adjustment as at 1 January 2019	Property
·	£m
Right to use assets	3.3
Discounted Lease liabilities*	(3.7)
Cumulative adjustment to retained earnings	(0.4)

<sup>\*</sup> rental prepayments of £0.2m will also be reclassified into the lease liability

The following table summarises the impacts of adopting IFRS 16 on the Group's opening consolidated balance sheet as at 1 January 2019:

	As reported 31 December 2018	Transitional adjustments	Opening balance 1 January 2019
	£m	£m	£m
Property, plant and equipment	57.8	3.3	61.1
Prepayments and other receivables	6.3	(0.2)	6.1
Provisions	(10.9)	1.0	(9.9)
Finance lease liabilities	-	(4.5)	(4.5)
Net assets and retained earnings	494.3	(0.4)	493.9

#### Interpretation 23 - Uncertainty over Income Tax Treatments as at 1 January 2019

IFRIC 23 has been issued to clarify the accounting for uncertainty within tax positions, and provides two methods for measurement. Where the outcome is considered binary, the "most likely amount" is applied, but where the results could be within a range, the "expected value method" (which considers the weighted average of possible outcomes) should be applied. The Group holds one uncertain tax position, and due to the binary nature of an outcome, the method adopted under IFRIC 23 is the most likely amount. As a result, the Group expects no change the recognition of the uncertain tax position under the new standard to be adopted from 1 January 2019.

# 20. Related-party transactions

#### **Associates**

In August 2018, the Group paid a final instalment of £150,000 to a German supplier on confirmation that a new Clickhaler® and Duohaler® cap filling and assembly line has received formal factory acceptance testing clearance and has been shipped to the Group's Chinese associate.

# Remuneration of key management personnel

The remuneration of the Directors, who are the key management personnel of the Group, was £2.0m and is set out below:

	Year ended	Year ended	
	31 December 2018	31 December 2017	
	£m	£m	
Short-term employee benefits	0.8	1.0	
Annual incentive plan	0.7	0.7	
Non-Executive Directors' fees	0.5	0.4	
Post-employment benefits	0.1	0.2	
Other	0.3	0.3	
Total remuneration of key management personnel	2.4	2.6	

Please refer to the Remuneration Report for the remuneration of each Director.

# 21. Risks and uncertainties

During the year, the Directors carried out a robust assessment of the principal risks and uncertainties facing the Group, including those that would threaten its business model, future performance, solvency, liquidity and viability.

As a result of further risk identification and risk mitigation planning relating to Brexit, the Group's principal risk of "Brexit uncertainty" is replaced by three separate risks. The Group continues to monitor closely evolving events concerning the UK's exit from the European Union. Despite the expectation of a transition period post 29 March 2019, the Group has implemented a number of measures to mitigate the risks should this not be the case. In such circumstances, the Group still expects transition to be relatively orderly within an expected range given the extent of these measures. However, if the transition is not orderly, then the Group believes that the supply chain for flutiform® could be materially disrupted.

The principal risk of "Failure or delay in partnering VR647 (US) and VR475 (EU)" has been updated to "Failure of delay in partnering VR647 (US)" following the VR475 Phase III study not meeting its primary endpoint and the decision not to pursue further development and partnering of VR475 (EU). Following increased focus on the Vectura enhanced therapies, with three new programmes targeting orphan or niche disease segments, a new risk has been added: "Failure to effectively scale up the manufacture of the Group's nebulised platforms for partnering".

The principal Group risks are summarised as follows:

# **Brexit specific risks**

- Supply chain disruption in the short term from the UK exiting the EU in the event of a "hard" Brexit
- Adverse regulatory changes resulting in higher operating costs over the short, medium and longer term

# **Non-Brexit risks**

- Supply chain disruption
- Failure to launch VR315 in a competitive timeframe
- Failure or delay in achieving development milestones required to advance the product pipeline
- Failure to effectively scale up the manufacture of the Group's nebulised platforms for partnering
- Changes in the regulatory, operating or pricing environment
- Failure to attract or retain talent/key personnel
- Failure to protect intellectual property

A summary of all the Group's principal risks which are monitored by the Board will be included in the Annual Report for the year ended 31 December 2018.