

29 September 2016

LSE: VER

**Vernalis plc**

**Results Announcement for the 12 months ended 30 June 2016**

*Significant investment in Tuzistra<sup>®</sup> XR US launch as transition to a commercial specialty pharmaceutical company continues*

Vernalis plc (LSE: VER) today announces its audited results for the 12 month period ended 30 June 2016.

	<b>(Audited) 12 months ended 30 June 2016 £000</b>	(Unaudited) 12 months ended 30 June 2015 £000	(Audited) 18 months ended 30 June 2015* £000
Revenue	<b>12,034</b>	13,712	19,882
Sales and marketing expenditure	<b>(20,428)</b>	-	-
Research and development expenditure	<b>(10,932)</b>	(15,687)	(22,563)
General and administrative expenditure (before exceptional items)	<b>(5,289)</b>	(6,019)	(8,635)
Operating loss			
- Before exceptional items	<b>(26,223)</b>	(8,224)	(12,078)
- After exceptional items	<b>(23,572)</b>	(7,981)	(11,835)
Net finance income	<b>8,273</b>	4,252	2,576
Loss before tax			
- Before exceptional items	<b>(17,950)</b>	(3,972)	(9,502)
- After exceptional items	<b>(15,299)</b>	(3,729)	(9,259)
Income tax credit	<b>804</b>	1,946	2,858
Loss after tax			
- Before exceptional items	<b>(17,146)</b>	(2,026)	(6,644)
- After exceptional items	<b>(14,495)</b>	(1,783)	(6,401)
Cash resources	<b>84,018</b>	61,258	61,258

\*The Group changed its accounting reference date from 31 December to 30 June on 18 November 2014 to align the external reporting period with the seasonality of the US cough cold market, which will become a major component of the Group's commercial business. While the financial highlights and financial review below focus on the audited 12 months ended 30 June 2016 compared to the unaudited 12 months ended 30 June 2015, figures for the audited 18 month period to 30 June 2015 are also presented.

## Financial Highlights for the 12 months ended 30 June 2016

- Revenue was £12.0 million (2015: £13.7 million):
  - Tuzistra<sup>®</sup> XR net revenue was £1.1 million and represents deliveries made to wholesalers by 30 June 2016
  - Research collaboration income was flat at £8.0 million (2015: £7.9 million) but included an increase in FTE income offset by a reduction in milestone receipts. Our research organisation remained self-funded
  - As expected frovatriptan royalty income was lower than the prior year at £2.9 million (2015: £4.9 million); most of this decrease was due to a volume decline, with two 12.5kg batches of API delivered to Menarini during the 12 months to 30 June 2016 (2015: three 12.5kg batches of API)
    - Menarini's underlying sales for the 12 months to 30 June 2016 were down 18 per cent at €20.8 million (2015: €25.2 million)
    - As previously highlighted, major patent expiry occurred in December 2015 and subsequent generic entries have already started to impact both pricing and volumes
- Operating costs before exceptional items were £36.6 million (2015: £21.7 million); the increase was due to the significant investment in Tuzistra<sup>®</sup> XR sales, marketing and other US commercial infrastructure
- Pre-exceptional loss for the period was £17.1 million (2015: £2.0 million) and loss after exceptional items was £14.5 million (2015: £1.8 million), including an exceptional gain on the surrender of an onerous building lease; the increase in the loss was due to the additional operating costs in excess of gross margin following the launch of Tuzistra<sup>®</sup> XR
- Cash resources including cash and cash equivalents and held to maturity assets increased by £22.8 million in the 12 months and included:
  - £38.9 million (net of expenses) equity placing completed in May 2016
  - \$5.4 million (£3.7 million) payment for the acquisition of Moxatag<sup>®</sup>
  - £8.0 million foreign exchange gain on retranslation of US dollar and euro cash resources into sterling (2015: £4.1 million)
  - Underlying net cash burn increased to £21.8 million for the year (2015: £8.5 million)
- Balance sheet remains strong with £84.0 million of cash resources and no debt at 30 June 2016

## Operational Highlights

### US Commercial Pipeline:

- Tuzistra<sup>®</sup> XR, the only 12-hour, extended-release, codeine based cough cold suspension product, launched in the US ahead of the 2015/16 cough cold season
- Focused US primary care sales force fully recruited, trained and deployed to the field
- US rights to Moxatag<sup>®</sup>, the only US approved once-a-day formulation of amoxicillin, acquired in October 2015, validating the Company's ability to expand its US commercial portfolio
- CCP-07 filed with FDA and accepted for review in September 2016. PDUFA date of 20 April 2017
- CCP-08 pivotal single-dose and multiple dose comparative bioavailability studies successfully completed and NDA submission remains on track for calendar year 2016
- Two further programmes in active development at Tris, with proof-of-concept ("POC") now targeted during the 2016/17 financial year

### Other:

- **NCE Development Pipeline:** Completion of the Phase 2 POC study of V158866 in August 2015 which ended in-house investment in NCE pipeline

- Corvus Pharmaceuticals, Inc. announced (in January 2016) as the worldwide licensee for the adenosine antagonist programme with CPI-444 (formerly V81444), initially being developed for immuno-oncology with clinical studies expected in 2016
- RedoxTherapies, our partner for vipadenant (V2006), acquired by Juno Therapeutics Inc. (Juno), a leader in CAR[-T] and TCR technologies. Juno will continue to explore the utility of vipadenant in immuno-oncology
- Verona Pharma plc announced positive phase II study results for RPL554 in COPD and raised £45 million via an equity placing
- **Research Collaborations:** Six active collaborations during the year ended 30 June 2016; business remained self-funded

**Expected 2016/17 Newsflow (all dates calendar year unless otherwise stated):**

- CCP-07: potential approval by FDA (Q2 2017 calendar year)
- CCP-08: NDA submission (2016 calendar year )
- Re-launch Moxatag<sup>®</sup> in the US market through our focused US primary care sales force (H2 2016 calendar year)
- POCs on two remaining programmes in cough cold pipeline (CCP-05 and CCP-06) (during 2016/17 financial year)
- Achieve milestones under existing collaborations
- Secure new research collaborations
- Continue to leverage our US commercial infrastructure with possible complementary new product acquisitions/in-licensing

**Ian Garland, Chief Executive Officer, commented,** “The last twelve months have seen a major transformation in our business as we launched the first product from our cough cold franchise, Tuzistra<sup>®</sup> XR, into the US market. We have made a significant investment in our commercial infrastructure to support the launch of Tuzistra<sup>®</sup> XR, and this will continue during the product’s launch phase as we seek to gain a greater share of the US cough cold market. We will leverage this investment and our US commercial infrastructure to launch the once-a-day antibiotic, Moxatag<sup>®</sup> in the second half of 2016. The cough cold pipeline continues to mature with CCP-07 and CCP-08 on track for potential approvals in 2017.

Our cash position was bolstered following the recent equity raise to continue the promotional investment in Tuzistra<sup>®</sup> XR as well as launch Moxatag<sup>®</sup> and our additional products, CCP-07 and CCP-08 in the near term. We remain very excited about the growth potential of the business.”

**Presentation & Conference Call**

Vernalis management will host a presentation at **9.30am** (UK) at the offices of FTI Consulting 200 Aldersgate, Aldersgate Street, London, EC1A 4HD. It will also be available via webcast at <http://www.vernalis.com/investor-centre/presentations-and-webcasts> and [www.cantos.com](http://www.cantos.com) and via conference call, which can be joined by dialling: **+44 (0) 20 3003 2666**. Please contact Matthew Moss at FTI consulting +44 (0) 20 3727 1000 for details.

The information contained within this announcement is deemed to constitute inside information as stipulated under the Market Abuse Regulations (EU) No. 596/2014. Upon the publication of this announcement, this inside information is now considered to be in the public domain.

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## Notes to Editors

### **About Vernalis**

Vernalis is a revenue generating, commercial stage pharmaceutical company with significant expertise in drug development. The Group has three approved products: Tuzistra<sup>®</sup> XR, targeting the US prescription cough-cold market; Moxatag<sup>®</sup>, a once-a-day formulation of the antibiotic, amoxicillin, indicated for the treatment of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes* in adults and pediatric patients 12 years and older; and frovatriptan for the acute treatment of migraine. It has an exclusive licensing agreement to develop and commercialise multiple novel products focussed on the US prescription cough-cold market as well as eight programmes in its NCE development pipeline. Vernalis has also significant expertise in fragment and structure based drug discovery which it leverages to enter into collaborations with larger pharmaceutical companies. The Company's technologies, capabilities and products have been endorsed over the last five years by collaborations with leading pharmaceutical companies, including Asahi Kasei Pharma, Biogen Idec, Endo, GSK, Genentech, Lundbeck, Menarini, Novartis, Servier, Taisho, and Tris.

For further information about Vernalis, please visit [www.vernalis.com](http://www.vernalis.com).

### **Vernalis Forward-Looking Statement**

*This news release may contain forward-looking statements that reflect the Company's current expectations regarding future events including the clinical development and regulatory clearance of the Company's products, the Company's ability to find partners for the development and commercialisation of its NCE pipeline, the Company's ability to successfully commercialise its cough-cold products and Moxatag<sup>®</sup> through its own sales force, as well as the Company's future capital raising activities. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors including the success of the Company's research strategies, the applicability of the discoveries made therein, the successful and timely completion of clinical studies, the uncertainties related to the regulatory process, the ability of the Company to identify and agree beneficial terms with suitable partners for the commercialisation and/or development of its products, as well as the achievement of expected synergies from such transactions, the acceptance of Tuzistra<sup>®</sup> XR, Moxatag<sup>®</sup>, frovatriptan and other products by consumers and medical professionals, the successful integration of completed mergers and acquisitions and achievement of expected synergies from such transactions, and the ability of the Company to identify and consummate suitable strategic and business combination transactions.*

## Operational Review

Vernalis' transition to a diversified self-sustaining specialty pharmaceutical company continues to plan with the launch of Tuzistra<sup>®</sup> XR, the acquisition of Moxatag<sup>®</sup>, the filing of CCP-07 NDA and the successful completion of CCP-08's development activities.

The business has made significant progress over the last 12 months in transitioning towards a self-sustaining specialty pharmaceutical company. Critical to this transition was the on-time FDA approval of Tuzistra<sup>®</sup> XR enabling its launch in September 2015 ahead of the 2015/16 cough cold season. This followed hiring our field sales team, which was established through the inVentiv contract sales organisation, and establishing supply chain, wholesaler and pharmacy distribution, payer access and full commercial support functions. While the initial season's prescription performance was modest, we successfully established full US commercial capability and our commercial priorities for the coming season are to continue to build pharmacy distribution, payer access and sales force effectiveness which are key to delivering an acceleration in prescription growth. One year into the launch, we remain extremely excited about the sales potential for Tuzistra<sup>®</sup> XR.

Our four cough cold pipeline programmes have progressed well under Tris' guidance. Both CCP-07 and CCP-08 could potentially be approved and launched into the 2017/18 cough cold season and CCP-05 and CCP-06 could achieve POC during the 2016/17 financial year.

In order to leverage our commercial infrastructure, in October 2015, we acquired the rights to Moxatag<sup>®</sup>, the only US approved once-daily amoxicillin to treat tonsillitis and pharyngitis. This product is an excellent fit with our US commercial capabilities and, following manufacture of launch stocks in Q2 2016, will be launched ahead of the 2016/17 winter season. In May 2016, we were informed that our existing supplier had gone into liquidation and following the liquidator's inability to find a purchaser of the Suir business, we will limit our commercial effort while we continue to work on re-establishing longer term supply of the product. We estimate that this could take 18-24 months to complete.

Historically, frovatriptan revenues have subsidised the cost of our development activities, but in December 2015 the core composition of matter patent expired, resulting in generic competition in several European markets. Sales have reduced and we expect to see further erosion in terms of both volume and price as more generics are approved.

Following the build out of our US commercial infrastructure, our operating costs, as expected, have increased significantly. In May 2016, we further strengthened our cash resources with a £38.9 million (net of expenses) equity fundraising and at 30 June 2016, we had £84.0 million of cash resources.

There have been a number of positive developments in our NCE pipeline, most notably our two A2A programmes, which are now both being investigated in immuno-oncology by our development partners. We announced Corvus as our partner for V81444 (now known as CPI-444) during the year and also that our vipadenant (V2006) partner, Redox, was acquired by Juno, a leading US immuno-oncology company. Both partners are extremely well positioned to progress these programmes and we hope for further positive news flow over the next 12 months.

The research business continued its strong performance, both operationally and financially. Revenues of £8.0 million again more than covered costs, including capital expenditures.

The focus for the Company over the next few years is to drive significant top line sales growth of our US commercial products and to move into profitability. We are well positioned to achieve such growth, initially through Tuzistra<sup>®</sup> XR and Moxatag<sup>®</sup> and in the near to medium term through the potential approval and launch of CCP-07 and CCP-08 in 2016/17 and CCP-05 and CCP-06 in 2018/19.

As we continue our transition to a commercial business, we have further strengthened our Board and management team. Dr Ian Gilham joined on 1 July 2015 as a Non-Executive Director and Chair of the Remuneration Committee and Lisa Schoenberg joined on 1 September 2015 as a Non-Executive Director. Lisa has substantial US commercial experience from her time as a senior member of AstraZeneca's US commercial operations. On 1 May 2016, we hired Sandy Sommer as President and Chief Operating Officer of our Vernalis Therapeutics, Inc. commercial business in

the US. Sandy joined us with 24 years of commercial experience in pharmaceutical sales, marketing and general management and is leading our US commercial business as it grows rapidly over the coming years.

We would like to thank the Board members and our staff for their contributions during another successful period and our shareholders for their continued support.

## **Financial Review**

### **Accounting reference date change**

The financial information within this annual report covers the year ended 30 June 2016 and the comparator period is the 18 months to 30 June 2015. The Group changed its accounting reference date from 31 December to 30 June on 18 November 2014, to align the external reporting period with the seasonality of the US cough cold market, which is a major component of the Company's future commercial business.

The financial review below includes unaudited comparative numbers for the 12 months ended 30 June 2015.

### **Total revenues of £12.0 million**

Revenue for the year ended 30 June 2016 totalled £12.0 million (2015: £13.7 million), a decrease of 12 per cent year-on-year. This comprised revenue from Tuzistra<sup>®</sup> XR of £1.1 million, which was recorded for the first time this year following its launch, £2.9 million related to the supply of frovatriptan (2015: £4.9 million) and £8.0 million (2015: £8.8 million) from research collaborations, and other collaboration income.

### **Tuzistra<sup>®</sup> XR**

Following approval by the FDA in April 2015, Tuzistra<sup>®</sup> XR was launched into the US prescription cough cold market in September 2015. Tuzistra<sup>®</sup> XR revenue is recognised when title and risk of loss passes to the customer and estimates are made for the relevant deductions and obligations so as to reflect the complete economic transaction.

Net revenue reflects the gross sales of product shipped to wholesalers, reduced by estimates of rebates, discounts, allowances and provision for product returns, given or expected to be given, which vary by product arrangements and buying groups. These estimates have been based on actual in-market data received pre- and post- the end of the accounting period and have been applied to inventory held at wholesalers and pharmacies.

### **Frovatriptan sales decline following patent expiry**

Sales of frovatriptan by Menarini in Europe and Central America were down 18 per cent in euro terms at €20.8 million for the year to 30 June 2016 (2015: €25.2 million) due to expiry of the composition of matter patents in December 2015. Volumes of tablet sales for the year to 30 June 2016 were also down at 9.0 million (2015: 9.8 million). Vernalis receives 25.25 per cent of Menarini sales via a royalty linked to the supply of API, so the reported royalties do not necessarily track the underlying performance of Menarini in the market.

The reported frovatriptan royalties for the year to 30 June 2016 were £2.9 million (2015: £4.9 million) and this £2.0 million decrease was mostly due to a volume decline with two 12.5kg batches of API delivered to Menarini during the 12 months ended 30 June 2016 (2015: three 12.5kg batches of API). In addition, there was a small decrease due to foreign exchange and a 6 per cent price reduction, owing to increased competition from generic alternatives. Based on Menarini's projections, we expect to deliver two batches of API for the 2016/17 financial year.

### **Research remained self-financing**

Research collaboration income was £8.0 million for the year to 30 June 2016 (2015: £7.9 million), an increase of £0.1 million. Although milestone income was lower in the year to 30 June 2016 at £0.6 million (2015: £1.1 million), which came from the Servier collaborations, this was more than offset by an increase in FTE income. We had six research collaborations during the year to 30 June 2016, which generated £7.4 million of FTE income (2015: £6.8 million). Research activity remained self-financing during the financial year ended 30 June 2016.

### **Other collaboration income**

In February 2015, we out-licensed CPI-444 for use in all therapeutic applications to Corvus. The transaction included a US\$1 million upfront payment (£0.7 million) which was included in collaboration income for the year to 30 June 2015.

### **R&D costs reduced following cessation of NCE development activity**

Research and development expenditure before exceptional items decreased 30 per cent to £10.9 million for the year to 30 June 2016 (2015: £15.7 million) and comprised £10.5 million (2015: £13.2 million) of internally funded research and development costs and £0.4 million (2015: £2.5 million) of external costs associated with the development pipeline. The decrease in both the internally funded and external research and development costs was primarily due to the completion of our in-house investment in the NCE development pipeline, announced in August 2015, and the pre-launch costs for Tuzistra<sup>®</sup> XR included in the prior financial year and not in the current financial year. The external development pipeline costs for the year to 30 June 2016 related to the completion of the V158866 Phase II study, announced in August 2015, whereas in the year to 30 June 2015 costs included the V158866 clinical study for the whole of the year.

### **S&M infrastructure established in the US**

Following the launch of Tuzistra<sup>®</sup> XR, sales and marketing costs have been recorded for the first time and were £20.4 million for the year to 30 June 2016. These costs include the set-up and ongoing costs of the contract sales organisation run by inVentiv together with the promotional costs associated with the launch of Tuzistra<sup>®</sup> XR, and other commercial support costs. The sales representatives were recruited, trained, equipped and deployed into the field in early September 2015. We will expand the sales force this year as we continue to build our US commercial infrastructure.

### **G&A costs decreased**

General and administrative expenditure before exceptional items was £5.3 million for the year to 30 June 2016 (2015: £6.0 million), a decrease of £0.7 million for the year. Adjusting both periods for the share option charge and associated national insurance accrual on the exercise of share options and foreign exchange from the retranslation of working capital balances, underlying G&A decreased by £0.2 million or 4 per cent.

### **Exceptional gain**

The exceptional gain in the year to 30 June 2016 of £2.7 million is a non-cash item and relates to the successful settlement of an onerous lease obligation. The exceptional gain in the year to 30 June 2015 of £0.2 million related to the effect of a reassessment of assumptions used to calculate the property provision recognising an improvement in the rental market at that time.

### **Operating loss increased significantly due to establishing our sales and marketing capabilities**

The operating loss before exceptional items increased significantly to £26.2 million for the year to 30 June 2016 (2015: £8.2 million) reflecting the increase in operating costs following the launch of Tuzistra<sup>®</sup> XR and the establishment of our sales and marketing capabilities focused on the US prescription cough cold market. The operating loss from continuing operations after the exceptional gain was £23.6 million (2015: £8.0 million).

### **Finance income increased significantly by strengthening of the US dollar**

Interest earned on cash resources was marginally higher at £0.3 million (2015: £0.2 million) reflecting the higher average cash balance for the year. With the majority of our cash held in US dollars in order to match our Tris and US commercial financing requirements, the yield on these deposits remained low. Finance income, however, was significantly impacted by the strengthening of the US dollar and euro after the 23 June 2016 UK EU referendum vote, with an £8.0 million unrealised foreign exchange gain on the conversion of US dollar- and euro-denominated cash deposits into sterling at 30 June 2016 for financial reporting purposes. For the year to 30 June 2015 there was an unrealised foreign exchange gain of £4.1 million due to the strengthening of the US dollar over this period. At 30 June 2016 the sterling:US dollar rate was 1.3370, compared to the 30 June 2015 rate of 1.5727.

**R&D tax credits decrease**

The tax credit of £1.1 million (2015: £2.1 million) represents recoverable amounts under current legislation on R&D tax credits for small- and medium-sized companies. The reduction in the R&D tax credit is primarily due to the tax credits associated with the POC milestone payment on CCP-08 and the acceptance filing milestone payment for Tuzistra<sup>®</sup> XR that were made in the year to 30 June 2015.

Payments made to Tris that relate to development work performed on our behalf will qualify for R&D tax credits but these do not include the approval milestone payments which acquire the rights to the programmes from Tris.

**Loss for the year increased significantly**

The pre-exceptional loss for the year to 30 June 2016 was £17.1 million (2015: £2.0 million) predominantly due to the increase in operating costs, offset by an increased unrealised foreign exchange gain on cash caused by the significant weakening of sterling against the US dollar and euro.

The post-exceptional loss for the year to 30 June 2016 was £14.5 million.

**Balance sheet remains strong**

Non-current assets increased to £19.9 million (2015: £15.1 million) due to the acquisition of Moxatag<sup>®</sup> in October 2015.

Current assets increased to £92.5 million (2015: £71.5 million) primarily due to the increase in cash resources following the £38.9 million equity placing in May 2016, offset by cash used in operations for the year of £23.6 million.

Total liabilities increased marginally to £9.8 million (2015: £9.5 million).

**Cash resources of £84 million**

Cash resources comprising held-to-maturity financial assets and cash and cash equivalents at 30 June 2016 totalled £84.0 million (30 June 2015: £61.3 million). A significant proportion of these cash resources are denominated in non-sterling currencies with most of the cash denominated in US dollars.

We continue to manage cash tightly. The £22.8 million increase in cash resources included equity fundraising proceeds of £38.9 million (net of expenses), US\$5.4 million (£3.7 million) payment to Pragma for the rights to Moxatag<sup>®</sup> as well as an £8.0 million unrealised foreign exchange gain arising from the conversion of our US dollars and euros into sterling for reporting purposes. Cash used in operations increased to £23.6 million (2015: £7.3 million) due to the costs of the US sales and marketing capabilities established in mid-2015.

Underlying net cash burn, which excludes milestone income received, milestone payments made, foreign exchange, interest and tax received, increased to £21.8 million (2015: £8.5 million), again reflecting the additional cost of the US commercial operations established to launch and promote Tuzistra<sup>®</sup> XR and Moxatag<sup>®</sup>.

**Outlook**

We have made significant progress in the last 12 months in establishing our US sales and marketing infrastructure and transforming the business into a commercial specialty pharmaceutical company. With a strong balance sheet supporting the US commercialisation of Tuzistra<sup>®</sup> XR and Moxatag<sup>®</sup>, the focus for the organisation is on executing our commercial plans. We remain excited about the growth potential of these products, together with the maturing pipeline of further cough cold products.



# Risks and Uncertainties

## Principal Risks and Uncertainties Facing the Business

### Risks

Like all businesses we face risks and uncertainties, many of which are inherent within any pharmaceutical company looking to develop and commercialise products. Below are those principal risks and uncertainties that we consider could have a material impact on our operational results, financial condition and prospects. These risks are not in any particular order of priority and there may be other risks that are either currently unknown or not considered material which could have a similar impact on our business in the future.

### Clinical and Regulatory Risk

There are significant inherent risks in developing drugs for commercialisation due to the long and complex development process. Any drug which we or our partners wish to offer commercially to the public must be put through extensive research, pre-clinical and clinical development all of which takes several years and is extremely costly. We and/or our collaborators may fail to successfully develop a drug candidate because of:

- The failure of the drug in pre-clinical studies.
- The inability of clinical trials to demonstrate the drug is safe and effective in humans.
- The failure of the drug in bioequivalence studies.
- The failure to develop a viable formulation with differing characteristics from existing drugs with acceptable stability.
- The failure to find a collaborator to take the drug candidate into expensive later-stage studies.
- The failure to manufacture three stable batches of product for NDA submission.
- The failure of the FDA to approve NDA submissions.
- The failure to comply with GxP.
- The failure to manufacture the drug substance in sufficient quantities and at commercially acceptable prices.

In addition, the complexity and multi-jurisdictional nature of the regulatory processes could result in either delays in achieving regulatory approval or non-approval. If a product is approved, the regulators may impose additional requirements, for example, restrictions on the product's indicated uses or the levels of reimbursement receivable, which could impact the commercial viability of the drug.

Once approved, the product and its manufacture will continue to be reviewed by the regulators and may be withdrawn or restricted in the future. The failure to comply with GxP and/or to manufacture the product in sufficient quantities and at commercially acceptable prices could significantly impact the financial results of the Company in the future.

### Intellectual Property

Intellectual property protection remains fundamental to our strategy of developing novel drug candidates. Our ability and that of our collaborators to stop others making a drug, using it or selling the invention or proprietary rights by obtaining and maintaining protection is critical to our success. We and our collaborators own portfolios of patents and patent applications which underpin our and our collaborators' research and development programmes. We invest significantly in maintaining and protecting this intellectual property to reduce the risks over the validity and enforceability of our patents. However, the patent position is always uncertain and often involves complex legal issues. Therefore, there is a risk that intellectual property may become invalid and/or expire before, or soon after, commercialisation of a drug product and we may be blocked by other companies' patents and intellectual property.

### In-Licensing Complementary Products

Our strategy is to augment the low development-risk, late-stage Tris portfolio of products by in-licensing complementary products to our commercial pipeline. This is an extremely competitive area, with many pharmaceutical companies also following a similar strategy, and consequently this may be difficult to achieve with our current financial resources and infrastructure. A failure to succeed in successfully in-licensing complementary products may affect our ability to grow revenues and attain profitability.

## **Pricing, Reimbursement and Competition**

Our commercial success depends on the acceptance of our and our collaborators' products by the market, including wholesalers, pharmacies, physicians, third-party payers and patients.

We may be adversely affected by our ability to get product into the targeted wholesalers and pharmacies at an affordable cost to us and within an acceptable timeline.

We may be adversely affected by third-party reimbursement and healthcare cost containment initiatives. Third-party payers, including government and private health insurers, are increasingly seeking to contain healthcare costs through measures that are likely to impact the products we are developing, including:

- Challenging the prices charged for healthcare products.
- Limiting both coverage and the amount of reimbursement for new therapeutic products.
- Refusing to provide coverage when an approved drug is used in a way that has not received regulatory marketing approval.
- Any reference pricing model (particularly in Europe where the amount of reimbursement is determined by consideration of reimbursement levels for comparable drugs in other countries) can severely restrict the potential per unit price for many drugs unless there is significant differentiation from existing products.

These or other healthcare reforms that may be adopted in the future could harm our business and, in particular, could have a material adverse effect on the amounts that public and private payers will pay for our or our collaborators' commercialised products. If we and/ or our collaborators develop products that are not covered by government or third-party reimbursement schemes, are reimbursed at prices lower than those expected or become subject to legislation controlling treatments or pricing, we and/or our partners may not be able to generate significant revenues or attain profitability for any products which are approved for marketing.

The cost to the patient of the product may not be affordable and this may adversely affect our ability to generate significant revenues or attain profitability. Our business faces intense competition from major pharmaceutical companies and specialised biotechnology companies developing drugs for the same market opportunities. Some factors that may affect the rate and level of market acceptance of any of our, or our collaborators' products include:

- The existence or entry into the market of superior competing products or therapies.
- Entry to the market of competing products earlier than our or our collaborators' products.
- The price of our or our collaborators' products compared to competing products.
- Competition for target physician time from other pharma companies.
- Public perception and publicity concerning the safety, efficacy, cost or benefits of our or our collaborators' products, compared to competing products and therapies.
- The ability to market the products and therapies to physicians to generate market share at an affordable cost.
- The effectiveness of the sale and marketing efforts of our sales force or our collaborators' sales force.
- Regulatory developments relating to manufacturing or use of our or our collaborators' products.
- The willingness of physicians to adopt a new treatment regimen.
- The ability to achieve adequate distribution and stocking levels of product at the wholesalers and pharmacies.
- A competitor's ability to gain approval of a substitutable copy of our or our collaborator's product (i.e. a generic).

## **Product Litigation and Corporate Compliance**

Failure of the Company and/or its collaborators to comply with regulations could damage the Company's reputation, leading to the possible withdrawal of the product from the market and legal action against the Company. Unanticipated side-effects or unfavourable publicity from complaints concerning any of the Company's products, or those of its competitors, could have an adverse effect on the Company's ability to obtain or maintain regulatory approvals or successfully market its products. Developing, manufacturing, marketing and selling pharmaceutical products involves a risk of product liability claims, product recalls, litigation and associated adverse publicity.

The cost of defending these types of claims is expensive, even when the claims have no merit. A successful product liability claim against the Company could result in the Company paying a substantial monetary award. Although the Company will carry product liability insurance when available, this may not be adequate to fully discharge such an award. Product liability insurance is expensive, sometimes difficult to obtain and may not be available on acceptable terms. If, in the absence of adequate insurance, the Company does not have sufficient financial resources to satisfy a

liability resulting from such a claim or to fund the legal defence of such a claim, it could become insolvent. Any adverse judgement in a product liability lawsuit, even if insured, could generate substantial negative publicity about the Company's products and business and inhibit its commercialisation strategy.

### **Manufacturing Risk**

We are reliant on one source of supply for both Tuzistra<sup>®</sup> XR and Moxatag<sup>®</sup>. If something were to happen to Tris, our sole source of supply for Tuzistra<sup>®</sup> XR, financial or otherwise, or to its manufacturing facility, or if Tris has insufficient manufacturing capacity, or fails to secure adequate quota of controlled substances from the DEA, or is not able to retain key personnel, the Company may be unable to supply sufficient product to the market, which may have a material adverse effect on sales, profits and cash liquidity.

Suir, our sole source of supply for Moxatag<sup>®</sup>, has gone into liquidation and we need to transfer the manufacturing processes, equipment and capabilities to an alternative facility. This will take time, will cost money and may impact our ability to supply sufficient product into the market in the future, which may have a material adverse effect on sales, profits and cash liquidity.

The qualification of a new supplier is not guaranteed as it may not be possible to transfer the approved process and/or gain regulatory approval for product manufactured by the new supplier. Even if successful, the time taken to receive new supplies from such new supplier is uncertain and we may exhaust our existing inventories and be unable to supply customers continually during the period of site transfer.

The supply of frovatriptan API to Menarini for the EU and Central American markets has historically been a large proportion of our income. Now with generic competition, although its importance may decrease, our ability to manufacture and supply this product on schedule will still be a key focus.

In addition, our ability to successfully scale-up production processes to clinical trial or commercial levels is vital to the commercial viability of any product. Availability of raw materials is extremely important to ensure that products are manufactured on schedule and, therefore, dual sourcing is used where possible.

Product manufacture is subject to continual regulatory control and products must be manufactured in accordance with good manufacturing practices. Any changes to the approved process may require further regulatory approval which may incur substantial cost and delays. These potential issues could adversely impact operations and cash flow.

### **Operating a US Commercial Business**

Over the last 24 months, we have established a US infrastructure in order to commercialise the late-stage Tris portfolio and other products in the US. The operational strategy to reduce the execution risk in setting this up has been to minimise the creation of our own infrastructure as far as possible and so we have used a Third Party Logistics company and a Contract Sales Organisation who provide the main operational services to our US business. Any issues in their operation may affect our ability to generate and grow revenues and attain profitability. Maintaining and growing this US infrastructure will require the recruitment and retention of suitably qualified individuals to implement the strategy. If we are unable to attract the talent required to undertake the key roles in the commercial organisation or retain them once recruited, this may also impact our ability to grow revenues and attain profitability.

The promotion, marketing and sale of pharmaceutical products in the US is highly regulated and the operations of those undertaking these activities are closely supervised by regulatory authorities and law enforcement agencies, including the US Department of Health and Human Services, the FDA, the US Department of Justice and the DEA. These authorities and agencies investigate any potential violations of laws relating to the sale, marketing and promotion of pharmaceutical products, including the False Claims Act, the Anti-Kickback Statute and the Foreign Corrupt Practices Act, for alleged improper conduct, including corrupt payments to government officials, improper payments to medical professionals, off-label marketing of pharmaceutical products and medical devices, and the submission of false claims for reimbursement by the federal government. Healthcare companies may also be subject to enforcement actions or prosecution if found guilty of any improper conduct.

Any inquiries or investigations into the operations of, or enforcement or other regulatory action against, the Company by such authorities could result in significant defence costs, fines, penalties and injunctive or

administrative remedies, distract management to the detriment of the business, result in the exclusion of certain products, or the Company, from government reimbursement programmes or subject the Company to regulatory controls or government monitoring of its activities in the future.

## **Financial Risks**

### **Liquidity Risk**

Our history of operating losses is anticipated to continue in the near term. Following the £38.9 million (net of expenses) equity fundraising in May 2016, the Company is well capitalised to execute its transition into a profitable and cash-generative pharmaceutical company over time. As at 30 June 2016, the Group had £84.0 million of cash resources and no debt. However, the Group may need to seek further capital through equity or debt financings in the future and if this is not successful, the financial condition of the Group may be adversely affected.

### **Counterparty Credit Risk**

The Company is exposed to credit-related losses on cash deposits in the event of non-performance by counterparties.

With the global economic uncertainty over the last few years, counterparty credit risk remains a key consideration when placing cash funds on deposit. The creditworthiness of counterparties is assessed prior to placing funds on deposit and is monitored to maturity. Under the Company treasury policy there is a maximum amount that can be placed with any single counterparty. If any counterparty were to experience financial difficulties this may adversely impact the Company's liquidity in the future.

### **Foreign Exchange**

We record our transactions and prepare our financial statements in sterling but almost all of our revenue is from licensing and collaborative agreements and frovatriptan royalties and product sales, which are received in US dollars or euros. A significant proportion of our expenditure will be incurred in US dollars, relating principally to the Tris agreement and the commercialisation of Tuzistra<sup>®</sup> XR and Moxatag<sup>®</sup> in the US. Our cash balances are predominantly held in US dollars, sterling and euros.

Owing to the global economic uncertainty, we minimised our exposure to foreign exchange movements by matching the currency in which our cash is held with our future obligations. Immediately following our two most recent equity issues in March 2012 and May 2016, we converted the majority of our cash into US dollars, to match our Tris and US commercial financing requirements. As a consequence of holding these foreign currency deposits, we have a financial reporting foreign exchange exposure on the retranslation of the US dollar cash balances back into sterling at each reporting date, but critically any changes in foreign exchange rates between sterling and the US dollar do not impact our ability to execute the US commercial plan.

To the extent that income and expenditure in currencies are not matched, fluctuations in exchange rates between sterling and these currencies, principally US dollars, may result in realised or unrealised foreign exchange gains and losses. Simple derivative contracts have been used to mitigate the risk of fluctuations in exchange rates where there has been certainty over the amount and timing of the income.

Where the timing and/or the amount to be received is uncertain, risk management is more difficult but the Group has used derivatives where possible and will continue to do so. To the extent that derivative instruments are considered too costly, because of the flexibility required or the time over which protection is sought, any fluctuations in foreign exchange movements may have a material adverse impact on the results from operations and our cash flow in the future.

### **Return on Investment**

As the drug development process is inherently risky and because it is conducted over several years, it can be extremely costly. Many drug candidates fail in development due to the clinical and regulatory risks, and even in those circumstances where drugs are approved, sales levels can be disappointing due to competition, healthcare regulation and/or intellectual property challenges. As a result, the returns achieved may be insufficient to cover the costs incurred. The Group attempts to mitigate the development and commercial risk of its NCE pipeline by partnering drug candidates at an appropriate stage. Such partnering crystallises part of the programme's value, with the goal of retaining an attractive proportion of the commercial benefit through future milestone payments and royalties from commercial sales.

### **Value of Intangible Assets**

Under the development and licensing agreement with Tris, milestone sums payable to Tris for the reimbursement of development costs, and for the approval of the NDA for each product, will be capitalised on the balance sheet as intangible assets and then amortised from commercialisation. Under IFRS there is a need to assess annually the carrying value of any asset that is not being amortised, or if there is a triggering event that suggests there may have been a change to its value. If the commercial value is less than the carrying value of the asset, this shortfall in value is reflected in the financial statements. The commercial value of an intangible asset could reduce if there is a problem in development, or if the FDA decides not to approve the product, or if there is a commercial concern because of competition or underperformance, and any adjustment to the carrying value may materially impact the financial results of the Company.

### **Related Parties**

Related parties disclosures are given in note 13.

### **Statement of directors' responsibilities**

Each of the directors, whose names and functions are listed in the directors report confirm that, to the best of their knowledge:

- the Group financial statements, which have been prepared in accordance with IFRSs as adopted by the EU, give a true and fair view of the assets, liabilities, financial position and loss of the Group; and
- the strategic report in the Report and accounts for the 12 month period ended 30 June 2016 includes a fair review of the development and performance of the business and the position of the Group, together with a description of the principal risks and uncertainties that it faces.

## Consolidated income statement

for the 12 months ended 30 June 2016

	Note	12 months ended 30 June 2016			18 months ended 30 June 2015		
		Pre-exceptional items £000	Exceptional items (note 3) £000	Total £000	Pre-exceptional items £000	Exceptional items (note 3) £000	Total £000
<b>Revenue</b>	2	<b>12,034</b>	-	<b>12,034</b>	19,882	-	19,882
Other income		<b>396</b>	-	<b>396</b>	611	-	611
Cost of sales		<b>(2,004)</b>	-	<b>(2,004)</b>	(1,373)	-	(1,373)
Sales and marketing expenditure		<b>(20,428)</b>	-	<b>(20,428)</b>	-	-	-
Research and development expenditure		<b>(10,932)</b>	-	<b>(10,932)</b>	(22,563)	-	(22,563)
General and administrative expenditure		<b>(5,289)</b>	<b>2,651</b>	<b>(2,638)</b>	(8,635)	243	(8,392)
<b>Operating (loss)/profit</b>		<b>(26,223)</b>	<b>2,651</b>	<b>(23,572)</b>	(12,078)	243	(11,835)
Finance income	4	<b>8,315</b>	-	<b>8,315</b>	2,733	-	2,733
Finance expense	4	<b>(42)</b>	-	<b>(42)</b>	(157)	-	(157)
<b>(Loss)/profit on ordinary activities before taxation</b>		<b>(17,950)</b>	<b>2,651</b>	<b>(15,299)</b>	(9,502)	243	(9,259)
Income tax credit	5	<b>804</b>	-	<b>804</b>	2,858	-	2,858
<b>(Loss)/profit for the period</b>		<b>(17,146)</b>	<b>2,651</b>	<b>(14,495)</b>	(6,644)	243	(6,401)
<b>Loss per share (basic and diluted)</b>	6	<b>(3.8)p</b>	<b>0.6p</b>	<b>(3.2)p</b>	(1.5)p	0.1p	(1.4)p

Following the launch of Tuzistra<sup>®</sup> XR in September 2015, an additional expense category of Sales and Marketing has been introduced which includes costs related to the commercialisation of pharmaceutical products including the sales force, marketing costs and other related expenditures. Pre-launch costs in the comparative period were reported as Research and Development expenses in line with group accounting policies.

The notes form part of this condensed consolidated financial information.

All activities related to continuing operations.

## Consolidated statement of comprehensive income

for the 12 month period ended 30 June 2016

	12 months ended 30 June 2016			18 months ended 30 June 2015		
	Pre-exceptional items £000	Exceptional items (note 3) £000	Total £000	Pre-exceptional items £000	Exceptional items (note 3) £000	Total £000
<b>(Loss)/profit for the period from continuing operations</b>	<b>(17,146)</b>	<b>2,651</b>	<b>(14,495)</b>	(6,644)	243	(6,401)
Other comprehensive income:						
Items that may subsequently be reclassified to profit and loss:						
Exchange loss on translation of overseas subsidiaries	<b>(100)</b>	-	<b>(100)</b>	(18)	-	(18)
<b>Total comprehensive (expense)/income for the period</b>	<b>(17,246)</b>	<b>2,651</b>	<b>(14,595)</b>	(6,662)	243	(6,419)

## Balance sheet

as at 30 June 2016

	Note	30 June 2016 £000	30 June 2015 £000
<b>Assets</b>			
Property, plant and equipment		1,673	1,637
Intangible assets	7	17,645	12,895
Trade and other receivables		631	534
<b>Non-current assets</b>		<b>19,949</b>	15,066
Inventories	8	233	-
Trade and other receivables		7,225	7,017
Tax receivable		1,065	2,933
Derivative financial instruments	10	-	301
Held-to-maturity financial assets		76,997	42,426
Cash and cash equivalents		7,021	18,832
<b>Current assets</b>		<b>92,541</b>	71,509
<b>Total assets</b>		<b>112,490</b>	86,575
<b>Liabilities and shareholders' equity</b>			
<b>Liabilities</b>			
Trade and other liabilities		1,422	744
Deferred income		85	-
Provisions for other liabilities and charges	9	504	3,510
Derivative financial instruments	10	37	-
<b>Non-current liabilities</b>		<b>2,048</b>	4,254
Trade and other liabilities		5,095	3,368
Deferred income		922	1,688
Tax payable		80	5
Provisions for other liabilities and charges	9	1,333	154
Derivative financial instruments	10	281	-
<b>Current liabilities</b>		<b>7,711</b>	5,215
<b>Total liabilities</b>		<b>9,759</b>	9,469
<b>Equity attributable to owners of the parent</b>			
Share capital	11	5,262	4,434
Share premium		514,791	476,392
Other reserves	12	253,932	253,365
Retained deficit		(671,254)	(657,085)
<b>Total equity</b>		<b>102,731</b>	77,106
<b>Total liabilities and equity</b>		<b>112,490</b>	86,575

## Statements of changes in shareholders' equity

for the 12 month period ended 30 June 2016

	Share capital £000	Share premium £000	Other reserves £000	Retained deficit £000	Total £000
Balance at 1 January 2014	4,421	476,392	252,416	(650,985)	82,244
Loss for the period	-	-	-	(6,401)	(6,401)
Other comprehensive expense for the period	-	-	(18)	-	(18)
Total comprehensive expense for the period	-	-	(18)	(6,401)	(6,419)
Transactions with owners:					
Exercise of share options	13	-	(301)	301	13
Share-based payments charge	-	-	1,268	-	1,268
	13	-	967	301	1,281
Balance at 30 June 2015	4,434	476,392	253,365	(657,085)	77,106
<b>Loss for the year</b>	-	-	-	<b>(14,495)</b>	<b>(14,495)</b>
Other comprehensive expense for the year	-	-	<b>(100)</b>	-	<b>(100)</b>
<b>Total comprehensive expense for the year</b>	-	-	<b>(100)</b>	<b>(14,495)</b>	<b>(14,595)</b>
Transactions with owners:					
Issue of equity share capital	<b>800</b>	<b>39,200</b>	-	-	<b>40,000</b>
Costs on issue of equity share capital	-	<b>(1,097)</b>	-	-	<b>(1,097)</b>
Exercise of share options	<b>28</b>	<b>296</b>	<b>(317)</b>	<b>326</b>	<b>333</b>
Share-based payments charge	-	-	<b>984</b>	-	<b>984</b>
	<b>828</b>	<b>38,399</b>	<b>667</b>	<b>326</b>	<b>40,220</b>
<b>Balance at 30 June 2016</b>	<b>5,262</b>	<b>514,791</b>	<b>253,932</b>	<b>(671,254)</b>	<b>102,731</b>



## Cash flow statement

for the 12 months ended 30 June 2016

	Note	12 months ended 30 June 2016 £000	18 months ended 30 June 2015 £000
<b>Cash flows from operating activities</b>			
Loss for the period		(14,495)	(6,401)
Taxation	5	(804)	(2,858)
Depreciation		607	797
Loss on disposal of tangible fixed assets		144	-
Amortisation of intangible fixed assets	7	713	571
Impairment charge on intangible fixed assets	7	-	300
Movement in provisions	9	(1,636)	(775)
Movement in deferred income		(681)	726
Share-based payments charge		984	1,855
Movement in derivative financial instruments		619	(279)
Finance income	4	(8,315)	(2,733)
Finance expense	4	42	157
Exchange gain		(203)	(239)
		(23,025)	(8,879)
<b>Changes in working capital</b>			
Inventories		(233)	130
Receivables		(1,109)	(3,373)
Liabilities		813	(13)
<b>Cash used in operations</b>		(23,554)	(12,135)
Taxation received		2,912	1,887
Taxation paid		(128)	(88)
<b>Net cash used in operating activities</b>		(20,770)	(10,336)
<b>Cash flows from investing activities</b>			
Purchase of property, plant and equipment		(212)	(1,005)
Purchase of intangible fixed assets		(71)	(7,474)
Movement in held-to-maturity financial assets*		(27,329)	7,903
Acquisition of business		(3,677)	-
Interest received on cash and cash equivalents		26	79
Interest received on held-to-maturity financial assets		204	274
<b>Net cash used in from investing activities</b>		(31,059)	(223)
<b>Cash flows from financing activities</b>			
Gross proceeds on issue of equity share capital		40,333	13
Costs on issue of equity share capital		(1,097)	-
<b>Net cash generated from financing activities</b>		39,236	13
Foreign exchange loss on cash and cash equivalents		782	1,057
<b>Movements in cash and cash equivalents in the period</b>		(11,811)	(9,489)
Cash and cash equivalents at the beginning of the period		18,832	28,321
<b>Cash and cash equivalents at the end of the period</b>		7,021	18,832
Held-to-maturity financial assets		76,997	42,426
<b>Total cash, cash equivalents and held-to-maturity financial assets</b>		84,018	61,258

\* Movement in held-to-maturity financial assets includes a foreign exchange gain of £7.2 million for the 12 months ended 30 June 2016 (£1.7 million for the 18 months ended 30 June 2015).

## **Notes to the financial statements**

### **1. Accounting policies and basis of preparation**

This financial information for the 12 month period ended 30 June 2016 and the 18 month period ended 30 June 2015 does not comprise statutory financial statements. This financial information and announcement was approved for issue on 28 September 2016 and has been extracted from the 30 June 2016 audited statutory financial statements that were also approved by the board on the same date and are available on the Company's website. These statutory financial statements have not yet been delivered to the registrar of Companies. Statutory financial statements for the 18 month period ended 30 June 2015 were approved by the Board of directors on 28 September 2015 and delivered to the Registrar of Companies. The auditors' report on the financial statements for the 12 month period ended 30 June 2016 and the 18 month period ended 30 June 2015 were (i) unqualified, (ii) did not include a reference to any matters to which the auditors drew attention by the 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.

#### *Basis of preparation*

These financial statements have been prepared in accordance with EU endorsed International Financial Reporting Standards (IFRS), IFRS IC interpretations and the Companies Act 2006 applicable to companies reporting under IFRS. The financial statements have been prepared on a going concern basis in accordance with the historical cost convention as modified by the revaluation of derivative financial instruments. Whilst the financial information included in this announcement has been prepared in accordance with IFRSs adopted for use in the European Union, this announcement does not itself contain sufficient information to comply with IFRSs.

The accounting policies applied are consistent with those of the audited financial statements for the 12 month period ended 30 June 2016 and the 18 month period ended 30 June 2015, as described in those financial statements.

Copies of this announcement are available from the company secretary and the announcement is also on the Company's website at [www.vernalis.com](http://www.vernalis.com). The audited Report and accounts for the 12 month period ended 30 June 2016 and the accounts are available on the investor's section of the Company's website.

### **2. Segmental information**

For the 12 months ended 30 June 2016, the Group has two segments, Commercial and Research & Development. Prior to the 12 months ended 30 June 2016, the Group had only one segment being the Research and Development and Commercialisation of pharmaceutical products. In line with the reporting to the Executive Committee, which comprises the executive directors and other senior management, the performance of these segments is reviewed at a sales and operating profit level which does not include the full allocation of general administrative costs which are reported separately. The Commercial segment covers all areas relating to the commercial sale of pharmaceutical products, the manufacture, distribution and operating expenses directly related to that activity. The Research and Development business includes all activities related to the research and development of pharmaceutical products for a range of medical disorders and includes the income generated by collaboration, milestones or royalties as well as the costs directly associated with those activities. There is no segmentation of the balance sheet. Charges such as depreciation, impairment, amortisation and other non-cash expense are expensed to the relevant segment.

The Group discloses the following other information, not all of which represents segmental information required by IFRS 8.

## Revenue analysis

The revenue analysis in the table below is based on the country of registration of the fee-paying party:

	<b>12 months ended 30 June 2016 £000</b>	18 months ended 30 June 2015 £000
United Kingdom	5	24
Rest of Europe	8,133	15,379
North America	1,162	1,004
Rest of the World	2,734	3,475
	<b>12,034</b>	<b>19,882</b>

	<b>12 months ended 30 June 2016 £000</b>	18 months ended 30 June 2015 £000
Product sales*	3,994	6,648
Royalties	5	212
Collaborative	8,035	13,022
	<b>12,034</b>	<b>19,882</b>

\*Includes frovatriptan royalty linked to the supply of API, received at 25.25 per cent of Menarini sales.

The analysis of segmental revenues and operating losses are as follows:

	<b>12 months ended 30 June 2016</b>			18 months ended 30 June 2015		
	<b>Commercial £000</b>	<b>Research and Development £000</b>	<b>Total £000</b>	Commercial £000	Research and Development £000	Total £000
<b>Revenue</b>	<b>3,994</b>	<b>8,040</b>	<b>12,034</b>	6,648	13,234	19,882
Other income	-	396	396	-	611	611
Cost of sales	(2,004)	-	(2,004)	(1,272)	(101)	(1,373)
Depreciation and amortisation	(763)	(401)	(1,164)	(585)	(816)	(1,401)
Share-based payments charge	(189)	(238)	(427)	(71)	-	(71)
Other operating expenses	(19,476)	(10,293)	(29,769)	(5,228)	(15,863)	(21,091)
<b>Segmented loss</b>	<b>(18,438)</b>	<b>(2,496)</b>	<b>(20,934)</b>	(508)	(2,935)	(3,443)
Corporate and unallocated cost			(2,638)			(8,392)
<b>Operating loss</b>			<b>(23,572)</b>			<b>(11,835)</b>
Net finance income			8,273			2,576
<b>Loss before tax</b>			<b>(15,299)</b>			<b>(9,259)</b>

### 3. Exceptional items

Exceptional items represent significant items of income and expense, which, due to their size, nature or the expected infrequency of the events giving rise to them, are presented separately on the face of the income statement to give a better understanding to shareholders of the elements of financial performance in the period, so as to facilitate comparison with prior periods and to better assess trends in financial performance. Exceptional items include, but are not limited to restructuring costs and the provision for vacant leases.

	<b>12 months ended 30 June 2016 £000</b>	18 months ended 30 June 2015 £000
Credit – release of provision for vacant leases	<b>2,651</b>	243

### 4. Finance income/expense

	<b>12 months ended 30 June 2016 £000</b>	18 months ended 30 June 2015 £000
<b>Finance income</b>		
Interest on cash, cash equivalents and held-to-maturity assets	<b>291</b>	341
Exchange gains on cash, cash equivalents and held-to-maturity assets	<b>8,024</b>	2,392
	<b>8,315</b>	2,733
<b>Finance expense</b>		
Unwinding of discount on accruals	<b>5</b>	-
Unwinding of discount on provision	<b>37</b>	157
	<b>42</b>	157

### 5. Income tax credit

Analysis of current tax credit in the period:

	<b>12 months ended 30 June 2016 £000</b>	18 months ended 30 June 2015 £000
Research and development tax credits	<b>1,065</b>	2,933
Corporation tax on Research and Development Expenditure Credit (RDEC)	<b>(79)</b>	(129)
Overseas corporation tax	<b>(161)</b>	(48)
Adjustments in respect of prior period	<b>(21)</b>	102
	<b>804</b>	2,858

## 6. Loss per share

Basic loss per share is calculated by dividing the loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period.

For diluted loss per share, the weighted average number of ordinary shares in issue is adjusted to assume conversion for all dilutive potential ordinary shares.

For diluted loss per share, all potential ordinary shares including options and deferred shares are antidilutive as they would decrease the loss per share.

	<b>12 months ended 30 June 2016</b>	18 months ended 30 June 2015
Attributable loss before exceptional items (£000)	<b>(17,146)</b>	(6,644)
Exceptional items (£000)	<b>2,651</b>	243
Attributable loss (£000)	<b>(14,495)</b>	(6,401)
Weighted average number of shares (basic and diluted) in issue (000)	<b>455,258</b>	442,280
Loss per ordinary share before exceptional items	<b>(3.8)p</b>	(1.5)p
Exceptional items	<b>0.6p</b>	0.1p
<b>Loss per share (basic and diluted)</b>	<b>(3.2)p</b>	(1.4)p

## 7. Intangible assets

	Goodwill £000	Assets in use £000	Assets not yet in use £000	Total £000
<b>Cost</b>				
At 1 July 2015	<b>8,954</b>	<b>37,570</b>	<b>13,042</b>	<b>59,566</b>
Additions – business combinations	-	<b>4,022</b>	-	<b>4,022</b>
Additions – other	-	<b>16</b>	<b>55</b>	<b>71</b>
Reclassification of royalty credit	-	<b>1,370</b>	-	<b>1,370</b>
Transferred to in use	-	<b>9,188</b>	<b>(9,188)</b>	-
<b>At 30 June 2016</b>	<b>8,954</b>	<b>52,166</b>	<b>3,909</b>	<b>65,029</b>
<b>Accumulated amortisation and impairment</b>				
At 1 July 2015	<b>(8,954)</b>	<b>(37,417)</b>	<b>(300)</b>	<b>(46,671)</b>
Amortisation charge in the year	-	<b>(713)</b>	-	<b>(713)</b>
<b>At 30 June 2016</b>	<b>(8,954)</b>	<b>(38,130)</b>	<b>(300)</b>	<b>(47,384)</b>
<b>Net book value at 30 June 2016</b>	<b>-</b>	<b>14,036</b>	<b>3,609</b>	<b>17,645</b>
<b>Cost</b>				
At 1 January 2014	8,954	37,408	5,730	52,092
Additions	-	162	7,312	7,474
At 30 June 2015	8,954	37,570	13,042	59,566
<b>Accumulated amortisation and impairment</b>				
At 1 January 2014	(8,954)	(36,846)	-	(45,800)
Impairment charge	-	-	(300)	(300)
Amortisation charge in the period	-	(571)	-	(571)
At 30 June 2015	(8,954)	(37,417)	(300)	(46,671)
Net book value at 30 June 2015	-	153	12,742	12,895

## Useful life and net book value of intangible assets

	<b>30 June 2016</b>	30 June 2015	<b>30 June 2016</b>	30 June 2015
	<b>Useful Life</b>	Useful Life	<b>£000</b>	£000
<b>Assets in use</b>				
Frova®	<b>to 2014</b>	to 2014	-	-
Finance software	<b>to 2022</b>	to 2022	<b>145</b>	153
License to Tris' extended release technology	<b>to 2036</b>	-	<b>3,281</b>	-
Tuzistra® XR	<b>to 2036</b>	-	<b>6,818</b>	-
Moxatag®	<b>to 2027</b>	-	<b>3,792</b>	-
<b>Total assets in use</b>			<b>14,036</b>	153
			<b>30 June 2016</b>	30 June 2015
			<b>£000</b>	£000
<b>Assets not yet in use – cough cold development pipeline</b>			<b>3,609</b>	12,742

In accordance with IAS 21 “The effects of changes in foreign exchange rates”, goodwill and other intangible assets that are created in relation to the acquisition of a foreign subsidiary are maintained in the functional currency of that subsidiary.

### Additions

Additions of £4.1 million were made during the 12 months ended 30 June 2016 of which £4.0 million related to the Moxatag® acquisition (see note 15). £9.2 million was moved to “assets in use” following the approval and subsequent launch of Tuzistra® XR and a further £1.4 million was reclassified from prepayments.

This amount was part of the NDA acquisition payment made and was treated as a prepayment in the accounts to 30 June 2015 as the amount can potentially be offset against future royalty payments to Tris. The recoverability of the royalty prepayment is dependent upon the net sales levels of Tuzistra® XR achieved over a 30 month period from commercial launch and the amount expected to be recovered from Tris is now £1.4 million lower. Accordingly this has been transferred from prepayments into the Tuzistra® XR intangible asset and will be amortised over the remaining useful economic life to 2036, consistent with other Tris milestone payments.

In the 18 month period ended 30 June 2015 there were additions of £7.5 million which relate primarily to Tris milestones payments made under the collaboration agreement. US\$6.0 million related to Tuzistra® XR paid in two milestones, the first for the FDA accepting the NDA filing and the second for the purchase of the NDA from Tris after FDA approval. This second milestone was US\$6.0 million but US\$3.0 million was initially treated as a royalty prepayment. Two POC milestones, each of US\$3.0 million for CCP-07 and CCP-08 were also paid during the 18 month period ending June 2015.

### Impairments

During the 12 months ended 30 June 2016 there were no impairments. In the year ended 30 June 2015, a charge of £0.3 million was made in relation to AUY922. This programme was out licensed in 2004 to Novartis. In December 2014, Novartis ceased all development work on AUY922 and rights will revert back to Vernalis.

### Impairment Review

Goodwill and intangible assets that are not yet ready for use are subject to impairment review at least annually. Intangible assets in use are amortised over their expected useful lives and are reviewed when there is an indication that an impairment may have occurred. If the balance sheet carrying amount of the asset exceeds the higher of its value in use to the Group or its anticipated fair value less cost of sale, an impairment loss for the difference is recognised.

Value in use calculations are utilised to calculate recoverable amounts. Value in use is calculated as the net present value of the projected risk-adjusted, post-tax cash flows of the cash-generating unit (being the related products) relating to the intangible asset, and applying a discount rate of the Group post-tax weighted average cost of capital of approximately 10 per cent. These calculations use cash flow projections based on financial budgets approved by management covering a five year period. Cash flows beyond the five year period are projected over the useful life of the products. In relation to intangible assets not yet in use, cash flows reflect zero growth beyond the approved five year financial plan.

The determination of these underlying assumptions relating to the recoverability of intangible assets is subjective and requires the exercise of considerable judgement. Key assumptions include:

- Outcome of research and development activities.
- Probability and timing of obtaining regulatory approval.
- Success in commercialising products, size of the market and speed of market penetration.
- Selling price and margins, together with erosion rates after the end of any patent protection due to generic competition.
- Behaviour of competitors (launch of competing products, marketing initiatives, etc.).

Any changes in key assumptions about our business and prospects, or changes in market conditions, could result in an impairment charge. Certain events could occur which could lead to an impairment e.g. regulatory approval not received from the FDA.

None of the Group's intangible assets at either 30 June 2016 or 30 June 2015 was internally generated.

#### ***Tuzistra<sup>®</sup> XR***

As a result of the modest sales performance of Tuzistra<sup>®</sup> XR over the last 12 months, the carrying value of the intellectual property, including the royalty prepayment, has been reviewed for impairment. The licence to Tris' extended release technology are not attributable to any product but have been aggregated with the carrying value of Tuzistra<sup>®</sup> XR, and a possible impairment considered with reference to the Tuzistra<sup>®</sup> XR sales forecasts.

The value in use calculation for Tuzistra<sup>®</sup> XR based on more conservative market penetration assumptions, does not indicate a need to impair the carrying value of the intangible asset at 30 June 2016.

#### ***Moxatag<sup>®</sup>***

After re-establishing supply of Moxatag<sup>®</sup> through its sole FDA approved supplier, Suir, £1.3 million of deferred consideration was paid to Pragma, in addition to the initial consideration of £2.4 million.

In May 2016, Suir entered voluntary liquidation. Because of the uncertainty over ongoing supply of the product by Suir, this triggered an impairment review. The total consideration, including an estimate for deferred consideration (based on future sales levels), has been reviewed for impairment based on future sales projections of Moxatag<sup>®</sup>. These projections have been further risk adjusted, because of the uncertainty over ongoing supply and incorporate both time and cost estimates for the validation of a new site of manufacture.

The value in use calculation for Moxatag<sup>®</sup> does not indicate a need to impair the carrying value of the intangible asset at 30 June 2016.

## 8. Inventories

	<b>30 June</b>	30 June
	<b>2016</b>	2015
	<b>£000</b>	£000
Raw materials	72	-
Finished goods	639	-
Less provision for obsolete inventories	(478)	-
<b>Inventories</b>	<b>233</b>	-

The cost of inventories recognised as an expense and included in cost of sales for the 12 month period ended 30 June 2016 amounted to £744,000 (18 month period ended 30 June 2015: £372,000).

Included in the cost of inventories for the 12 months ended 30 June 2016 is an obsolescence provision of £478,000 (18 months period ended 30 June 2015: £nil) where it is estimated that inventory will not be sold prior to becoming short dated.

## 9. Provisions for other liabilities and charges

	Property	Revenue	Total
	£000	£000	£000
<b>At 1 July 2015</b>	3,664	-	3,664
Arising during the period	-	1,753	1,753
Credit – provision released during the period (note 3)	(2,651)	-	(2,651)
Arising on business combination (note 15)	-	99	99
Transfer to Trade and Other Liabilities	(474)	-	(474)
Utilised during the period	(72)	(666)	(738)
Exchange differences	-	147	147
Unwinding of discount (note 4)	37	-	37
<b>At 30 June 2016</b>	<b>504</b>	<b>1,333</b>	<b>1,837</b>

### Property Provision

Where leasehold properties become vacant the Group provides for all costs, net of anticipated income, to the end of the lease or the anticipated date of the disposal or sublease. At 1 July 2015, this provision primarily related to properties in Cambridge and was expected to be utilised over the life of the related leases to 2019 and 2023, discounted to fair value at the balance sheet date. Also included were dilapidation provisions which related to costs associated with the Group's obligation to reinstate leased buildings to their original state. During the period the Group reached a settlement for the early termination of an onerous lease on a property in Cambridge which has resulted in an exceptional credit of £2,651,000. £474,000 has also been transferred to trade and other liabilities and will be paid over the next four years, reflecting that this amount is now certain.

As at 30 June 2016 the Group had no vacant or tenanted properties. The remaining amounts relate to dilapidation provisions.

### Revenue Provision

When calculating US commercial revenues, provisions are made for rebates, discounts, allowances and product returns estimated, given or expected to be given which vary by product arrangements and buying groups. These provisions are calculated based on contractual obligations, available current / future market information and historic experience. Amounts are reviewed throughout the reporting period and reflect the best estimate at each reporting date. These provisions are expected to be settled within the ordinary operating cycle of the business.



## 10. Derivative financial instruments

	<b>30 June 2016 £000</b>	30 June 2015 £000
<b>Financial (liabilities)/assets carried at fair value through profit or loss</b>		
Current - Foreign currency forward contracts	(281)	301
Non-current -Foreign currency forward contracts	(37)	-
	<b>(318)</b>	<b>301</b>

The fair value of all forward currency forward contracts are based on period-end prices in an active market.

## 11. Share capital

	Number issued 000	Number authorised 000	Nominal Value £	Issued £000	Authorised £000
<b>Ordinary</b>					
1 July 2015	443,442	Unlimited	0.01	4,434	Unlimited
Issue of shares	82,754	-	0.01	828	-
<b>30 June 2016</b>	<b>526,196</b>	<b>Unlimited</b>	<b>0.01</b>	<b>5,262</b>	<b>Unlimited</b>
<b>Ordinary</b>					
1 January 2014	442,126	Unlimited	0.01	4,421	Unlimited
Issue of shares	1,316	-	0.01	13	-
30 June 2015	443,442	Unlimited	0.01	4,434	Unlimited

### *Issue of shares – 12 month period ended 30 June 2016*

2,754,138 shares were issued following the exercise of options under the Long Term Incentive Plan and Sharesave schemes.

On the 13 May 2016, 80,000,000 shares were issued on a non-pre-emptive basis to institutional investors and certain directors at a placing price of 50 pence per share.

### *Issue of shares – 18 month period ended 30 June 2015*

1,316,301 shares were issued following the exercise of options under the Long Term Incentive Plan and Sharesave schemes.

## 12. Other reserves

	Merger reserve £000	Other reserve £000	Options reserve £000	Warrant reserve £000	Translation reserve £000	Capital redemption reserve £000	Total £000
At 1 January 2014	101,985	78,125	9,929	1,155	3,556	57,666	252,416
Share-based payments charge	-	-	1,268	-	-	-	1,268
Exercise of share options	-	-	(301)	-	-	-	(301)
Exchange loss on translation of overseas subsidiaries	-	-	-	-	(18)	-	(18)
<b>At 30 June 2015</b>	<b>101,985</b>	<b>78,125</b>	<b>10,896</b>	<b>1,155</b>	<b>3,538</b>	<b>57,666</b>	<b>253,365</b>
Share-based payments charge	-	-	984	-	-	-	984
Exercise of share options	-	-	(317)	-	-	-	(317)
Exchange loss on translation of overseas subsidiaries	-	-	-	-	(100)	-	(100)
<b>At 30 June 2016</b>	<b>101,985</b>	<b>78,125</b>	<b>11,563</b>	<b>1,155</b>	<b>3,438</b>	<b>57,666</b>	<b>253,932</b>

## 13. Related party transactions

### *Identity of related parties*

The Group consists of a parent, Vernalis plc, and principally three wholly owned trading subsidiaries. The main trading companies are Vernalis (R&D) Limited, the US registered Vernalis Therapeutics, Inc and Vernalis Development Limited.

The Parent company is responsible for financing and setting Group strategy. Vernalis (R&D) Limited carries out the Group research and development strategy, employs all the UK staff including the directors, and owns and manages all of the Group's intellectual property including Tuzistra<sup>®</sup> XR and Moxatag<sup>®</sup> (but excluding Vernalis<sup>®</sup>, Frova<sup>®</sup> and Migard<sup>®</sup> trademarks and any frovatriptan-related patents, all of which are owned by Vernalis Development Limited). The proceeds of the issue of shares by the Parent are passed from Vernalis plc to Vernalis (R&D) Limited as a loan, and Vernalis (R&D) Limited manages Group funds and makes payments, including the expenses of the Parent company. Vernalis Therapeutics, Inc. (VTI) was registered in 2011 and began trading in 2014, employs all US staff and is the Group's sales and distribution company through which the commercial products are sold in the US market.

### *Group*

At 30 June 2016, an amount of £4,903 (30 June 2015: £7,921) was due from Dr Fellner and companies where Dr Fellner is a board member, in respect of certain travel costs. Of the amount due at 30 June 2016, £3,434 had been repaid at 31 August 2016. The amount due at 30 June 2015 was repaid in full by 21 March 2016.

## 14. Seasonality

The Group's financial results have not historically been subject to significant seasonal trends. However the revenue recognised in relation to royalties received for the supply of product to Menarini is dependent upon the timing of shipments made. In addition milestone revenue is dependent upon progression of the related clinical trial and research collaborations.

## 15. Business Combinations

On 2 October 2015, Vernalis acquired the US rights to Moxatag<sup>®</sup>, which is the only once a day formulation of the antibiotic, amoxicillin. Moxatag<sup>®</sup> expands the US product portfolio and complements Tuzistra<sup>®</sup> XR within the US commercial business. Total consideration, which was fair valued at acquisition, comprised three parts: an upfront cash payment of £2.4 million (\$3.6 million); fixed deferred consideration of £1.3 million (\$1.8 million) contingent on the completion of the first successful manufacture of the product; and further deferred consideration owed by Vernalis on future net revenues of Moxatag<sup>®</sup> for milestone and royalty payments which management have estimated the fair value at acquisition to be £0.9 million (\$1.4 million).

The purchase has been treated as a business combination in accordance with the Group's policies under the acquisition method. The acquisition did not result in goodwill and resulted in the following fair value additions to assets and liabilities:

	<b>Acquisition Fair Value 2 October 2015 £000</b>
Property, plant and equipment	558
Intangible assets	4,022
<b>Non-current assets</b>	<b>4,580</b>
Provision for other liabilities and charges	99
<b>Current liabilities</b>	<b>99</b>
<b>Total acquisition at fair value</b>	<b>4,481</b>
<b>Consideration</b>	
Cash paid	2,386
Deferred cash consideration	2,095
<b>Total consideration at fair value</b>	<b>4,481</b>

No book values were made available by the vendor at the date of acquisition. Fair values of the acquired assets and liabilities as at 2 October 2015 are detailed in the table above.

Since the acquisition, the Group has been focused on the manufacturing of the product and developing sales and marketing strategies for a relaunch. Very limited commercial sales have occurred to date. The charges for the period relate to the amortisation of the intangible asset which in accordance with the Group's accounting policy is being amortised from the first month in which the intangible asset is available for use, and depreciation of the property, plant and equipment. A summary of the financial impact of Moxatag<sup>®</sup> from the date of acquisition in the consolidated group is:

	<b>30 June 2016 £000</b>
Net revenue	<b>8</b>
Loss for the period	<b>(796)</b>

A view of the potential financial impact of the Moxatag<sup>®</sup> purchase on the Group on a proforma basis from 1 July was considered impracticable due to its significant reliance on several uncertain estimates, making the information unreliable for the purposes of comparative analysis.

Contingent consideration relating to the first successful manufacture of product was £1.3 million and was paid in March 2016. A further amount of contingent consideration which may be payable by Vernalis, is in the form of royalties and sales milestones and is dependent on net sales levels achieved in the future.

For the 12 month period ended 30 June 2016, the Group expensed costs of £135,000 relating to the acquisition of Moxatag<sup>®</sup> which have been recorded within the consolidated income statement, within operating expenditure.

## **16. Post-balance sheet events**

On 8 July 2016, the Group announced the successful completion of the CCP-08 pivotal multi-dose comparative bio-availability study.

On 15 July 2016 the Group announced that Juno Therapeutics Inc had entered into a share purchase agreement with Redox, the licensee of vipadenant (V2006). Redox retains the worldwide licence to vipadenant and the clinical and regulatory milestones and commercial royalties due to Vernalis remain unchanged.

On 6 September 2016, the Group announced FDA acceptance of the CCP-07 NDA filing, with a PDUFA date of 20 April 2017.