

1 April 2014

LSE: VER

### **Announcement of Results for the year ended 31 December 2013**

Vernalis plc (LSE: VER) today announces its audited results for the year ended 31 December 2013.

#### **Financial Highlights**

- Financial performance ahead of market expectations
  - Revenue was £14.1 million (2012: £14.6 million)
    - Frovatriptan royalty income was up 16 % at £6.7 million (2012: £5.7 million) primarily due to a 14% increase in volume of active pharmaceutical ingredient (API) supplied, with underlying in-market sales made by Menarini flat
    - Research collaboration income was £7.1 million (2012: £8.7 million) including £2.5 million of milestones payments (2012: £2.6 million) allowing our research organisation to remain self-funding
  - Operating costs before exceptional items were £19.3 million (2012: £18.2 million), up 6% due to preparatory activities for expansion into the US and investment in the NCE pipeline (V158866 and V81444)
  - Pre-exceptional loss for the year was £5.6 million (2012: £5.2 million) and £4.0 million (2012: £5.2 million) on a post-exceptional basis
  - Cash resources including cash and cash equivalents and held to maturity assets reduced by £4.7 million in the year following:
    - £2.0 million proof-of-concept milestone payment to Tris for CCP-01 and
    - £0.9 million foreign exchange loss on the conversion of cash held in US dollars into sterling
  - Balance sheet remains strong with £76.9 million of cash resources and no debt

#### **Operational Highlights**

##### **Cough Cold Commercial Pipeline:**

- CCP-01 proof-of-concept achieved and milestone paid to Tris (March 2013)
  - Successfully completed single and multi-dose pivotal bioavailability studies (November 2013 and February 2014), completing the clinical studies required for NDA filing
  - Positive interim six months stability data for CCP-01 has been generated and NDA filing on track for mid-2014
- Four further programmes in active development at Tris, and we aim to achieve POC on all four of the remaining programmes during 2014

##### **Frovatriptan (marketed) (Migraine):**

- Underlying Menarini sales flat at €26.4 million (2012: €26.5 million)
- Menarini outlook for 2014 is for flat underlying sales vs 2013, both in tablet volumes and sales revenue
- We expect Menarini to reduce stock in 2014 with 2 shipments of API, one in each half of the year

#### **NCE Development Pipeline:**

V81444 (CNS diseases)

- Phase Ib/II POC study initiated (July 2013) with data anticipated in H1 2014

V158866 (Pain)

- Phase II POC study initiated (April 2013) and progressing well. Of a total of 36 subjects, 16 have completed and a further 4 are enrolled. Data now anticipated around the end of 2014

AUY922 (Cancer)

- Phase I and Phase II studies in multiple oncology indications including lung and breast continue with Novartis

Tosedostat - CHR2797 (Cancer)

- Cell Therapeutics reported positive interim results from an investigator-initiated Phase II trial at the 55th American Society of Haematology annual meeting (December 2013)
- The partial clinical hold on investigator led trials was removed by FDA in January 2014 enabling studies to resume

RPL554

- Anti-inflammatory study results announced by Verona Pharma (March 2013)
- Verona announced a successful £14 million fundraising in March 2014. Some of the proceeds are intended to be used to develop RPL554 in three clinical studies using a nebulised formulation in patients with severe COPD and additional studies are planned to prepare for a larger Phase IIb study in hospitalised COPD patients. Results are expected in 2015

#### **Research Collaborations:**

- New collaboration with AKP announced (October 2013) and £0.3 million milestone earned (March 2014)
- First Servier collaboration extended for a further 2 years (March 2013)
- £2.5 million of milestones earned from successful collaboration with Genentech (February and March 2013)

#### **Expected 2014 Newsflow:**

- V81444 (CNS diseases) - Complete Phase Ib/II POC study (Data H1 2014)
- CCP-01 - Filing of NDA (Mid 2014)
- Proofs-of-concept on all four remaining programmes in cough cold pipeline (by 2014 year end)
- V158866 (Pain) - Complete Phase II POC study (Data around 2014 year end)
- AUY922 (Cancer) - Multiple Phase I and II study results (Novartis) (undisclosed)

- Tosedostat - CHR2797 (Cancer)- Phase II study results (Chroma) (undisclosed)
- Achieve milestones under existing collaborations (undisclosed)
- Secure new research collaborations (undisclosed)

Ian Garland, Chief Executive Officer, commented, "We made significant progress across all three elements of our strategy during 2013 and continued our strong financial and operational performance. Our lead cough cold programme, CCP-01, progressed rapidly achieving proof-of-concept, successfully completing both required pivotal clinical studies and achieving six month accelerated stability. We are on target therefore for an NDA filing in mid-2014. With four further cough cold programmes in development we aim to achieve POC on all four of these programmes in the coming year.

In the NCE pipeline we initiated two POC studies for V81444 and V158866 and expect data from both, during 2014. We also had another positive year in our research business following on from last year's record performance and continue to be self-funding.

The outlook for 2014 and beyond is extremely positive as we get closer to our first NDA filing from the cough cold portfolio and its potential approval in the first half of 2015."

#### **Presentation & Conference Call**

Vernalis management will host a presentation at **9.00am** (UK) at Brunswick's offices, 16 Lincoln's Inn Fields, London WC2A 3ED today. 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 3139 4830**, Passcode **#35707904**.

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#### **Enquiries:**

##### **Vernalis plc:**

Ian Garland, Chief Executive Officer **+44 (0) 118 938 0015**  
David Mackney, Chief Financial Officer

##### **Canaccord Genuity Limited (Nominated Adviser):** **+44 (0) 20 7523 8350**

Lucy Tilley  
Dr Julian Feneley  
Henry Fitzgerald-O'Connor

##### **Shore Capital (Joint Broker)** **+44 (0)20 7408 4090**

Bidhi Bhoma  
Toby Gibbs

##### **Brunswick Group:** **+44 (0) 20 7404 5959**

Jon Coles

#### **Notes to Editors**

##### **About Vernalis**

Vernalis is a revenue generating development stage pharmaceutical company with significant expertise in drug development. The Group has one marketed product,

frovatriptan for the acute treatment of migraine, an exclusive licensing agreement to develop and commercialise multiple novel products focussed on the US prescription cough cold market as well as seven 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 AKP, Biogen Idec, Endo, GSK, Genentech, Lundbeck, Menarini, Novartis, Servier 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 products, 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 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

The last 12 months have seen continued progress across all three elements of our business. Two years since completing our transformational development and licensing agreement and associated financing, we are within six months of our first cough cold New Drug Application (NDA) filing. Our new chemical entity (NCE) programmes have progressed according to plan and our research group continues to generate sufficient income to cover its avoidable costs.

A key early priority for 2013 was to confirm with the FDA the regulatory pathway for our pipeline of cough cold programmes under development with Tris Pharma, Inc. (Tris). Following feedback from the FDA early in the year, we focused on five prescription cough cold programmes that can all be developed as NDAs based on comparative bioavailability.

Tris achieved proof-of-concept for the most advanced of these programmes, CCP-01, at the end of March 2013 and has subsequently successfully completed two pivotal bioavailability studies and six months of accelerated stability. Tris plans to submit the CCP-01 NDA in mid-2014, when the remaining stability data at 12 months will be available. This submission will start a ten-month review at the FDA. If successful, this NDA could be approved in the first half of 2015 and then launched in the US into the 2015-16 winter cough cold season.

A further four programmes are in development at Tris, three of which have already been tested in at least one human POC bioavailability study. Tris continues to work on formulations for all four of these programmes and aims to achieve further POC for all four in 2014 that could allow for further NDA filings in 2015 and 2016.

In parallel with Tris development activity we continue to progress the build-out of our US commercial infrastructure, ahead of our first product launch in 2015. We plan to establish our US commercial organisation with a small core group of management complemented by class-leading external experts. For example, we have already selected our third-party logistics (3PL) provider that will store and distribute our products, and in the first half of 2014, expect to select our contract sales organisation (CSO) that will recruit and manage field-based sales staff.

During 2013, we initiated proof-of-concept studies for both V81444 (our A<sub>2A</sub> antagonist programme for Parkinson's and other CNS diseases) and V158866 (our FAAH inhibitor for pain). Both of these studies are expected to complete in 2014, with V81444 in the first half and V158866 now expected around year end. Our goal of partnering both programmes is highly dependent on positive results from the ongoing studies. We do not intend to invest further in either programme beyond the current studies. Our previously partnered NCE pipeline has also progressed in 2013, with Novartis continuing to enrol patients in multiple Phase II cancer studies for AUY922.

During 2013, research continued to perform well both operationally and financially, following a record year in 2012. Revenues in 2013 were slightly lower than 2012 but importantly more than covered costs, including capital expenditure. Of note in 2013, the Group secured its first Japanese collaboration and in March 2014 earned its first milestone of £0.3 million from this collaboration.

Financially, we remain exceptionally strong with £76.9 million of cash resources, no debt and a 2013 cash burn of only £4.7 million. Our cash burn continues to benefit from the frovatriptan royalty income received from Menarini and SK Chemicals which at £6.7 million was 16 per cent above 2012's income. We continue to carefully control expenses and cash burn and benefit from our success-based deal structure with Tris.

The Company is positioned well for further significant advancement in 2014 across all three elements of our business with our first cough cold NDA filing planned for mid 2014, four further cough cold programmes that could achieve proof-of-concept, key data expected on our two in-house NCEs and further progress in our existing research collaborations.

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



## Financial Review

### Total revenues of £14.1 million

Revenue from continuing operations totalled £14.1 million (2012: £14.6 million) a reduction of 4 per cent year-on-year. Revenue included £6.7 million from the supply of frovatriptan (2012: £5.7 million) and £7.4 million (2012: £8.9 million) in respect of collaborations and the release of deferred revenue.

### Research remains self-financing with £7.1 million of revenue

Research collaboration income was £7.1 million (2012: £8.7 million), down £1.6 million or 18 per cent. Milestone income was £2.5 million for the year (2012: £2.6 million) and all came from the Genentech collaboration that was successfully completed in March 2013.

A new collaboration with AKP was secured in October 2013, adding to three existing collaborations with Servier and one with Lundbeck. We finished the year with five active collaborations. Our collaborations generated £4.6 million of FTE income (2012: £6.1 million) in addition to the milestone income and importantly, research activity remained self-financing during 2013.

### Frovatriptan sales stable but royalties increase by 16 per cent

Sales of frovatriptan by Menarini in Europe and Central America were stable in euro terms at €26.4 million, flat compared to 2012 (€26.5 million). Volumes of tablet sales in 2013 were also flat at 9.7 million compared to 2012 (9.6 million). Vernalis receives 25.25 per cent of Menarini sales via a royalty linked to the supply of active pharmaceutical ingredients (API) so the reported royalties do not necessarily track the underlying performance of Menarini in the market.

The reported frovatriptan royalties of £6.7 million were 16 per cent up on 2012 (£5.7 million) and this £1.0 million increase was due to a 14 per cent increase in volume, a 4 per cent increase from foreign exchange offset by a 2 per cent price reduction.

In 2013, we shipped to Menarini 2.5kg of API for non-EU territories, two batches of tablets for the Central American market (2012: one batch) and the usual three API shipments of 12.5kg each. We also shipped one batch of tablets to SK Chemicals (2012: nil) for the South Korean market. Income increased due to a strengthening of the euro during 2013, as shipments to Menarini are invoiced in euros and then converted into sterling for financial reporting purposes. The average sterling:euro exchange rate for 2013 was 1.1821, up 5 per cent from 1.2410 in 2012.

We expect Menarini to reduce its stock holdings of frovatriptan in 2014 ahead of the composition of matter patent expiry at the end of 2015. Even though underlying sales of frovatriptan by Menarini are expected to remain flat in 2014, we expect only two API shipments of 12.5kg in 2014 as opposed to the usual annual requirement of three shipments. As the royalty received from Menarini is linked to the supply of API, this will impact our reported revenue in 2014.

### Development costs remain focused on V158866 and V81444

Research and development expenditure from continuing operations increased 11 per cent to £14.4 million (2012: £13.0 million) and comprised £10.7 million (2012: £11.2 million) of internally funded research and development costs and £3.7 million (2012: £1.8 million) of external costs associated with the development pipeline. The development costs remain focused on the two clinical proof-of-concept studies for V81444 and V158866, both to be completed in 2014.

### G&A cost control

General and administrative expenditure before exceptional items was £4.9 million (2012: £5.2 million), a decrease of £0.3 million for the year. Adjusting for Tris-related costs in 2012 of £0.4 million, underlying G&A was flat at £4.8 million. Tight management of G&A expenditure remains a key priority for the business and we have successfully managed to absorb the increase in costs related to the US expansion strategy, within our overall historic levels of operating costs.

The exceptional gain in 2013 of £1.6 million relates to the effect of a reassessment of assumptions used to calculate the property provision recognising an improvement in the rental market.

### Operating loss increase due to NCE pipeline investment



The operating loss for the year from continuing operations before exceptional items increased to £7.3 million (2012: £5.2 million), reflecting the investment in the NCE pipeline together with a small reduction in revenues. The operating loss from continuing operations after the exceptional gain was £5.7 million (2012: £5.2 million).

**Finance income reduced by further weakening of the US dollar**

Finance income was stable at £0.4 million (2012: £0.4 million). 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. This finance income was offset by a finance expense of £1.0 million (2012: £2.0 million) comprising £0.9 million unrealised foreign exchange loss on the conversion of US dollar-denominated cash deposits into sterling at the yearend for financial reporting purposes (2012: £1.9 million) and other finance costs of £0.1 million (2012: £0.1 million). The unrealised foreign exchange loss arose due to the further weakening of the US dollar; at 31 December 2013 the sterling:US dollar rate was 1.6563, compared to 31 December 2012 year-end rate of 1.6255.

**R&D tax credits increase through Tris development payments**

The tax credit of £2.3 million (2012: £1.6 million) represents recoverable amounts under current legislation on research and development tax credits for small- and medium-sized companies. The tax credit for the year was £1.8 million (2012: £1.4 million) and the balance of £0.5 million (2012: £0.2 million) represents claims in relation to prior years.

Payments made to Tris that relate to development work performed on our behalf, will qualify for R&D tax credits. The increase in the current year tax credit arises not only from the tax credit on the POC milestone that was paid in March 2013 but also £0.5 million from 2012 relating to the US\$5.0 million upfront payment made to Tris.

**Loss for the year after exceptional items reduced**

The pre-exceptional loss for the year was £5.6 million (2012: £5.2 million) but after exceptional items was £4.0 million (2012: £5.2 million).

**Balance sheet remains exceptionally strong**

Non-current assets increased to £7.7 million (2012: £6.9 million) due to the US\$3 million milestone payment to Tris on achieving POC for CCP-01, partially offset by the continued amortisation of the frovatriptan intangible asset.

Current assets decreased to £83.3 million (2012: £88.6 million) primarily due to the £4.7 million reduction in cash over the year. Total liabilities decreased to £8.8 million (2012: £10.1 million) due to a reduction in our property provision and we remain debt free.

**Cash remains key to executing commercial strategy**

Cash resources, comprising held-to-maturity financial assets and cash and cash equivalents decreased by £4.7 million to £76.9 million (2012: £81.6 million).

We continue to manage cash tightly. The £4.7 million cash burn in the year included a US\$3 million (£2.0 million) payment to Tris as well as a £0.9 million unrealised foreign exchange loss arising from the conversion of our US dollars into sterling for reporting purposes. Excluding these amounts, the net burn for the year was £1.8 million.

Underlying cash burn, which excludes milestone income received, Tris milestone payments and foreign exchange on US dollar cash, increased to £6.3 million from £4.5 million, reflecting the additional investment in the NCE pipeline and the reduction in research collaboration income.

**Outlook for 2014 and beyond**

The Group continues to be well positioned for 2014 and beyond with a robust balance sheet, no debt and sufficient cash to reach profitability. It is anticipated that annual cash flows will increase in the near term with further progress of the Tris pipeline expected, alongside the establishment of a US infrastructure, as we approach filing, approval and then launch of our first cough cold product.



## Risks and Uncertainties

### Risks

Like all businesses we face risks and uncertainties, many of which are inherent within any pharmaceutical development company looking to establish commercial operations. 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. Our risk management process is explained in the annual report.

### 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 GMP.
- 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 products' indicated uses or the levels of reimbursement receivable that 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.

### Pricing, reimbursement and competition

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

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 attempting 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.
- Moving towards a reference pricing model, particularly in Europe where the amount of reimbursement is determined by consideration of reimbursement levels for comparable drugs in other countries, which 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.

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 and 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 regime.
- The ability to achieve adequate distribution and stocking levels of product at the wholesalers and pharmacies.

#### **Intellectual property**

Intellectual property protection remains fundamental to our strategy of developing novel drug candidates. Our ability 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 own a portfolio of patents and patent applications which underpin our 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.

#### **Product Litigation and Corporate Compliance**

Failure of the Company and/or its collaborators to comply with regulations could result in damage to the Company's reputation, the 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 involve 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 pay 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 judgment in a product liability suit, even if insured, could generate substantial negative publicity about the Company's products and business and inhibit its commercialisation strategy.

#### **Manufacturing risk**

The supply of frovatriptan API to Menarini for the EU and Central American markets constitutes a substantial proportion of our income and so our ability to manufacture and supply this product on schedule is critical. 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 manufacturing campaigns are performed on schedule and therefore dual sourcing is used where possible. For the cough cold portfolio we are however reliant on one source of supply for the finished product. If something were to

happen to Tris, financial or otherwise, or to its manufacturing facility, or if Tris has insufficient manufacturing capacity, or prioritises other non-Vernalis product manufacture, 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 volume to the market which may then have a material impact on sales, profits and cash liquidity.

Product manufacture is subject to continual regulatory control and products must be manufactured in accordance with good manufacturing practice. 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 liquidity.

#### **In-licensing complementary products**

Our strategy is to augment the low-risk, late-stage Tris Pharma portfolio of products by in-licensing complementary products to our commercial pipeline. This is an extremely competitive area, with many large and mid-sized pharmaceutical companies also having 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.

#### **Establishing a US commercial operation**

Commercialising the late-stage Tris portfolio of products in the US will require a US infrastructure to be established as the Group currently has no operations in the US. The operational strategy to reduce this execution risk is to minimise the creation of our own infrastructure as far as possible and so we will use a 3PL and likely use a CSO which will provide the main operational services to our US business. Any delays or issues either in establishing these relationships or in their operation may affect our ability to generate and grow revenues and attain profitability. Establishing 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.

#### **Financial risks**

##### **Cash flow**

We have a history of operating losses which are anticipated to continue in the near term. Following the £65.9 million (net of expenses) equity fundraising announced in February 2012, the Company is well capitalised to execute its transition into a profitable and cash generative pharmaceutical company over time. At 31 December 2013 the Group had £76.9 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 recent global economic uncertainty, counterparty credit risk was and 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 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 which are received in US dollars or euros. A proportion of our expenditure is incurred in US dollars and other currencies, relating principally to clinical trials and the Tris Pharma agreement. Our cash balances are predominantly held in sterling, US dollars and euros.

With 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 the equity issue in March 2012, we purchased US\$100 million, 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 other than sterling and US dollars are not matched, fluctuations in exchange rates between sterling and these currencies, principally euros, 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 liquidity 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 looks to mitigate the development and commercial risk of its NCE pipeline by partnering drug candidates at an appropriate stage. This partnering event crystallises part of the programme's value, with the goal of retaining an attractive proportion of the commercial upside through future milestones and ongoing royalties from commercial sales.

### **Value of Intangible Assets**

Under the development and licensing agreement with Tris, milestones payable to Tris for the reimbursement of development costs together with the NDA milestone 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 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 9.



**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 annual report 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 year ended 31 December 2013

	Note	2013			2012
		Pre-exceptional items £000	Exceptional items (note 3) £000	Total £000	Total £000
<b>Revenue</b>	2	<b>14,084</b>	-	<b>14,084</b>	14,616
Other income		180	-	180	-
Cost of sales		(2,244)	-	(2,244)	(1,581)
Research and development expenditure		(14,416)	-	(14,416)	(12,975)
General and administrative expenditure		(4,907)	1,608	(3,299)	(5,249)
<b>Operating (loss)/profit</b>		<b>(7,303)</b>	<b>1,608</b>	<b>(5,695)</b>	(5,189)
Finance income	4	420	-	420	390
Finance expense	4	(999)	-	(999)	(2,039)
<b>(Loss)/profit before income tax</b>		<b>(7,882)</b>	<b>1,608</b>	<b>(6,274)</b>	(6,838)
Income tax credit		2,273	-	2,273	1,595
<b>(Loss)/profit for the year</b>		<b>(5,609)</b>	<b>1,608</b>	<b>(4,001)</b>	(5,243)
<b>(Loss)/profit per share (basic and diluted)</b>	5	<b>(1.3)p</b>	<b>0.4p</b>	<b>(0.9)p</b>	(1.4)p

## Consolidated statement of comprehensive income

for the year ended 31 December 2013

		2013			2012
		Pre-exceptional items £000	Exceptional items (note 3) £000	Total £000	Total £000
(Loss)/profit for the year		(5,609)	1,608	(4,001)	(5,243)
Other comprehensive income:					
Items that may subsequently be reclassified to profit and loss:					
Exchange gain on translation of overseas subsidiaries			2	-	2
<b>Total comprehensive (expense)/income for the year</b>		<b>(5,607)</b>	<b>1,608</b>	<b>(3,999)</b>	(5,242)





**Balance sheet**

as at 31 December 2013

	Note	2013 £000	2012 £000
<b>Assets</b>			
Property, plant and equipment		1,438	1,218
Intangible assets	6	6,292	5,665
<b>Non-current assets</b>		<b>7,730</b>	6,883
Inventories		130	250
Trade and other receivables		4,443	5,440
Tax receivable		1,785	1,400
Derivative financial instruments		22	-
Held-to-maturity financial assets		48,597	54,510
Cash and cash equivalents		28,321	27,045
<b>Current assets</b>		<b>83,298</b>	88,645
<b>Total assets</b>		<b>91,028</b>	95,528
<b>Liabilities and shareholders' equity</b>			
<b>Liabilities</b>			
Trade and other liabilities		156	-
Deferred income		-	9
Provisions	7	4,127	5,810
<b>Non-current liabilities</b>		<b>4,283</b>	5,819
Trade and other liabilities		3,384	3,206
Deferred income		962	897
Provisions	7	155	144
Derivative financial instruments		-	7
<b>Current liabilities</b>		<b>4,501</b>	4,254
<b>Total liabilities</b>		<b>8,784</b>	10,073
<b>Equity attributable to owners of the parent</b>			
Share capital	8	4,421	4,421
Share premium		476,392	476,389
Other reserves		252,416	251,629
Retained deficit		(650,985)	(646,984)
<b>Total equity</b>		<b>82,244</b>	85,455
<b>Total liabilities and equity</b>		<b>91,028</b>	95,528





## Statements of changes in shareholders' equity

	Note	Share capital £000	Share premium £000	Other reserves £000	Retained deficit £000	Total £000
<b>Balance at 1 January 2012</b>		<b>996</b>	<b>413,881</b>	<b>250,844</b>	<b>(641,741)</b>	<b>23,980</b>
Loss for the year		-	-	-	(5,243)	(5,243)
Other comprehensive income for the year		-	-	1	-	1
<b>Total comprehensive income/(expense) for the year</b>		<b>-</b>	<b>-</b>	<b>1</b>	<b>(5,243)</b>	<b>(5,242)</b>
Transactions with owners:						
Issue of equity share capital	8	3,425	65,081	-	-	68,506
Expenses on issue of share capital		-	(2,573)	-	-	(2,573)
Share-based payments charge		-	-	784	-	784
		3,425	62,508	784	-	66,717
<b>Balance at 31 December 2012</b>		<b>4,421</b>	<b>476,389</b>	<b>251,629</b>	<b>(646,984)</b>	<b>85,455</b>
Loss for the year		-	-	-	(4,001)	(4,001)
Other comprehensive income for the year		-	-	2	-	2
<b>Total comprehensive income/(expense) for the year</b>		<b>-</b>	<b>-</b>	<b>2</b>	<b>(4,001)</b>	<b>(3,999)</b>
Transactions with owners:						
Exercise of share options		-	3	(3)	-	-
Share-based payments charge		-	-	788	-	788
		-	3	785	-	788
<b>Balance at 31 December 2013</b>		<b>4,421</b>	<b>476,392</b>	<b>252,416</b>	<b>(650,985)</b>	<b>82,244</b>





**Cash flow statement**

for the year ended 31 December 2013

	Note	2013 £000	2012 £000
<b>Cash flows from operating activities</b>			
Loss for the year		(4,001)	(5,243)
Taxation		(2,273)	(1,595)
Depreciation		426	419
Profits on disposal of property, plant and equipment		-	(4)
Amortisation of intangible fixed assets	6	1,349	1,349
Movement in provisions		(1,767)	(1,151)
Movement in deferred income		56	(396)
Share-based payments charge		876	784
Movement in derivative financial instruments		(29)	55
Finance income	4	(420)	(390)
Finance expense	4	999	2,039
Exchange (gain)/loss		(229)	61
		(5,013)	(4,072)
<b>Changes in working capital</b>			
Inventories		120	255
Receivables		1,143	(74)
Liabilities		264	(1,228)
		(3,486)	(5,119)
<b>Cash used in operations</b>			
Taxation received		1,929	1,816
		(1,557)	(3,303)
<b>Net cash used in operating activities</b>			
<b>Cash flows from investing activities</b>			
Purchase of property, plant and equipment		(646)	(785)
Proceeds from sale of property, plant and equipment		-	4
Purchase of intangible fixed assets		(1,976)	(3,454)
Interest received on cash and cash equivalents		88	117
Interest received on held-to-maturity financial assets		358	264
		(2,176)	(3,854)
<b>Net cash used in investing activities</b>			
<b>Cash flows from financing activities</b>			
Movement in held-to-maturity financial assets		5,913	(34,971)
Issue of shares	8	-	68,506
Share issue costs		-	(2,573)
		5,913	30,962
<b>Net cash generated from financing activities</b>			
Foreign exchange loss on cash and cash equivalents		(904)	(1,921)

<b>Movements in cash and cash equivalents in the year</b>	<b>1,276</b>	21,884
Cash and cash equivalents at the beginning of the year	<b>27,045</b>	5,161
<b>Cash and cash equivalents at the end of the year</b>	<b>28,321</b>	27,045
Held-to-maturity financial assets	<b>48,597</b>	54,510
<b>Total cash, cash equivalents and held-to-maturity financial assets</b>	<b>76,918</b>	81,555



## Notes to the financial statements

### 1. Accounting policies and basis of preparation

This financial information for the year ended 31 December 2013 and 31 December 2012 does not comprise statutory financial statements but is derived from the financial statements. This financial information and announcement was approved for issue on 31 March 2014 and has been extracted from the 31 December 2013 audited statutory financial statements that were also approved by the board on the same date and are available on the Company's website [www.vernalis.com](http://www.vernalis.com). These statutory financial statements have not yet been delivered to the registrar of Companies. Statutory financial statements for the year ended 31 December 2012 were approved by the Board of directors on 9 April 2013 and delivered to the Registrar of Companies. The auditors' report on the financial statements for the year ended 31 December 2013 and 31 December 2012 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), IFRIC 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 year ended 31 December 2013 and 31 December 2012, as described in those annual 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 Annual Report and the accounts are available on the investor's section of the Company's website and are submitted to the National Storage Mechanism and will shortly be available for inspection at [www.hemscott.com/nsm.do](http://www.hemscott.com/nsm.do)

The Group's Annual Report and Accounts will be posted to shareholders on 15 April 2014

### 2. Segmental information

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The chief operating decision maker has been identified as the Executive Committee.

The Group has only one segment, being the research, development and commercialisation of pharmaceutical products for a range of medical disorders. All costs to acquire property, plant, equipment and intangible assets as well as all related depreciation, impairment and amortisation expense borne by the Group relate to this one segment. In addition, all other non-cash expenses incurred by the Group relate to this one 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>2013</b>	2012
	<b>£000</b>	£000
United Kingdom	<b>20</b>	21
Rest of Europe	<b>10,639</b>	12,743
North America	<b>3,051</b>	1,818
Rest of the World	<b>374</b>	34
	<b>14,084</b>	14,616

An analysis of revenue by category is set out in the table below:

	<b>2013</b>	2012
	<b>£000</b>	£000
Product sales*	<b>6,684</b>	5,740
Royalties	<b>250</b>	200
Collaborative agreement	<b>7,150</b>	8,676
	<b>14,084</b>	14,616

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

## 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 year, so as to facilitate comparison with prior years and to better assess trends in financial performance. Exceptional items include, but are not limited to, impairments of goodwill and intangible assets, restructuring costs and the provision for vacant leases.

	<b>2013</b>	2012
	<b>£000</b>	£000
Credit - release of provision for vacant leases (note 7)	<b>1,608</b>	-
Total exceptional items	<b>1,608</b>	-

## 4. Finance income/expense

	<b>2013</b>	2012
	<b>£000</b>	£000
<b>Finance income</b>		
Interest on cash, cash equivalents and held-to-maturity assets	<b>420</b>	390

	<b>420</b>	390
<b>Finance expense</b>		
Exchange loss on cash	<b>904</b>	1,921
Unwinding of discount on provision (note 7)	<b>95</b>	118
	<b>999</b>	2,039

#### 5. 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 year.

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>2013</b>	2012
Attributable loss before exceptional items (£000)	<b>(5,609)</b>	(5,243)
Exceptional items (£000)	<b>1,608</b>	-
Attributable loss (£000)	<b>(4,001)</b>	(5,243)
Weighted average number of shares (basic and diluted) in issue (000)	<b>442,115</b>	384,868
Loss per ordinary share before exceptional items	<b>(1.3)p</b>	(1.4)p
Exceptional items	<b>0.4p</b>	-
Loss per share (basic and diluted)	<b>(0.9)p</b>	(1.4)p

#### 6. Intangible assets

	Goodwill £000	Assets in use £000	Assets not yet in use £000	Total £000
<b>Cost</b>				
At 1 January 2013	8,954	37,408	3,754	50,116
Additions	-	-	1,976	1,976
At 31 December 2013	8,954	37,408	5,730	52,092



<b>Accumulated amortisation and impairment</b>				
At 1 January 2013	(8,954)	(35,497)	-	(44,451)
Amortisation charge in the year	-	(1,349)	-	(1,349)
At 31 December 2013	(8,954)	(36,846)	-	(45,800)
<b>Net book value at 31 December 2013</b>	<b>-</b>	<b>562</b>	<b>5,730</b>	<b>6,292</b>
<b>Cost</b>				
At 1 January 2012	8,954	37,408	300	46,662
Additions	-	-	3,454	3,454
At 31 December 2012	8,954	37,408	3,754	50,116
<b>Accumulated amortisation and impairment</b>				
At 1 January 2012	(8,954)	(34,148)	-	(43,102)
Amortisation charge in the year	-	(1,349)	-	(1,349)
At 31 December 2012	(8,954)	(35,497)	-	(44,451)
<b>Net book value at 31 December 2012</b>	<b>-</b>	<b>1,911</b>	<b>3,754</b>	<b>5,665</b>

#### Useful life and net book value of intangible assets

	<b>2013</b>	2012	<b>2013</b>	2012
	<b>Useful life</b>	Useful life	<b>£000</b>	£000
Assets in use				
Frova®	<b>to 2014</b>	to 2014	<b>562</b>	1,911
			<b>2013</b>	2012
			<b>£000</b>	£000
Assets not yet in use			<b>5,730</b>	3,754

#### Additions

Additions of £2.0 million were made during the year ended 31 December 2013. These additions relate to a US\$3.0 million milestone paid to Tris, in consideration for development and in recognition of the achievement of POC for the first collaboration programme, CCP-01. Additions of £3.5m were made in the year ended 31 December 2012 and related to a \$5.0m upfront milestone paid to Tris, together with professional fees incurred in relation to the Tris agreement.

#### 7. Provisions

Property

	£000
At 1 January 2013	5,954
Credit -provisions reversed during the year (note 3)	(1,608)
Utilised during the year	(159)
Unwinding of discount (note 4)	95
<b>At 31 December 2013</b>	<b>4,282</b>

Provisions have been analysed between current and non-current as follows:

	<b>2013</b>	2012
	<b>£000</b>	£000
Current	<b>155</b>	144
Non-current	<b>4,127</b>	5,810
	<b>4,282</b>	5,954

#### Property provisions

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. This provision relates to properties in Oxfordshire and Cambridge and is expected to be utilised over the life of the related leases to 2015, 2019 and 2023 and has been discounted to fair value at the balance sheet date. Discount rates are based on Bank of England risk-free rates over the period of each lease. Included in the onerous lease provision is a dilapidation provision which principally relates to costs associated with the Group's obligation to reinstate leased buildings to their original state. The provision reversed during the year relates to a reassessment by the directors of the assumptions used.



## 8. Share capital

	Number issued '000	Number authorised '000	Price	Issued £000	Authorised £000
<b>Ordinary</b>					
1 January 2013	442,113	Unlimited	£0.01	4,421	Unlimited
Issue of shares	13	-	£0.01	-	-
<b>31 December 2013</b>	<b>442,126</b>	<b>Unlimited</b>	<b>£0.01</b>	<b>4,421</b>	<b>Unlimited</b>
<b>Ordinary</b>					
1 January 2012	99,585	Unlimited	£0.01	996	Unlimited
Firm Placing and Placing and Open offer	342,528	-	£0.01	3,425	-
<b>31 December 2012</b>	<b>442,113</b>	<b>Unlimited</b>	<b>£0.01</b>	<b>4,421</b>	<b>Unlimited</b>

## Issue of shares - 2013

During 2013, shares were issued following the exercise of an option under the Long Term Incentive Plan.

## Issue of shares - 2012

On 2 March 2012, the Group listed 342,528,564 ordinary shares of 1 pence each in connection with a Firm Placing and Placing and Open Offer announced on 10 February 2012, and priced at 20p per share.

## Removal of share capital limits

An ordinary resolution to remove the limit on the Company's ability to issue shares in the capital of the Company was passed at the General Meeting on 1 March 2010.

## 9. Related party transactions

## Identity of related parties

The Group consists of a parent, Vernalis plc and principally two wholly owned trading subsidiaries. The main trading company is Vernalis (R&D) 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 (excluding Vernalis®, Frova® and Migard® 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.

## Group

At 31 December 2013, an amount of £12,629 (2012: £3,246) 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 31 December 2013, £419 had been repaid at 28 February 2014. The amount due at 31 December 2012 was repaid in full by 31 March 2013.

#### 10. Post-balance sheet events

On 27 March 2014, the Group announced the achievement of the first milestone of £0.3 million from its research collaboration with AKP.