5 August 2014 LSE: VER

#### Interim results for the six months ended 30 June 2014

Vernalis plc (LSE: VER) today announces its results for the six months ended 30 June 2014.

# **Financial Highlights**

- Continued strong financial performance ahead of market expectations
  - Revenue was £6.2 million (H1 2013: £7.6 million)
    - Frovatriptan royalty income at £1.8 million (H1 2013: £2.6 million) was in line with market expectations, with one 12.5 kg batch of API delivered to Menarini
    - Collaboration income was £4.4 million (H1 2013: £5.0 million) with £1.1 million of milestones earned (H1 2013: £2.5 million) and the remaining income derived from FTE funding
  - Operating costs (including R&D) before exceptional items marginally higher at £9.5 million (2013: £9.1 million)
  - R&D spend remains largely flat at £6.9 million (H1 2013: £6.5 million)
    - External R&D expenditure increased to £1.4 million (H1 2013: £1.0 million) due to investment in V158866, V81444 and increased activity on Tris related projects
  - Operating loss before exceptional items was £3.9 million (H1 2013: £2.6 million)
  - Loss for the period after exceptional items was £4.6 million (H1 2013: profit of £4.2 million) including a £1.7 million unrealised foreign exchange loss (H1 2013: £4.4 million gain) due to the strength of Sterling
- Balance sheet remains strong with £70.3 million of cash resources (including cash, cash equivalents and held-to-maturity financial assets) and debt free
  - Net decrease in cash resources of £6.6 million for the first six months of 2014
  - Large proportion of cash still denominated in US dollars, with a £1.7 million unrealised foreign exchange loss reported for the period
  - Proof-of-Concept (POC) payment on CCP-07 of £1.8 million paid to Tris in April 2014
  - Underlying cash burn increased to £3.8 million (2013: £2.6 million) resulting from decline in revenue and small increase in operating costs

# **Operational Highlights**

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

- NDA for Tuzistra<sup>TM</sup> XR (CCP-01) submitted to the FDA at the end of June as expected
- POC achieved for both CCP-07 and CCP-08 triggering milestone payments to Tris in April and July 2014 respectively
- Two further programmes continue in active development at Tris and are targeted to achieve POC before the end of 2014

# **NCE Development Pipeline:**

Frovatriptan (marketed) (Migraine):

• H1 2014 Menarini frovatriptan sales were in line with the same period in 2013 (€13.2 million vs €13.1 million)

## V81444 (CNS diseases):

Results of the Phase Ib/II POC study in Attention Deficit Hyperactivity Disorder (ADHD) (April 2014) were promising and the goal is now to partner this programme for further development in ADHD, PD or other CNS disorders where A<sub>2Δ</sub> receptor antagonists show potential patient benefit

## V158866 (Pain):

The Phase II POC study in spinal cord injury neuropathic pain continues with data now expected in 2015, due to slower than anticipated patient recruitment

#### AUY922 (Cancer):

Multiple Phase I and Phase II studies with Novartis continue in a variety of cancers with a focus on non-small-cell lung cancers

#### Tosedostat - CHR2797 (Cancer):

- The partial clinical hold on investigator led trials was removed by the FDA in January 2014 enabling studies to resume
- CTI Biopharma Corp. (previously Cell Therapeutics Inc.) is hoping that data from these trials in acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS) may inform the appropriate design of a Phase III study
- CTI Biopharma also announced in June, the initiation of an international co-operation group Phase II study of tosedostat in combination with low dose cytarabine in older patients with AML or MDS

## Servier 1 (Cancer):

- Servier signed a global strategic agreement with Novartis to develop and commercialise drug candidates from this collaboration (May 2014)
- The lead molecule from this collaboration with Servier, a selective BCL-2 inhibitor, has progressed into Phase I (June 2014) triggering a £0.8 million (€1 million) milestone receipt

#### **Research Collaborations:**

- Milestone achieved in collaboration with Asahi Kasei Pharma triggering a £0.3 million payment to Vernalis (March 2014)
- Winner of Queen's Award for Enterprise (April 2014)
- Two milestones achieved in our collaborations with Servier triggering, in total, a €0.75 million payment to Vernalis (August 2014)

# **Potential Newsflow**

- Tuzistra<sup>TM</sup> XR NDA filing acceptance by FDA (Q3 2014)
- Achieve POC for remaining two cough cold pipeline programmes (before year end 2014)
- V158866 (Pain) Completion of Phase II POC study (2015)
- AUY922 (Cancer) Multiple Phase I and II study results (Novartis, timing not disclosed)
- Achieve further milestones under existing research collaborations
- Secure new research collaborations

Ian Garland, Chief Executive Officer, commented, "We have made excellent progress across all aspects of our business during the first half of this year.

The cough cold commercial pipeline has advanced significantly with submission of the Tuzistra<sup>TM</sup> XR NDA to the FDA and proof-of-concept achieved for both CCP-07 and CCP-08. We aim to achieve proof-of-concept on the two remaining cough cold products before the end of 2014.

We also announced positive news from the NCE pipeline with promising results from V81444's phase Ib/II study in ADHD. We now aim to partner this programme having significantly enhanced the data package. In the period we also announced that Servier 1, a selective BCL-2 inhibitor had entered Phase 1.

Research continues to perform well and remains self-funding with more milestones earned and five collaborations active during the period. Our financial results overall continue to be strong and we are well positioned for the launch of our first cough cold product into the US market in 2015."

## Presentation & Conference Call

Vernalis management will host a presentation at **09.00 am** (UK) today (5 August 2014) at Brunswick's offices, 16 Lincoln's Inn Fields, London WC2A 3ED. It will also be available via webcast at <a href="http://www.vernalis.com/investor-centre/presentations-and-webcasts">http://www.vernalis.com/investor-centre/presentations-and-webcasts</a> and <a href="http://www.vernalis.com/investor-centre/presentations-and-webcasts">www.cantos.com</a>.

Please contact Valerie Mugridge at Brunswick on +44 (0) 207 396 5325 for details.

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#### **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

# **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.

# Strategic and operational review

During the first six months of 2014, Vernalis has continued to make strong and rapid progress towards becoming a self-sustaining cash generative pharmaceutical company. Our late-stage, low-risk pipeline of differentiated prescription cough cold candidates has seen multiple positive advances since the end of 2013 and in parallel, we continue to realise value from historical investments in higher risk novel potential treatments in the oncology, CNS and respiratory fields as well as in our drug discovery operations. Our key priority remains to advance the Tris commercial pipeline and steer the Company to sustainable profitability, whilst continuing to exploit the potential in our novel drug pipeline and research capabilities with only modest investment and at low levels of risk.

# Late stage low-risk development and commercialisation

The licensing deal with Tris combines Tris' extended release liquid technology with the Vernalis management team's substantial experience in the US cough cold sector to produce an exciting, high potential value but low-risk commercial pipeline.

We have prioritised development of five products under the Tris collaboration following feedback from the FDA that confirmed an accelerated regulatory path based on comparative bioavailability for these products. All five are extended release formulations of existing immediate release prescription cough cold products.

The first candidate, Tuzistra<sup>TM</sup> XR (formerly CCP-01), has progressed rapidly since achieving POC in March 2013. Following production of three stability batches in mid-2013 and positive pivotal study results in November 2013 and February 2014, an NDA for Tuzistra<sup>TM</sup> XR was submitted on schedule to the FDA at the end of June 2014. The next steps for Tuzistra<sup>TM</sup> XR are confirmation of acceptance to file from the FDA, which is expected by mid-September, and potential approval and launch in the US in summer 2015, ahead of the 2015-16 cough cold season.

The remaining four cough cold programmes under active development are also progressing very well. In April this year, CCP-07 achieved POC and we recently announced in July that CCP-08 has also achieved this milestone. Based on current development timelines, both CCP-07 and CCP-08 NDAs could be submitted to the FDA in the second half of 2015. The remaining two active programmes, CCP-05 and CCP-06 are expected to enter POC studies in the second half of 2014 and could both achieve POC by the end of the year.

The latest 2013-14 US prescription cough cold market data became available in July and shows that the market continues to be large and attractive, with significant potential for extended release formulations of current immediate release products. The total market fluctuates with the severity of the cough cold season. The latest IMS prescription data indicates that 31.5 million prescriptions were written for cough cold products in the US in the year to June 2014, representing a moderate season. By way of comparison 34.2 million prescriptions were written in the US in the year to June 2013 (also a moderate season) and 29.4 million in the same period to June 2012 (a very mild season). We estimate the potential market size for extended release cough cold products to be around \$2 billion annually.

During the first half of 2014 we have continued to prepare for commercialisation of our cough cold products, with the initial focus on the potential launch of Tuzistra<sup>TM</sup> XR which is now expected to be just 12-months away. As explained at the time of our 2013 year end results, we intend to align ourselves with class leading service providers for the critical aspects of our US commercial strategy. We have selected our third party logistics provider, our contract sales provider and our National Accounts Manager. In addition to selecting these external strategic partners, we expect to hire a US based SVP Medical Affairs to complement our two existing executive US employees. Our US staff will be based in a new office which we expect to open in Q4 this year, which will be located on the East Coast in the Philadelphia area.

#### Frovatrintan

Underlying frovatriptan sales made by Menarini in H1 2014 continue to perform broadly in line with the same period of 2013 (€13.2 million compared to €13.1 million). Menarini is anticipating sales will remain stable for 2014. The royalties on these underlying sales are based on shipment of active pharmaceutical product (API) to Menarini and are paid in Euros. We indicated at the time of the 2013 year end results that Menarini anticipates ordering just two batches of API this year, one of which was shipped in the first half. Our reported Menarini frovatriptan royalty revenue will continue to fluctuate depending on the number of batches of API shipped and changes in foreign exchange rates. Royalties included in revenue for the period to 30 June 2014 were £1.8 million (H1 2013: £2.6 million) with the decrease driven primarily by a reduction in volume but also due to some foreign exchange movement and pricing.

#### Realising value from the NCE pipeline

The NCE pipeline at 30 June 2014 comprised seven development programmes focusing on central nervous disorders, cancer and inflammation. Four of these programmes are partnered, one each with Novartis, Chroma, Verona Pharma and Servier. This pipeline continues to progress and importantly includes several products with significant commercial potential.

In April 2014 we announced the results of a POC study for V81444, an A<sub>2A</sub> receptor antagonist which is being investigated as a treatment for diseases of the central nervous system. This POC study, which was in adult subjects with a confirmed diagnosis of ADHD, did not achieve statistical significance in its primary ADHD rating scale endpoint but did achieve a statistically

significant improvement in the PERM-P secondary endpoint. We have initiated a partnering process for this programme.

Our other in-house NCE programme in which we are investing is V158866, a FAAH inhibitor being investigated as a treatment for neuropathic pain as a result of spinal cord injury. Recruitment into this study continues to be slow and data will not now be available until 2015.

We continue to seek a partner for our remaining in-house programme, V158411, a Phase I-ready Chk1 inhibitor for cancer.

AUY922 (our Hsp90 inhibitor from a research collaboration with Novartis) is being evaluated by Novartis in Phase II cancer studies. We remain excited about the commercial potential of this product. We can potentially receive clinical milestones and royalties on sales as this programme progresses.

The lead molecule from the Servier 1 collaboration, a selective BCL-2 inhibitor, progressed into Phase I in June 2014, triggering a €1 million milestone. Servier signed a global strategic agreement with Novartis to commercialise drug candidates from this collaboration in May 2014.

Tosedostat, which is being advanced by CTI Biopharma, completed an investigator led study in June 2014. CTI Biopharma also announced in June, the initiation of an international co-operation group-sponsored Phase II study of tosedostat in combination with low dose cytarabine in older patients with AML or MDS. This study is being conducted by the National Cancer Research Institute Haemological Oncology Study Group, under the sponsorship of Cardiff University. The other two partnered programmes continue to progress and we will provide updates as results of on-going studies become available.

#### Maintaining a balanced approach to research

Research has continued to perform strongly in H1 2014, albeit slightly below the exceptional performance in the first half of 2013, which included a £2.5 million milestone receipt from Genentech. Income from the five active collaborations, including two milestones was £4.4 million (H1 2013: £5.0 million). We continue to follow a lower risk collaborative research strategy, leveraging our expertise and strong track record in fragment and structure based drug design.

In August 2014 we announced two further milestones from collaborations with Servier, totalling €0.75 million.

#### We maintain a robust debt free financial position

At 30 June 2014 the Company had £70.3 million of cash resources and no debt. The majority of the cash remains held in US dollars to match the currency in which our future cough cold obligations in the US will be paid. As a consequence of holding these foreign currency deposits, we report exchange exposure on the retranslation of the US dollar cash deposits into sterling at each reporting date and on that basis a £1.7 million loss on our US dollar deposits has been recorded for the period to 30 June 2014 (H1 2013: £4.4 million gain). Critically, any changes in the foreign exchange rates between sterling and the US dollar will not impact our ability to execute our US commercial strategy, albeit that reported cash and held to maturity financial assets in sterling will be affected. This cash resources position, together with the frovatriptan royalty stream and multiple development and research collaborations, provide the company with an exceptionally strong financial platform for future growth.

# **Financial Review**

#### Income statement

#### Revenue from collaborations and royalties underpin current activities

Revenue for the six months ended 30 June 2014 was £6.2 million (2013: £7.6 million). Revenues comprised income of £1.8 million (2013: £2.6 million) from the supply of frovatriptan active pharmaceutical ingredient (API) to Menarini and collaboration income of £4.4 million (2013: £5.0 million).

#### Collaboration milestone income

Collaboration income for the first six months of 2014 decreased by £0.6 million or 12 per cent due to a reduction in research milestone income. In 2014 we earned £1.1 million of milestones in total with £0.3 million from AKP and £0.8 million (€1 million) from Servier. In 2013 we received £2.5 million of milestone income from the Genentech collaboration which concluded in the period to 30 June 2013. This fall in 2014 milestone income has been offset by an increase in FTE income with five active collaborations at the end of June 2014 compared with four at June 2013.

#### Frovatriptan underlying sales remain flat

Underlying sales of frovatriptan by Menarini in Europe and Central America were €13.2 million; broadly flat compared with 2013 (H1 2013: €13.1 million). Underlying volumes of tablet sales in 2014 were also flat compared with 2013 at 4.9 million (H1 2013: 4.7 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 sales of frovatriptan.

The reported £1.8 million of frovatriptan royalties for the first six months of 2014 was a decrease of £0.8 million or 31 per cent compared with the same period last year with 27 per cent of this due to volume and 4 per cent due to foreign exchange and pricing. In the first half 2014, we delivered one 12.5Kg batch of API to Menarini in line with our expectations. This compares with the first half of 2013 when we delivered 2.5kg of API to Menarini for non-EU territories, one batch of tablets for the Central American market and the usual 12.5kg shipment normally made in H1. API shipments are invoiced in Euros and translated into sterling for financial reporting purposes. For the first half of 2014 there was a foreign exchange loss of 4 per cent due to the weakening of the Euro against sterling when compared with the first six months of 2013.

#### External R&D spend remains focused

Research and development expenditure for the six months ended 30 June 2014 was marginally higher compared with the first six months of 2013, at £6.9 million (H1 2013: £6.5 million). External R&D expenditure increased for the first six months of 2014 to £1.4 million (H1 2013: £0.9 million) with the focus continuing to be on both V81444 and V158866 together with increased activity on Tris related projects. Expenditure on internal R&D activities was flat at £5.5 million (H1 2013: £5.6 million).

#### Operating costs before exceptional items remain tightly managed

General and administrative expenses before exceptional items for the six months ended 30 June 2014 were flat compared to the first six months of 2013 at £2.6 million (H1 2013: £2.6 million). Included within the costs in the first six months of 2014 was a foreign exchange gain of £0.1 million for the period (H1 2013: £0.2 million loss). Adjusting for these items the underlying costs for the first six months of 2014 have increased by £0.3 million or 12 per cent primarily due to advisory costs in advance of the US commercial launch.

The exceptional gain of £0.5 million recognised in 2013 related to a reassessment of assumptions used to calculate the property provision. There have been no exceptional items in H1 2014.

#### **Operating loss increases due to reduction in revenues**

The operating loss for the period before exceptional items was £3.9 million (H1 2013: £2.6 million) and increased due to a reduction in revenues and a marginal increase in operating costs. There were no exceptional items for the first six months of 2014 but the operating loss after exceptional items for the first six months of 2013 was £2.1 million.

#### Foreign exchange loss impacts half year performance

Finance income has decreased to £0.1 million for the first six months of 2014 (H1 2013: £4.7 million) and comprised interest received on cash, cash equivalents and held-to-maturity financial assets (H1 2013: £0.2 million). Finance income in H1 2013 also included a £4.4 million unrealised foreign exchange gain on the retranslation of cash and held-to-maturity financial assets into sterling at 30 June 2013. The majority of the gain arose because the US dollar strengthened by 7 per cent against sterling in the first half of 2013.

Finance expense increased to £1.8 million (H1 2013: £0.1 million) due to a £1.7 million foreign exchange unrealised loss on the retranslation of cash and held-to-maturity financial assets into sterling at 30 June 2014. The majority of the loss has arisen because the US dollar has weakened by 3 per cent against sterling in the first half of 2014. With a large proportion of our cash remaining in US dollars we will continue to recognise foreign exchange gains and losses on this cash at the end of each reporting period, based on the prevailing exchange rates.

### **R&D** tax credit on qualifying payments made to Tris

The R&D tax credit of £0.9 million (H1 2013: £1.6 million) represents amounts recoverable under current legislation relating to research and development expenditure. Payments made to Tris that relate to development work performed on our behalf will qualify for R&D tax credits and so the R&D credit for the first six months of 2014 includes the tax credit on the CCP-07 POC payment. The reduction in R&D tax credit for the first six months of 2014 is primarily due to the R&D tax credit on the US\$5 million upfront payment made to Tris, reclaimed in 2013.

#### Reported loss for the period

The Group reported a loss before exceptional items for the six month period to 30 June 2014 of £4.6 million (H1 2013: profit of £3.6 million). The movements in US dollar and sterling exchange rates between the two reporting periods accounts for £6.1 million of the £8.2 million difference in reported results. Profit after exceptional items for the six month period to 30 June 2013 was £4.2 million.

#### **Balance Sheet**

#### Well positioned for commercial success

Non-current assets at 30 June 2014 were £9.3 million (31 December 2013: £7.7 million). The increase reflects the POC payment to Tris for CCP-07 announced in April 2014, which has been capitalised in the period within intangible assets. This increase has been offset by the amortisation of the frovatriptan intellectual property.

Current assets at 30 June 2014 amounted to £77.4 million (31 December 2013: £83.3 million). Cash resources decreased by £6.6 million to £70.3 million. This cash decrease is offset by an increase to trade and other receivables balances following the announcement of a Servier milestone in June 2014. The R&D tax credit receivable at the end of June 2014 is lower however, following receipt of the R&D tax credit for 2013 from HMRC.

Total liabilities at 30 June 2014 were £8.6 million (31 December 2013: £8.8 million) and importantly we remain debt free.

At 30 June 2014 the Group had net assets of £78.0 million (31 December 2013: £82.2 million).

#### Cash flow

#### Cash management remains a key focus with sufficient cash to fully execute the commercial strategy

Cash resources comprising held-to-maturity financial assets and cash and cash equivalents, at 30 June 2014 totalled £70.3 million (31 December 2013: £76.9 million). A significant proportion of these cash resources are denominated in non-sterling currencies with most of the cash denominated in US dollars.

The decrease in cash resources over the six months to 30 June 2013 was £6.6 million and included a £1.7 million loss on the retranslation of foreign currencies into sterling for financial reporting purposes. The underlying cash burn was £3.8 million (underlying cash burn represents the movement in cash resources during the year excluding one off items and milestone income received) an increase of £1.2 million when compared with the first six months of 2013 (H1 2013: £2.6 million). This is primarily due to a decrease in revenue and a slight increase in operating costs. During the period we paid £1.8 million (\$3 million) to Tris for the CCP-07 POC milestone announced in April 2014, and received £0.3 million having achieved a milestone in the AKP collaboration.

#### Outlook

We continue to progress our US commercial plans in anticipation of further Tris' success, with the pipeline maturing well, behind our first FDA submitted product Tuzistra XR. With our first product launch potentially in the next 12 months, the company is rapidly transitioning into a specialty pharma company. Cash resources of £70.3 million, no debt and tight financial control provide a very strong platform for delivering on our cough cold strategy without the need to seek further funding. We look forward to the future with confidence.

# **Principal Risks**

Vernalis considers strategic, operational and financial risks and identifies actions to mitigate risks. The principal risks and uncertainties for the remaining six months of the financial year are discussed below. Further details of the Group's risk profile can be found in the Annual Report for the year ended 31 December 2013, available on the website <a href="www.vernalis.com">www.vernalis.com</a>. There are no changes to these principal risks. No further risks are anticipated for the remaining six months of the year.

Vernalis is a revenue generating development stage pharmaceutical company with one marketed product and a portfolio of development and research programmes. Across the pharmaceutical industry as a whole, competition is intense in the selling of approved products and more product candidates fail in clinical studies than produce successful marketed products. Success or failure with Vernalis' approved products and product candidates will have a significant impact on the Company's prospects including the ability to secure licensing agreements on existing products and to secure further finance in the future should this be required.

#### Related Parties

Related party disclosures are given in note 11.

## Going concern

At 30 June 2014, the Group had cash resources (being cash and cash equivalents and held-to-maturity financial assets) of £70.3 million.

After making enquiries and taking into account management's estimate of future revenues and expenditure, the directors have a reasonable expectation that the Group will have adequate financial resources to continue in operation for the foreseeable future.

## Independent review report to Vernalis plc

#### Introduction

We have been engaged by the company to review the condensed consolidated financial statements in the half-yearly financial report for the six months ended 30 June 2014, which comprises the unaudited consolidated income statement, unaudited consolidated balance sheet, unaudited consolidated statement of comprehensive income, unaudited consolidated statement of changes in equity, unaudited consolidated statement of cash flows and related notes. We have read the other information contained in the half-yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the condensed set of financial statements.

## Directors' responsibilities

The half-yearly financial report is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the half-yearly financial report in accordance with the AIM Rules for Companies which require that the financial information must be presented and prepared in a form consistent with that which will be adopted in the company's annual financial statements.

As disclosed in note 1, the annual financial statements of the group are prepared in accordance with IFRSs as adopted by the European Union. The condensed set of financial statements included in this half-yearly financial report has been prepared in accordance with International Accounting Standard 34, "Interim Financial Reporting", as adopted by the European Union.

## Our responsibility

Our responsibility is to express to the company a conclusion on the condensed set of financial statements in the half-yearly financial report based on our review. This report, including the conclusion, has been prepared for and only for the company for the purpose of the AIM Rules for Companies and for no other purpose. We do not, in producing this report, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

#### Scope of review

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, 'Review of Interim Financial Information Performed by the Independent Auditor of the Entity' issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK and Ireland) and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the condensed set of financial statements in the half-yearly financial report for the six months ended 30 June 2014 is not prepared, in all material respects, in accordance with International Accounting Standard 34 as adopted by the European Union and the AIM Rules for Companies.

PricewaterhouseCoopers LLP Chartered Accountants 4 August 2014 Reading

# **Unaudited consolidated income statement**

for the six months ended 30 June 2014

			Six mont	hs ended 30 June	2013
		Six months	Pre-	Exceptional	
		ended	exceptional	items	
	Note	30 June 2014	items	(note 3)	Total
		£000	£000	£000	£000
Revenue	2	6,170	7,561	-	7,561
Other income		190	-	-	-
Cost of sales		(722)	(1,056)	-	(1,056)
Research and development expenditure		(6,876)	(6,487)	-	(6,487)
General and administrative expenditure		(2,616)	(2,573)	505	(2,068)
Operating (loss)/profit		(3,854)	(2,555)	505	(2,050)
Finance income	4	117	4,671	-	4,671
Finance expense	4	(1,793)	(50)	-	(50)
(Loss)/profit before income tax		(5,530)	2,066	505	2,571
Income tax credit	5	912	1,579	-	1,579
(Loss)/profit for the period		(4,618)	3,645	505	4,150
(Loss)/profit per share - basic	6	(1.0)p	0.8p	0.1p	0.9p
(Loss)/profit per share - diluted	6	(1.0)p	0.8p	0.1p	0.9p

The notes form part of this condensed financial information.

# Unaudited consolidated statement of comprehensive income

for the six months ended 30 June 2014

		hs ended 30 June 2	ne 2013	
	Six months	Pre-	Exceptional	
	ended	exceptional	items	
	30 June 2014	items	(note3)	Total
	£000	£000	£000	£000
(Loss)/profit for the period	(4,618)	3,645	505	4,150
Other comprehensive income:				
Items that may subsequently be reclassified to the				
income statement:				
Exchange loss on translation of overseas subsidiaries	1	-	-	
Total comprehensive (expense)/income for the period	(4,617)	3,645	505	4,150

The notes form part of this condensed financial information.

# **Unaudited consolidated balance sheet**

as at 30 June 2014

			1 December
		2014	2013
	Note	£000	£000
Assets			
Property, plant and equipment	7	1,684	1,438
Intangible assets	8	7,609	6,292
Non-current assets		9,293	7,730
Inventories		196	130
Trade and other receivables		5,888	4,443
Tax receivable		858	1,785
Derivative financial instruments		124	22
Held-to-maturity financial assets		44,902	48,597
Cash and cash equivalents		25,434	28,321
Current assets		77,402	83,298
Total assets		86,695	91,028
Liabilities and shareholders' equity	y		
Liabilities	-		
Trade and other liabilities		215	156
Provisions		4,105	4,127
Non-current liabilities		4,320	4,283
Trade and other liabilities		2,634	3,384
Deferred income		1,544	962
Provisions		149	155
Current liabilities		4,327	4,501
Total liabilities		8,647	8,784
Equity attributable to owners of			
the parent			
Share capital	9	4,423	4,421
Share premium		476,455	476,392
Other reserves	10	252,773	252,416
Retained deficit		(655,603)	(650,985)
Total equity		78,048	82,244
Total liabilities and equity		86,695	91,028

The notes form part of this condensed financial information.

# **Unaudited consolidated statement of changes in equity** for the six months ended 30 June 2014

	Share	Share	Other	Retained	
	capital	premium	reserves	deficit	Total
	£000	£000	£000	£000	£000
Balance at 1 January 2013	4,421	476,389	251,629	(646,984)	85,455
Profit for the period	_	-	-	4,150	4,150
Total comprehensive income for the period	-	-	-	4,150	4,150
Transactions with owners:					
Share-based payments charge	-	_	392	-	392
	-	-	392	-	392
Balance at 30 June 2013	4,421	476,389	252,021	(642,834)	89,997
Balance at 1 January 2014	4,421	476,392	252,416	(650,985)	82,244
Loss for the period			_	(4,618)	
Other comprehensive income for the period	_		1	( )/	(4.618)
	-	_	1	-	(4,618) 1
Total comprehensive income/(expense) for the period	<del></del>	<u> </u>	1	(4,618)	` ' '
		-			<u> </u>
Total comprehensive income/(expense) for the period	2	63			<u> </u>
Total comprehensive income/(expense) for the period Transactions with owners:	2	63	1		<u> </u>
Total comprehensive income/(expense) for the period Transactions with owners: Exercise of share options	2 - 2	63	(63)		(4,617) 2

# Unaudited consolidated statement of cash flows

for the six months ended 30 June 2014

	30 June 2014 £000	30 June 2013 £000
Cash flows from operating activities		
(Loss)/profit for the period	(4,618)	4,150
Taxation	(912)	(1,579)
Depreciation	241	203
Amortisation of intangible fixed assets	562	674
Movement in provisions	(81)	(584)
Movement in deferred income	582	(17)
Share-based payments charge	419	392
Movement in derivative financial instruments	(102)	222
Finance income	(117)	(4,671)
Finance expense	1,793	50
Exchange loss/(gain)	68	(217)
	(2,165)	(1,377)
Changes in working capital		
Inventories	(66)	111
Receivables	(1,565)	1,694
Liabilities	(1,037)	(761)
Cash used in operations	(4,833)	(333)
Taxation received	1,887	1,929
Taxation paid	(48)	-
Net cash (used in)/generated from operating activities	(2,994)	1,596
Cash flows from investing activities		
Purchase of property, plant and equipment	(130)	(88)
Purchase of intangible fixed assets	(1,857)	(1,976)
Interest received on cash and cash equivalents	37	33
Interest received on held-to-maturity financial assets	100	115
Net cash used in investing activities	(1,850)	(1,916)
Cash flows from financing activities		
Movement in held-to-maturity financial assets	2,645	10,362
Issue of shares	2	-
Net cash generated from financing activities	2,647	10,362
Foreign exchange (loss)/gain on cash and cash equivalents	(690)	1,747
Movements in cash and cash equivalents in the period	(2,887)	11,789
Cash and cash equivalents at the beginning of the period	28,321	27,045
Cash and cash equivalents at the end of the period	25,434	38,834

Held-to-maturity financial assets at the end of the period	44,902	46,824
Total cash, cash equivalents and held-to-maturity financial assets		
at the end of the period	70,336	85,658

#### 1 Accounting policies and basis of preparation

Vernalis plc ('the Company') and its subsidiaries (together 'the Group') are a revenue generating research and development stage pharmaceutical business with significant experience in drug development and discovery.

The Company is a public limited company incorporated and domiciled in the UK. The address of its registered office is 100 Berkshire Place, Wharfedale Road, Winnersh, Berkshire, RG41 5RD and its primary listing is on the Alternative Investments Market (AIM).

This condensed consolidated financial information has been reviewed but not audited and was approved for issue on 4 August 2014.

This condensed consolidated interim financial information does not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006. Statutory accounts for the year ended 31 December 2013 were approved by the Board of directors on 31 March 2014 and delivered to the Registrar of Companies. The report of the auditors on those accounts was unqualified, did not contain an emphasis of matter paragraph and did not contain any statement under section 498 of the Companies Act 2006. This condensed consolidated financial information for the six months ended 30 June 2014 has been prepared in accordance with the Disclosure and Transparency Rules of the Financial Services Authority and with IAS 34, 'Interim financial reporting' as adopted by the European Union as if the company were listed on a market regulated under EU law. The condensed consolidated financial information should be read in conjunction with the annual financial statements for the year ended 31 December 2013, which have been prepared in accordance with IFRSs as adopted by the European Union.

Exceptional items are disclosed and described separately in the financial statements where it is necessary to do so to provide further understanding of the financial performance of the Group. They are material items of income or expense that have been shown separately due to the significance of their nature or amount.

The preparation of interim financial statements requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results may differ from these estimates. Accruals made in respect of incentive schemes are accrued throughout the year using management's best estimate of the expected outcome as at the date of the interim report.

In preparing these condensed interim financial statements, the significant judgements made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the consolidated financial statements for the year ended 31 December 2013.

Taxes on income in the interim periods are accrued using the tax rate that would be applicable to expected total annual earnings.

The accounting policies applied are consistent with those of the annual financial statements for the year ended 31 December 2013, as described in those annual financial statements.

There are no new IFRSs or IFRICs that are effective for the first time for this interim period that would be expected to have a material impact on this Group.

#### 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.

# 3 Exceptional items

Six months	Six months
ended	ended 30 June
30 June 2014	2013
€000	£000
Credit - release of provision for vacant leases	505

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, impairments of goodwill and intangible assets, restructuring costs and the provision for vacant leases.

# 4 Finance income/expense

•	Six months	Six months
	ended 30 June	ended 30 June
	2014	2013
	£000	£000
Finance income		
Interest on cash, cash equivalents and held-to-maturity assets	117	248
Exchange gains on cash, cash equivalents and held-to-maturity assets	-	4,423
	117	4,671
Finance expense		
Exchange loss on cash, cash equivalents and held-to-maturity assets	1,740	-
Unwinding of discount on provision	53	50
	1,793	50

#### 5 Income tax credit

Analysis of current tax credit in the 6 months to 30 June:

	Six months	Six months
	ended 30 June	ended 30 June
	2014	2013
	£000	£000
Research and development tax credits	858	1,050
Corporation tax on Research and Development Expenditure Credit	(41)	-
Overseas corporation tax	(4)	-
Adjustments in respect of prior year	99	529
	912	1,579

# 6 (Loss)/profit 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 share in issue is adjusted to assume conversion for all dilutive potential ordinary shares unless their effect is antidilutive.

	Six months	Six months
	ended 30	ended 30
	June 2014	June 2013
Attributable (loss)/profit before exceptional items (£000)	(4,618)	3,645
Exceptional items (£000)	-	505
Attributable (loss)/profit (£000)	(4,618)	4,150
Weighted average number of shares (basic) in issue (000)	442,182	442,113
(Loss)/profit per ordinary share before exceptional items	(1.0)p	0.8p
Exceptional items	-	0.1p
(Loss)/profit per share (basic)	(1.0)p	0.9p
	<b>~</b>	a
	Six months	Six months
	ended 30	ended 30
	June 2014	June 2013
Weighted average number of shares (basic) in issue (000)	442,182	442,113
Adjustment for dilutive potential ordinary shares:		
Vernalis plc shares under employee share plans (000)	-	20,234
Weighted average number of shares (diluted) (000)	442,182	462,347
(Loss)/profit per ordinary share before exceptional items	(1.0)p	0.8p
Exceptional items		
	-	0.1p

# 7 Property, plant and equipment

Additions of £0.5m were made during the six months ended 30 June 2014 (£0.1m in the six months ended 30 June 2013).

Assets with a cost of £0.4m (six months ended 30 June 2014 £0.1m) and net book value of £nil (six months ended 30 June 2014 £nil) were disposed of during the six months ended 30 June 2014. There were capital commitments of £8,000 at 30 June 2014 (at 30 June 2013:£513,000).

## 8 Intangible assets

		Assets	Assets not	
	Goodwill	in use	yet in use	Total
	£000	£000	£000	£000
Cost				
At 1 January 2014	8,954	37,408	5,730	52,092
Additions	-	-	1,879	1,879
At 30 June 2014	8,954	37,408	7,609	53,971
Accumulated amortisation and impairment				
At 1 January 2014	(8,954)	(36,846)	-	(45,800)
Amortisation charge in the period	-	(562)	-	(562)
At 30 June 2014	(8,954)	(37,408)	-	(46,362)
Net book value at 30 June 2014	-	-	7,609	7,609
Cost				
At 1 January 2013	8,954	37,408	3,754	50,116
Additions	-	-	1,976	1,976
At 30 June 2013	8,954	37,408	5,730	52,092
Accumulated amortisation and impairment				
At 1 January 2013	(8,954)	(35,497)	-	(44,451)
Amortisation charge in the period	-	(674)	-	(674)
At 30 June 2013	(8,954)	(36,171)	-	(45,125)
Net book value at 30 June 2013		1,237	5,730	6,967

Additions of £1.9m were made during the six months ended 30 June 2014. £1.8m of these additions relate to a \$3.0m milestone paid to Tris Pharma, in recognition of the achievement of POC for the second collaboration programme, CCP-07. The remaining £0.1m relates to the capitalisation of software under construction. Additions of £2.0m were made during the six months ended 30 June 2013 and relate to a \$3.0m milestone paid to Tris Pharma, in recognition of the achievement of POC for the first collaboration programme, CCP-01.

# 9 Share capital

	issued '000	authorised '000	Price	Issued £000	Authorised £000
Ordinary					
1 January 2014	442,126	Unlimited	£0.01	4,421	Unlimited
Issue of shares	139		£0.01	2	
30 June 2014	442,265	Unlimited	£0.01	4,423	Unlimited

Ordinary					
1 January 2013 and 30 June 2013	442,113	Unlimited	£0.01	4,421	Unlimited

Issue of shares - 2014

During the six months ended 30 June 2014, 139,531 shares were issued following the exercise of options under the Long Term Incentive Plan.

# 10 Other reserves

						Capital	
	Merger	Other	Options	Warrant		redemption	
	reserve	reserve	reserve	reserve	reserve	reserve	Total
	£000	£000	£000	£000	£000	£000	£000
At 1 January 2013 Share-based payments	101,985	78,125	9,144	1,155	3,554	57,666	251,629
charge	-	-	392	-	-	-	392
At 30 June 2013	101,985	78,125	9,536	1,155	3,554	57,666	252,021
	Merger reserve £000	Other reserve £000	Options reserve £000	Warrant reserve £000	Translation reserve £000	Capital edemption 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	_	_	419	_	_	_	419
Exercise of share option Exchange gain on	-	-	(63)	-	-	-	(63)
translation of overseas subsidiaries					1		1
At 30 June 2014	101,985	78,125	10,285	1,155	3,557	57,666	252,773

# 11 Related party transactions

Key management compensation amounted to £1,060,000 for six months ended 30 June 2014 (six months ended 30 June 2013:£1,003,000). Key management includes only executive and non-

executive directors.

# 12 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.

# 13 Post balance sheet events

On 22 July 2014, the Group announced the achievement of POC for CCP-08, triggering a milestone payment to Tris.

## Statement of directors' responsibilities

The directors have voluntarily complied with the requirements of the Disclosure and Transparency Rules 4.2.7 and 4.2.8 as if the company were listed on a regulated market under EU law.

The directors confirm, to the best of their knowledge, that these condensed interim consolidated financial statements have been prepared in accordance with IAS 34 as adopted by the European Union and that the interim management report herein includes a fair review of the information required by DTR 4.2.7 and DTR 4.2.8, namely:

- An indication of important events that have occurred during the first six months of the financial year and their impact on the condensed set of financial statements, and a description of the principal risks and uncertainties for the remaining six months of the financial year; and
- Material related party transactions in the first six months of the financial year and any material changes in the related party transactions described in the last annual report.

The directors of Vernalis plc are listed in the Vernalis plc annual report for 31 December 2013. A list of current directors is maintained on the Vernalis plc website: www.vernalis.com.

The directors are responsible for the maintenance and the integrity of the Group's website. Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

By order of the Board

David Mackney Chief Financial Officer 4 August 2014