

# Verona Pharma plc

("Verona Pharma" or the "Company")

#### 2013 Interim Results

### Significant clinical progress

**London, UK, 30 September 2013 –** Verona Pharma plc (AIM:VRP), the drug development company focused on "first-in-class" medicines to treat respiratory diseases, today announces its interim results for the six months ended 30 June 2013.

### **Operational Highlights**

- Lead molecule, RPL554 a "first-in-class", inhaled, dual PDE3/4 inhibitor, demonstrates anti-inflammatory effects in man
  - o Consistent with profile as a unique drug for the treatment of COPD & asthma
- VRP700 administered to first patient in Phase 2 clinical trial to further evaluate efficacy
  - Continue to expect data in 1H 2014
- Peer-reviewed paper highlights potential for synergy by combining RPL554 with muscarinic receptor antagonists as drugs for the treatment of COPD
- Clinical data presented on the potent bronchodilator effects of RPL554 at the high profile American Thoracic Society (ATS) International conference in Philadelphia, USA
- Formation of a Clinical and Scientific Advisory Board (CSAB) to help guide the clinical development of RPL554
  - Nebulised bronchodilator for treatment of patients with severe COPD in the hospital and home healthcare setting remains initial focus

#### **Financial Highlights**

- Loss after tax of £1.02 million (2012: £1.06 million) or 0.31 pence (2012: 0.35 pence) per ordinary share
- Net cash outflows from operating activities £1.29m (2012: £1.18m)
  - Cash and cash equivalents as at 30 June 2013 of £0.93 million (2012: £2.36 million)
- Completed a £1.1m share placing and entered into a £5m equity financing facility with Darwin Strategic

#### **Post Period Highlights**

- Appointed Richard Bungay as Chief Financial Officer at the beginning of September
- RPL554 anti-inflammatory data presented at the European Respiratory Society meeting
- The Company is in discussions with potential strategic investors to cornerstone an equity issue to further progress the RPL554 and VRP700 programmes

Dr. Jan-Anders Karlsson, CEO of Verona Pharma, commented: "Last year we changed Verona Pharma's strategy to focus on opportunities of significant unmet medical need. As a result, we tailored development of our "first-in-class" lead drug, RPL554, a PDE3 and 4 inhibitor, to treat patients with severe COPD, and



VRP700 to treat chronic, severe cough. We are pleased to report important progress in the clinic on both programmes during the period.

"Data from the RPL554 anti-inflammatory clinical study suggested that it has a broader-based anti-inflammatory effect than we had expected. We have begun to present our clinical results with RPL554 in peer-reviewed publications and also at scientific conferences where the data has been met with great interest. We have also begun a further Phase 2 clinical study of VRP700 in patients presenting with chronic severe cough as the result of underlying idiopathic pulmonary fibrosis. We look forward to reporting results from this study in 1H 2014 where data will hopefully confirm the potent cough suppressing effect seen in the earlier pilot study."

"We believe that the data on our key asset, RPL554, positions the compound as a unique, "first-in-class" drug with both bronchodilator and anti-inflammatory properties and support its further development as a differentiated treatment that will provide both meaningful benefit to patients with COPD and significant shareholder value in the near to medium term."

-Ends-

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#### **Notes to Editors**

#### **About Verona Pharma plc**

Verona Pharma is developing "first-in-class" drugs to treat respiratory disease, such as COPD, asthma and chronic, severe cough. The Company has three drug programmes, two of which are in Phase 2. The lead programme, RPL554, is an innovative dual phosphodiesterase (PDE) 3 and 4 inhibitor with both bronchodilator and anti-inflammatory properties. VRP700 is an innovative product for suppressing chronic, severe cough in patients with underlying lung disease. In its third programme, Verona Pharma is investigating novel anti-inflammatory molecules, called NAIPs, for a wide range of respiratory and inflammatory diseases.

#### About RPL554 for the treatment of COPD and Asthma

Verona's lead drug, RPL554, is a dual phosphodiesterase (PDE) 3 and 4 inhibitor being developed as a novel treatment for chronic obstructive airways disease such as COPD and asthma with bronchodilator and anti-inflammatory effects. Both effects are essential to improve symptoms in patients with COPD or asthma. RPL554 is currently in phase 2 for both diseases.

COPD is a chronic lung disease with significant unmet need for which current treatment is far from optimal, as it often has unwanted side-effects and/or limited effectiveness. COPD is most commonly characterised by fixed airflow obstruction and chronic airways inflammation resulting from exposure to irritants like tobacco smoke. Asthma, which remains one of the most common chronic diseases in the world, is characterised by recurrent breathing problems and symptoms such as breathlessness, wheezing, chest tightness, and



coughing. The market for COPD and asthma drugs is currently estimated to be GBP20 billion [source: visiongain].

## About VRP700 for the treatment of Cough

VRP700 is Verona Pharma's lead drug compound for the treatment of cough, having a novel mechanism of action involving the suppression of cough initiating signals originating from cough sensory nerve endings located in the lungs. A clinical trial completed at the University of Florence, Italy in September 2011 demonstrated significant anti-tussive effects with nebulised VRP700 in hospitalized patients with chronic severe cough.

Cough can be a very debilitating comorbidity reported by patients, especially those with respiratory conditions such as asthma, COPD, lung cancer, interstitial lung disease, fibrosis or lung infections. It is a neglected symptom which is often self-medicated. Consumer spending on OTC medications, including those for cough, grew by 10% over 2005-10, to reach GBP532 million in the UK [source: Mintel]. However, there is very little clinical evidence for such OTC cough medications being really effective and it is widely recognised by the medical community that there is a large need for more effective drugs to control and prevent pathologically induced coughing.



#### Chairman and Chief Executive Officer's Joint Statement

#### Introduction

Verona Pharma is a biopharmaceutical company focused on the development of high value, "first-in-class" drugs for specialist-treated respiratory diseases. The Company has two drug programmes in Phase 2, both of which are initially being developed for use in a hospital setting. The lead programme, RPL554, is an innovative inhaled dual phosphodiesterase (PDE) 3 and 4 inhibitor with both bronchodilator and anti-inflammatory properties, initially focused on patients with COPD. The second programme is VRP700, an innovative inhaled product for suppressing intractable, chronic cough in patients with underlying severe lung disease. Both drugs address specific medical needs in patients that currently are not optimally treated. There is little competition in the form of novel types of bronchodilator or anti-cough drugs for these patient groups and the Board therefore believes that these are very attractive commercial markets for Verona Pharma.

During the first 6 months of 2013, the Company completed an anti-inflammatory study with RPL554 and reported the first headline data. It also commenced a second Phase 2 study with VRP700 in patients with chronic, severe cough and streamlined operations by closing down the Company's office in Vancouver, Canada.

The Company continued to implement the new strategy to accelerate shareholder value creation that was announced at the end of last year. Further steps have been taken to focus the initial development of RPL554 as a nebulised treatment for patients in hospital with severe COPD. Most of these patients are in hospital because of exacerbations of COPD that cannot be prevented by current medications and are in need of more intensive care and treatment. The bronchodilator and anti-inflammatory properties of RPL554 should be beneficial to these patients and the Company is strongly encouraged by the recent data showing the synergistic effect of RPL554 and the anti-muscarinic drugs (an important drug class currently used in the treatment of patients with COPD) on human airway smooth muscle, published in the prestigious peer-reviewed scientific journal, the Journal of Pharmacology and Experimental Therapeutics. The Board believes that the new strategy will accelerate access to multi-billion dollar commercial markets and increase the flexibility in the timing for achieving attractive commercial partnerships.

The Company presented scientific data on the bronchodilator effects of RPL554 in patients with asthma and COPD at the American Thoracic Society's annual conference in Philadelphia in May, and data on the anti-inflammatory effects of the drug at the European Respiratory Society meeting in Barcelona in September, further enhancing the profile of these innovative agents.

#### **RPL554**

RPL554 is a novel inhaled dual phosphodiesterase 3 and 4 inhibitor that was selected for clinical development following pre-clinical studies which demonstrated both potent bronchodilator and anti-inflammatory properties. RPL554 is currently being developed as a potential "first-in-class" treatment for patients with chronic respiratory diseases such as COPD and asthma.

RPL554 has successfully completed a number of early clinical Phase 1 and 2 clinical studies. These single and multiple dose studies suggest that RPL554, when inhaled across a range of doses, is an effective bronchodilator in patients with COPD or asthma and is an excellent candidate for further development as a new class of bronchodilator. Importantly for the positioning of RPL554 as a novel inhaled treatment for patients with COPD, in an experimental clinical trial at the Tor Vergata Clinic at the University of Rome, the magnitude of the bronchodilator response produced by the drug showed a statistically significant difference to placebo and was at least equivalent to that produced by a standard dose of the reference bronchodilator beta<sub>2</sub>-agonist salbutamol in these patients. Importantly, no safety issues were observed.

A randomized, double blind, placebo-controlled clinical trial to examine the potential anti-inflammatory effects of RPL554 was completed at MEU in Manchester and reported in March 2013. The trial was conducted in healthy subjects, treated once daily for 6 consecutive days with either inhaled RPL554 or inhaled placebo before being challenged on the last day by an irritant agent that provokes a COPD-like inflammatory response in their airways.



The primary end point chosen for this exploratory trial was a reduction in the proportion of neutrophils (an inflammatory cell type recognised for its central role in COPD or severe asthma), to total inflammatory cells in the sputum, and secondary endpoints included reductions in total inflammatory cell numbers. While there was a strong trend in favour of the primary endpoint, the study narrowly missed reaching statistical significance as there was a highly significant reduction not only in the absolute numbers of neutrophils but also in the total inflammatory cells in sputum, with no clinically significant adverse events reported. Most important for the further development of RPL554, the absolute numbers of all types of inflammatory cells were statistically significantly reduced in the 6 hour sputum sample after only one week of once-daily treatment: neutrophils (p=0.002), eosinophils (p=0.001), lymphocytes (p=0.001), and macrophages (p=0.04), in addition to the total number of inflammatory cells (p=0.002). These data indicate that RPL554 has anti-inflammatory properties, most likely due to inhibition of PDE4 (or perhaps the combined inhibition of PDE3 and 4), and it is believed that this adds to the direct bronchodilator effect of the drug and contributes to the improvement of symptoms of COPD.

A novel nebulised formulation of RPL554 is under development and it is anticipated that this will become available around the year-end. This will allow the further development of this unique drug with both bronchodilator and anti-inflammatory properties for the treatment of hospitalized patients with severe COPD.

#### **VRP700**

Cough is the most common symptom of many lung diseases. Chronic cough of more than eight weeks duration can be a debilitating symptom when associated with severe lung diseases such as interstitial lung disease, including idiopathic pulmonary fibrosis (IPF), lung cancer, cystic fibrosis, asthma and COPD. Currently available cough remedies are widely considered to be relatively ineffective, often with significant side effects. To the best of the Company's knowledge, there are no novel and effective inhaled therapies for treating the severe, intractable cough associated with these lung diseases in clinical development. The Company is initially evaluating VRP700 as a potential "first-in-class" treatment in patients with chronic cough due to severe lung disease.

A clinical trial of VRP700 at the University of Florence, Italy, showed a very effective reduction in chronic cough in a small group of patients with various forms of severe lung disease. A follow-on study in patients with IPF was commenced at the Respiratory and Allergy Centre at the University of Manchester, UK, during the reporting period. In this randomised, double-blind, placebo-controlled clinical study with inhaled VRP700, IPF patients are treated with a single dose of either VRP700 or placebo and the effect on cough and other symptoms are recorded. The study is expected to be completed in the first half of 2014.

#### **NAIPS**

The Company retains its interest in the NAIPs program, including recent patent filings as a basis for securing ownership and creating value from this research program in the longer term.

#### **Financials**

The loss from operations after tax for the six months period ended 30 June, 2013 (the "Period") was £1.02 million (2012: £1.06 million) or 0.31 pence (2012: 0.35 pence) per ordinary share. The loss includes a non-cash share based payment charge of £0.03 million (2012 £0.04 million) and a research and development tax credit of £0.29 million (2012: £Nil).

Research and development expenditure, which was expensed as incurred, amounted to £0.80 million (2011: £0.59 million). Programme expenditures incurred during the Period for RPL554 amounted to £0.50 million (2012: £0.44 million) and for VRP700 programme amounted to £0.30 million (2012: £0.15 million).

Expenditures in RPL554 increased by £0.06 million, primarily due to the cost associated with planning and preparing for further RPL554 clinical trials. The increase of £0.15 million in expenditure in the VRP700 programme is due to costs associated with the ongoing Phase 2 clinical trial at the Respiratory and Allergy Centre, Manchester.



Administrative expenses for the six months period were £0.51 million (2012: £0.49 million). The increase of £0.02 million over the prior period reflected a small increase in general and administrative expense of £0.03 million, partially offset by a decrease in share based payment of £0.01 million.

On 31 January 2013, the Company announced that it had raised £1.1 million (gross) from a placing of new shares, and entered into a £5.0 million equity financing facility with Darwin Strategic Limited, a company majority-owned by a subsidiary of Henderson Global Investors. The Company is in discussions with potential strategic investors to cornerstone an equity issue to further progress the RPL554 and VRP700 programmes.

As at 30 June 2013, the Company had approximately £0.93 million (2012: £2.36 million) in cash and cash equivalents.

#### The Board and Management

Post period end, at the beginning of September, the Company appointed Richard Bungay as Chief Financial Officer, initially on a part-time basis. Richard has close to 20 years' experience in corporate and senior finance roles within R&D-based companies within the biotechnology and pharmaceutical sector. He was also Director of Corporate Communications and Strategic Planning at Celltech Group plc until its acquisition by UCB in 2004. Richard qualified as a Chartered Accountant with Deloitte. His experience will be invaluable as the key clinical programmes move forward and the Company grows.

#### Outlook

During the reporting period, Verona Pharma has taken further steps to implement the new strategy of creating a biopharmaceutical company focused on developing high value, "first-in-class" drugs for specialist-treated respiratory diseases. The initial focus of the RPL554 programme is to develop a nebulised treatment for hospitalized patients with severe COPD, and to develop VRP700 as a novel inhaled treatment for patients with intractable, chronic cough due to severe lung disease. The Board believes that both drugs address specific patient groups that are currently under-treated, that there is little competition, and therefore very attractive commercial opportunities that will afford the greatest prospect of generating significant shareholder value for Verona Pharma.

The Company will continue to operate with a strong focus and financial discipline, and remains very positive about its progress to date and the opportunities for its two lead drug development programmes.

Professor Clive P. Page Chairman

Dr. Jan-Ander Karlsson Chief Executive Officer



# **Group Statement of Comprehensive Income For the six months ended 30 June 2013**

	Notes	6 months ended 30 June 2013 (unaudited) £	6 months ended 30 June 2012 (unaudited) £	Year ended 31 December 2012 (audited) £
Revenue Cost of sales		<u>-</u>	-	- -
Gross profit/(loss)		-	-	-
Research and development Administration expenses		(800,036) (508,866)	(587,890) (487,667)	(1,674,977) (910,372)
Operating loss		(1,308,902)	(1,075,557)	(2,585,349)
Finance revenue		1,875	12,826	20,177
Loss before taxation		(1,307,027)	(1,062,731)	(2,565,172)
Taxation - credit	2	289,400	-	48,069
Total comprehensive loss for the period		(1,017,627)	(1,062,731)	(2,517,103)
Loss per ordinary share – basic and diluted	3	(0.31)p	(0.35)p	(0.82)p



# Group Statement of Financial Position As at 30 June 2013

	As at 30 June 2013	As at 30 June 2012	As at 31 December 2012
	(unaudited)	(unaudited)	(audited)
	£	£	£
ASSETS			
Non current assets			
Plant and equipment	33,519	11,870	39,484
Intangible assets – patents	160,321	106,251	125,280
Goodwill	1,469,112	1,469,112	1,469,112
	1,662,952	1,587,233	1,633,876
Current assets			
Trade and other receivables	208,070	191,111	208,051
Cash and cash equivalents	930,753	2,355,789	960,870
	1,138,823	2,546,900	1,168,921
Total assets	2,801,775	4,134,133	2,802,797
EQUITY AND LIABILITIES			
Capital and reserves attributable to equity holders			
Share capital	336,175	307,203	307,203
Share premium	13,434,648	12,447,364	12,447,364
Share-based payment reserve	494,520	554,158	470,577
Retained losses	(11,638,056)	(9,274,557)	(10,621,672)
Total equity	2,627,287	4,034,168	2,603,472
Current liabilities			
Trade and other payables	174,488	99,965	199,325
Total liabilities	174,488	99,965	199,325
Total equity and liabilities	2,801,775	4,134,133	2,802,797



# Group Statement of Cash Flows For the six months ended 30 June 2013

	6 months ended 30 June 2013	6 months ended 30 June 2012	Year ended 31 December 2012
	£	£	£
Net cash outflow from operating activities	(1,291,199)	(1,183,937)	(2,573,609)
Cash inflow from taxation	289,400	-	48,069
Cash flow from investing activities			
Interest received	1,827	3,586	20,194
Purchase of plant and equipment	(1,197)	(9,623)	(46,594)
Payment for patents	(45,204)	-	(27,953)
Net cash outflow from investing activities	(44,574)	(6,037)	(54,353)
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Cash flow from financing activities			
Financing costs	-	17,074	12,074
Net proceeds from issue of shares	1,016,256	1,002,494	1,002,494
Net cash inflow from financing activities	1,016,256	1,019,568	1,014,568
Net decrease in cash and cash			
equivalents	(30,117)	(170,406)	(1,565,325)
Cash and cash equivalents at the beginning of the period	960,870	2,526,195	2,526,195
Cash and cash equivalents at the end of the period	930,753	2,355,789	960,870
Reconciliation of operating loss to net cash outflow from operating activities			
Operating loss	(1,308,902)	(1,075,557)	(2,585,349)
Cost of issuing share options	25,186	43,659	67,335
Decrease/(increase) in trade and other	_0,.00	. 5, 555	5.,553
receivables	29	(108,087)	(129,284)
(Decrease)/increase in trade and other			
payables	(24,837)	(56,044)	43,316
Depreciation of tangible assets	7,162	3,774	13,131
Amortisation of intangible assets	10,163	8,318	17,242
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Net cash outflow from operating activities	(1,291,199)	(1,183,937)	(2,573,609)



# **Group Statement of Changes in Equity For the six months ended 30 June 2013**

	Share capital £	Share premium £	Option reserve £	Retained losses	Total £
Balance at 1 January 2013	307,203	12,447,364	470,577	(10,621,672)	2,603,472
Total comprehensive loss for the period	-	-	_	(1,017,627)	(1,017,627)
-	307,203	12,447,364	470,577	(11,639,299)	1,585,845
Issue of shares	28,972	1,129,889	-	-	1,158,861
Issue costs	-	(142,605)	-	-	(142,605)
Share based payment Transfer of previously expensed share based payment	-	-	25,186	-	25,186
charge upon lapse of options	-	-	(1,243)	1,243	
Balance at 30 June 2013 (unaudited)	336,175	13,434,648	494,520	(11,638,056)	2,627,287
Balance at 1 January 2012	285,844	11,466,229	510,499	(8,211,826)	4,050,746
Total comprehensive loss for the period	-	-	-	(1,062,731)	(1,062,731)
	285,844	11,466,229	510,499	(9,274,557)	2,988,015
Issue of shares	21,359	1,046,607	-	_	1,067,966
Issue costs	-	(65,472)	-	-	(65,472)
Share based payment	-	-	43,659	-	43,659
Balance at 30 June 2012 (unaudited)	307,203	12,447,364	554,158	(9,274,557)	4,034,168
	005.044	44 400 000	540,400	(0.044.000)	4.050.740
Balance at 1 January 2012  Total comprehensive loss for the	285,844	11,466,229	510,499	(8,211,826)	4,050,746
year	-	-	-	(2,517,103)	(2,517,103)
	285,844	11,466,229	510,499	(10,728,929)	1,533,643
Issue of shares	21,359	1,046,607	-	-	1,067,966
Issue costs	-	(65,472)	-	-	(65,472)
Share based payment Transfer of previously	-	-	67,335	-	67,335
expensed share based payment charge upon lapse of options	-	-	(107,257)	107,257	<del>-</del>
Balance at 31 December 2012 (audited)	307,203	12,447,364	470,577	(10,621,672)	2,603,472



## Notes to the financial information For the six months ended 30 June 2013

#### 1. Publication of non-statutory accounts

i) This interim financial information for the six months ended 30 June 2013 is unaudited and does not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006. It was approved by the board of directors on 27 September 2013. The figures for the year ended 31 December 2012 have been extracted from the statutory accounts which have been reported on by the Company's auditor. The financial statements for the year ended 31 December 2012 have been delivered to the Registrar of Companies and the auditor's report on those financial statements was unqualified and did not contain a statement made under section 498 (2) or section 498 (3) of the Companies Act 2006.

#### ii) Accounting policies

The interim financial information for the six months ended 30 June 2013 includes the results of Verona Pharma plc and its wholly-owned subsidiary Rhinopharma Limited. The unaudited results for the period have been prepared on the basis of accounting policies adopted in the audited accounts for the year ended 31 December 2012.

- iii) The directors do not recommend the payment of a dividend (period to 30 June 2012 £Nil; year ended 31 December 2012 £Nil).
- iv) A copy of the interim report is available on the Company's website www.veronapharma.com.

## 2. Taxation

The £289,400 research and development tax credit recognised in 2013 was received during the six months period ended 30 June 2013. The tax credit is a cash refundable tax credit of 11% on the enhanced qualifying research and development expenditures made by the Company in fiscal year 2012. The tax credit of £48,069 recognised in fiscal year 2012 is a cash refundable tax credit for the enhanced qualifying research and development expenditures made by the Company in fiscal year 2011.

#### 3. Loss per share

- i) The basic loss per share of 0.31p (30 June 2012: loss of 0.35p; 31 December 2012: loss of 0.82p) for the Group is calculated by dividing the loss for the period by the weighted average number of ordinary shares in issue of 329,133,121 (30 June 2012: 306,030,806; 31 December 2012: 306,620,807).
- ii) The diluted loss per share has not been presented since the Company's stock options are anti-dilutive.

# 4. Comparatives

The comparatives include audited figures for the year ended 31 December 2012 and unaudited figures for the six months ended 30 June 2012.