

VERONA PHARMA PLC
INTERIM REPORT
FOR THE SIX MONTHS ENDED 30 JUNE 2015

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DIRECTORS, SECRETARY AND ADVISERS

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**JOINT STATEMENT FROM THE CHAIRMAN AND CHIEF EXECUTIVE OFFICER
FOR THE SIX MONTHS ENDED 30 JUNE 2015**

OPERATIONAL HIGHLIGHTS

- Successfully completed dosing of healthy volunteers in Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) studies with our new, commercially scalable, proprietary nebulized formulation of RPL554.
 - The formulation was well tolerated with subjects dosed with up to 16 times the dose of RPL554 previously shown to produce significant bronchodilation without a maximum tolerated dose being reached.
- Commenced a MAD study of RPL554 in June 2015 in up to 30 chronic obstructive pulmonary disease (COPD) patients to further confirm the safety and tolerability seen in earlier parts of the trial, with this new formulation.
 - Data are expected from the combined SAD/MAD study in healthy subjects and COPD patients in early Q4 2015.
- Initiated a phase 2a dose-finding trial in asthma patients with new proprietary formulation of RPL554, to explore a dose-response relationship in this setting.
 - Headline data from this study are anticipated in Q1 2016.

FINANCIAL HIGHLIGHTS

- Loss after tax for the period of £3.69 million (2014: £1.39 million) or 0.37 pence (2014: 0.19 pence) per ordinary share, reflecting increased R&D activities.
- Net cash outflows from operating activities during the six month period of £3.92m (2014: £1.47m), with cash and cash equivalents as at 30 June 2015 of £6.09 million (2014: £12.10 million).

POST PERIOD AND OTHER EVENTS

- Completed dosing with new nebulized formulation in MAD study in COPD patients with data expected in early Q4 2015.
- Appointed Ken Cunningham MD and Anders Ullman MD PhD as Non-Executive Directors to the Board. Both are recognized leaders within the pharmaceutical and biotechnology industry and have particular clinical development expertise in the area of respiratory drug development.
- The Company undertook a secondary listing of its shares on the Xetra Exchange in Frankfurt to increase awareness of the Company and to facilitate trading in its shares in Continental Europe.

**JOINT STATEMENT FROM THE CHAIRMAN AND CHIEF EXECUTIVE OFFICER
FOR THE SIX MONTHS ENDED 30 JUNE 2015**

INTRODUCTION

Verona Pharma is a UK-based clinical stage biopharmaceutical company focused on the development of innovative prescription medicines to treat respiratory diseases with significant unmet medical needs such as chronic obstructive pulmonary disease (COPD), asthma and cystic fibrosis. The Company's lead product, RPL554, is a first-in-class drug currently in phase 2 clinical trials as a nebulised formulation for acute exacerbations of COPD. The drug is an inhaled dual phosphodiesterase PDE3/ PDE4 inhibitor and has already demonstrated clinically relevant bronchodilator and anti-inflammatory effects which are essential to the improvement of symptoms of patients with COPD and asthma.

The Board believes that broadening the development strategy for RPL554 over time, to include combination products and new indications, together with strengthening the IP coverage around the programme, has the potential to add significant value to the Company. The Board further believes that this approach should accelerate access to multi-billion dollar commercial markets, increase Verona Pharma's flexibility in negotiating attractive commercial partnerships and prolong patent protection for the emerging franchise.

Phase 2 clinical programme for RPL554 in new formulation yields encouraging interim results

We are initially developing RPL554 as a treatment for acute exacerbations of COPD. Despite the many recently introduced novel maintenance treatments for COPD, patients frequently experience acute exacerbations and become hospitalised. The older, short-acting nebulized bronchodilators are still used on hospital wards and there is clearly a need for effective treatments in this acute hospital setting. We believe RPL554 can become an attractive add-on therapy to provide extra clinical benefit in patients with acute exacerbations of COPD. There is little innovation in the form of novel classes of bronchodilator drugs for these acutely ill patients, or for the maintenance treatment of COPD patients, and the Board therefore believes that these are very attractive commercial opportunities for Verona Pharma.

An increasing awareness of the problem of COPD patients returning for hospital treatment within 30 days of discharge has triggered a strong interest from industry, regulators and healthcare payers in optimising treatment of acute COPD exacerbations and beyond, when patients are discharged from hospital. This provides a unique opportunity for RPL554 that we intend to explore in further phase 2 clinical studies.

RPL554 successfully completed a number of early clinical phase 1 and phase 2 studies based on the previous nebulized formulation. These single and multiple dose studies demonstrate that RPL554, when inhaled across a range of doses, is an effective bronchodilator in patients with COPD and asthma. RPL554 has a rapid onset of action and the magnitude of the bronchodilator effect seems to be at least as profound as that of other commonly used bronchodilator drugs.¹

RPL554 has also been demonstrated to have a potent anti-inflammatory effect in a clinical trial. This property is unique to RPL554 and is not shown by other bronchodilator drugs of the beta2 agonists or anti-muscarinic classes. RPL554 showed a broad inhibitory effect on inflammatory cells in the airways, including a significant reduction in the number of neutrophils, a cell type thought to be involved in COPD (and cystic fibrosis). This effect sets RPL554 apart from steroids as this class of drugs seem to have little effect on neutrophils and increasingly the use of inhaled steroids in COPD patients is being questioned as they seem to have limited beneficial effects. Therefore, RPL554 as a combined bronchodilator and anti-

¹ Pre-clinical studies in isolated airway muscle have demonstrated that RPL554 is an effective bronchodilator also in highly constricted airways, to some extent mimicking bronchospasm in patients with respiratory disease, where other bronchodilators of the currently used beta2-agonist and anti-muscarinic types are less effective. If a similar effect is seen in patients with highly obstructed airway muscles, RPL554 has the potential to be advantageous compared to other types of bronchodilators.

**JOINT STATEMENT FROM THE CHAIRMAN AND CHIEF EXECUTIVE OFFICER
FOR THE SIX MONTHS ENDED 30 JUNE 2015**

inflammatory agent offers unique benefits to COPD patients, both as a novel type of bronchodilator, and as an anti-inflammatory compound offering additional benefits over and above those of steroids.

In line with the new development strategy announced in 2014, a novel nebulized proprietary formulation of RPL554 was developed which is stable, scalable and suitable for commercial use. The first phase 1/2a study with the new nebulized formulation started at the end of 2014 and the clinical phases of the SAD and MAD (5 days, twice daily dosing) study in healthy subjects and the MAD study in COPD patients have been completed. Initial observations from the SAD part of the study indicated that the new formulation is well tolerated as 16 times the previously used bronchodilator dose (with the old formulation) could be administered without reaching a maximum tolerated dose. Pharmacokinetic analysis revealed lower peak plasma concentrations and a longer plasma half-life than the previously used formulation, suggesting that twice daily dosing could perhaps be achieved. A more comprehensive data-set from these studies is expected in early Q4 2015.

We have also initiated a second, single-dose phase 2a dose-finding study in up to 30 asthma patients. This study with the new formulation is being carried out in asthma patients because typically a dose response relationship to bronchodilators can be more accurately established in this group of patients with highly reversible airways obstruction compared to patients with COPD. A wide range of RPL554 doses will be compared to two different doses of salbutamol, a standard bronchodilator used in both asthma and COPD patients, and placebo. The primary objective is to establish the bronchodilator effect and duration of action and data are expected in Q1 2016.

We are also investigating RPL554 as a combination product with an anti-muscarinic drug, such as glycopyrrolate, a class of drugs that is widely used in treating COPD patients. We have been strongly encouraged by data showing a synergistic effect of RPL554 in combination with anti-muscarinic drugs in isolated human airway smooth muscle. Such a combination product could have significant advantages over the many dual long-acting β 2-agonists/ long acting-muscarinic antagonists (LABA / LAMA) bronchodilator inhalers available to COPD patients and could be used both in acute hospital care and in long-term maintenance treatment.

In addition to treatment of acute exacerbations, RPL554 clearly has potential as a chronic maintenance therapy in patients with COPD. Both the bronchodilator and the anti-inflammatory properties would be beneficial to these out-patients and it is a larger market opportunity. The new nebulized formulation could be developed into an attractive maintenance treatment for moderate to severe COPD patients.

We believe there is also an opportunity to develop RPL554 as a maintenance therapy for mild to moderate COPD patients, a much larger addressable market. These patients are routinely treated with Dry Powder Inhaler (DPI) or pressurized Metered Dose Inhaler (pMDI) and we have previously demonstrated that RPL554 can be formulated for use in both a DPI and a pMDI. The Board takes the view that larger, later-stage clinical studies and commercialisation in this out-patient setting are better undertaken together with a suitable partner.

RPL554 also shows promise in cystic fibrosis

Additional pre-clinical data demonstrates that RPL554 is an activator of the cystic fibrosis transmembrane conductance regulator (CFTR) that is dysfunctional in cells of cystic fibrosis patients. This adds a further dimension to the potential utility of the drug. Asthma patients may also benefit from this action of RPL554, as it may improve mucociliary clearance in addition to its bronchodilator and anti-inflammatory properties. Further studies exploring the potential of RPL554 in cystic fibrosis are planned for 2016.

**JOINT STATEMENT FROM THE CHAIRMAN AND CHIEF EXECUTIVE OFFICER
FOR THE SIX MONTHS ENDED 30 JUNE 2015**

FINANCIALS

The loss from operations after tax for the six month period ended 30 June 2015 (the “Period”) was £3.69 million (2014: £1.39 million) or 0.37 pence (2014: 0.19 pence) per ordinary share. The reported loss includes a non-cash share-based payment charge of £0.26 million (2014: £0.06 million) and receipt of a research and development tax credit of £0.74 million (2014: £Nil).

Research and development expenditure, which was expensed as incurred, amounted to £3.48 million (2014: £0.87 million). Development programme expenditures expensed during the period amounted to £3.37 million for RPL554 (2014: £0.57 million), and £0.11 million (2014: £0.30 million) for VRP700.

Expenditures in RPL554 increased by £2.80m as a result of accelerating the clinical trials for the SAD/MAD and asthma studies and advancing preparations for a commercially scaleable formulation of the compound.

Administrative expenses for the six month period were £0.98 million (2014: £0.53 million). The increase of £0.45 million over the prior period was due to an increase in the share-based payments and other administrative items including the strengthened board and senior management team.

As at 30 June 2015, the Group had approximately £6.09 million (2014: £12.10 million) in cash and cash equivalents.

FURTHER DEVELOPMENT & COMMERCIALISATION STRATEGY

The fundraising in March 2014 enabled us to advance the new commercial formulation of RPL554 through clinical studies up to the start of phase 2b, which is expected in H2 2016. Additional pre-clinical and manufacturing work will be performed to satisfy certain regulatory guidelines. In parallel, we are continuing to strengthen the IP coverage to provide comprehensive patent protection for RPL554 in its various forms with the intent to expand the use of RPL554 in new indications and in combination products.

Our initial focus to develop the nebulized formulation of RPL554 for hospital use is motivated in part by the increasing concern and intent to tackle the high rates of 30-day hospital re-admissions for COPD. This has recently gained impetus following the implementation by the U.S. Government in Q4 2014 of a new policy which penalizes hospitals with high 30-day re-admission rates for select conditions, including COPD. Interestingly, such a policy has already been introduced by the NHS in the UK. In our clinical studies in hospitalised patients, we will explore the possibility that treatment with RPL554 will reduce such re-admission rates and so demonstrate a clear health-economic benefit of treatment with the drug.

The Board believes that products combining RPL554 with other classes of bronchodilators are potentially highly attractive for the respiratory market and expand the RPL554 product franchise. Indeed, while there has been significant interest in the novel dual bronchodilator products containing a LABA and a LAMA recently introduced as chronic treatments for COPD, a combination between RPL554 and, for example, the LAMA glycopyrrolate, would contain two different bronchodilator components, with the added benefit that RPL554 would also provide an anti-inflammatory component to create in essence a triple-combination product.

We further plan to expand the use of RPL554 beyond COPD, and explore the possible use of nebulized RPL554 to treat acute asthma attacks in the A&E unit. When used as an addition to standard treatment, it is expected that RPL554 would rapidly improve lung function, reduce symptoms and reduce the number of hospital admissions from the A&E unit. Again, this treatment would generate a clear health-economics benefit. In addition, pre-clinical work demonstrating a potentiating activity on CFTR, suggests that cystic fibrosis could be a potential novel indication. We will further explore this opportunity in pre-clinical and exploratory clinical trials.

**JOINT STATEMENT FROM THE CHAIRMAN AND CHIEF EXECUTIVE OFFICER
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The Company recognises that an experienced and resourceful commercial partner could bring significant value to the development of RPL554 for chronic maintenance treatment in COPD and perhaps asthma and therefore continues to be involved in business development discussions around the RPL554 programme. However, the Company intends to partner its drug candidates only when it can extract a commercially attractive return for the Company and its shareholders.

BOARD CHANGES

Post period, we were pleased to announce the appointment of Ken Cunningham, MD and Anders Ullman, MD, PhD, as Non-Executive Directors to the Board. Both are highly respected industry leaders with invaluable expertise in the field of respiratory drug development. We very much look forward to working with them as we continue our focused clinical development of lead pipeline asset RPL554.

Ms Claire Poll, Executive Director, Mr Stuart Bottomley and Professor Trevor Jones, both Non-Executive Directors, will be retiring from the Verona Board after having served since 2006. Ms Poll will continue to work with the Company as a consultant. We would like to thank Claire, Stuart and Trevor for all their hard work and support over the years. Their long tenure on our Board is testament to the value of their advice and their numerous contributions on many fronts. They have all been instrumental in nurturing a fledgling biotech company on AIM as it progressed its pipeline into the clinic. We warmly wish them the very best for the future.

OUTLOOK

We continue to develop the Company by searching for suitable products to enhance our pipeline, and by expanding the expertise of our management team and Board of Directors, especially in developing and commercialising respiratory products. The Company operates with a strong focus and financial discipline, and we remain very positive about progress to date in our lead drug development programme, RPL554, and the opportunities for its further development and commercialisation.

Dr. David Ebsworth
Chairman

7 September 2015

Dr. Jan-Anders Karlsson
Chief Executive Officer

7 September 2015

**GROUP STATEMENT OF COMPREHENSIVE INCOME
FOR THE SIX MONTHS ENDED 30 JUNE 2015**

	Notes	6 months ended 30 June 2015 (unaudited) £	6 months ended 30 June 2014 (unaudited) £	Year ended 31 December 2014 (audited) £
Continuing operations				
Revenue		-	-	-
Cost of sales		-	-	-
Gross profit		-	-	-
Research and development		(3,477,322)	(865,646)	(2,634,848)
Administration expenses		(982,199)	(525,620)	(1,157,925)
Operating loss		(4,459,521)	(1,391,266)	(3,792,773)
Finance revenue		27,169	3,220	29,978
Loss before taxation		(4,432,352)	(1,388,046)	(3,762,795)
Taxation – credit	2	743,762	-	1,004,065
Total comprehensive loss for the period		(3,688,590)	(1,388,046)	(2,758,730)
Loss per ordinary share – basic and diluted (pence)	3	(0.37)p	(0.19)p	(0.32)p

**GROUP STATEMENT OF FINANCIAL POSITION
AS AT 30 JUNE 2015**

	As at 30 June 2015 (unaudited) £	As at 30 June 2014 (unaudited) £	As at 31 December 2014 (audited) £
ASSETS			
Non-current assets			
Plant and equipment	17,512	23,505	21,847
Intangible assets – patents	286,017	347,463	380,540
Goodwill	1,469,112	1,469,112	1,469,112
	<u>1,772,641</u>	<u>1,840,080</u>	<u>1,871,499</u>
Current assets			
Trade and other receivables	1,880,194	324,093	1,287,535
Cash and cash equivalents	6,093,913	12,099,601	9,969,759
	<u>7,974,107</u>	<u>12,423,694</u>	<u>11,257,294</u>
Total assets	<u>9,746,748</u>	<u>14,263,774</u>	<u>13,128,793</u>
EQUITY AND LIABILITIES			
Capital and reserves attributable to equity holders			
Share capital	1,009,923	1,009,923	1,009,923
Share premium	26,650,098	26,669,298	26,650,098
Share-based payments reserve	912,016	653,931	677,946
Retained losses	(19,396,536)	(14,474,741)	(15,733,487)
Total equity	<u>9,175,501</u>	<u>13,858,411</u>	<u>12,604,480</u>
Current liabilities			
Trade and other payables	571,247	405,363	524,313
Total liabilities	<u>571,247</u>	<u>405,363</u>	<u>524,313</u>
Total equity and liabilities	<u>9,746,748</u>	<u>14,263,774</u>	<u>13,128,793</u>

**GROUP STATEMENT OF CASH FLOWS
FOR THE SIX MONTHS ENDED 30 JUNE 2015**

	6 months ended 30 June 2015 (unaudited) £	6 months ended 30 June 2014 (unaudited) £	Year ended 31 December 2014 (audited) £
Net cash outflow from operating activities	(3,915,651)	(1,469,753)	(3,833,926)
Cash inflow from taxation	69,150	-	293,263
Cash flow from investing activities			
Interest received	32,969	3,220	24,178
Purchase of plant and equipment	(616)	(1,507)	(4,882)
Payment for patents	(61,698)	(158,361)	(215,676)
Net cash outflow from investing activities	(29,345)	(156,648)	(196,380)
Cash flow from financing activities			
Financing costs	-	-	-
Net proceeds from issue of shares	-	13,122,211	13,103,011
Net cash inflow from financing activities	-	13,122,211	13,103,011
Net (decrease)/increase in cash and cash equivalents	(3,875,846)	11,495,810	9,365,968
Cash and cash equivalents at the beginning of the period	9,969,759	603,791	603,791
Cash and cash equivalents at the end of the period	6,093,913	12,099,601	9,969,759
Reconciliation of operating loss to net cash outflow from operating activities			
Operating loss	(4,459,521)	(1,391,266)	(3,792,773)
Cost of issuing share options	259,611	56,233	192,186
Decrease/(increase) in trade and other receivables	76,153	(74,454)	(321,294)
(Decrease)/increase in trade and other payables	46,934	(83,957)	34,993
Depreciation of plant and equipment	4,951	5,649	10,682
Write-off of intangible assets	134,533	-	-
Amortisation of intangible assets	21,688	8,042	42,280
Net cash outflow from operating activities	(3,915,651)	(1,469,753)	(3,833,926)

**GROUP STATEMENT OF CHANGES IN EQUITY
FOR THE SIX MONTHS ENDED 30 JUNE 2015**

	Share capital £	Share premium £	Option reserve £	Retained losses £	Total £
Balance at 1 January 2015	1,009,923	26,650,098	677,946	(15,733,487)	12,604,480
Total comprehensive loss for the period	-	-	-	(3,688,590)	(3,688,590)
	1,009,923	26,650,098	677,946	(19,422,077)	8,915,890
Issue of shares	-	-	-	-	-
Share issue costs	-	-	-	-	-
Share-based payments	-	-	259,611	-	259,611
Transfer of previously expensed share-based payment charge upon lapse of options	-	-	(25,541)	25,541	-
Balance at 30 June 2015 (unaudited)	<u>1,009,923</u>	<u>26,650,098</u>	<u>912,016</u>	<u>(19,396,536)</u>	<u>9,175,501</u>
Balance at 1 January 2014	372,598	14,184,412	640,579	(13,129,576)	2,068,013
Total comprehensive loss for the period	-	-	-	(1,388,046)	(1,388,046)
	372,598	14,184,412	640,579	(14,517,622)	679,967
Issue of shares	637,325	13,383,821	-	-	14,021,146
Share issue costs	-	(898,935)	-	-	(898,935)
Share-based payments	-	-	56,233	-	56,233
Transfer of previously expensed share-based payment charge upon lapse of options	-	-	(42,881)	42,881	-
Balance at 30 June 2014 (unaudited)	<u>1,009,923</u>	<u>26,669,298</u>	<u>653,931</u>	<u>(14,474,741)</u>	<u>13,858,411</u>
Balance at 1 January 2014	372,598	14,184,412	640,579	(13,129,576)	2,068,013
Total comprehensive loss for the year	-	-	-	(2,758,730)	(2,758,730)
	372,598	14,184,412	640,579	(15,888,306)	(690,717)
Issue of shares	637,325	13,383,821	-	-	14,021,146
Share issue costs	-	(918,135)	-	-	(918,135)
Share-based payments	-	-	192,186	-	192,186
Transfer of previously expensed share-based payment charge upon lapse of options	-	-	(154,819)	154,819	-
Balance at 31 December 2014 (audited)	<u>1,009,923</u>	<u>26,650,098</u>	<u>677,946</u>	<u>(15,733,487)</u>	<u>12,604,480</u>

**NOTES TO THE FINANCIAL INFORMATION
FOR THE SIX MONTHS ENDED 30 JUNE 2015**

1. Publication of non-statutory accounts

- i) This interim financial information for the six months ended 30 June 2015 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 7 September 2015. The figures for the year ended 31 December 2014 have been extracted from the audited statutory accounts which have been reported on by the Company's auditor. The financial statements for the year ended 31 December 2014 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 statements for the six months ended 30 June 2015 includes the results of Verona Pharma plc and its wholly-owned subsidiaries Verona Pharma Inc. and 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 2014 and expected to be adopted in the financial year ending 31 December 2015.

In the opinion of the Directors, the interim financial information for the period presents fairly the financial position and the results from operations and cash flows for the period.

No new IFRS standards, amendments or interpretations became effective in the six months to 30 June 2015 which had a material effect on this interim financial information.

- iii) The directors do not recommend the payment of a dividend (period to 30 June 2014 - £Nil; year ended 31 December 2014 - £Nil).
- iv) A copy of the interim report is available on the Company's website www.veronapharma.com.

2. Taxation

The current period tax credit, £743,762, represents the estimated research and development tax credit receivable on qualifying expenditure incurred during the six month period ended 30 June 2015.

3. Loss per share

- i) The basic loss per share of 0.37p (30 June 2014: loss of 0.19p; 31 December 2014: loss of 0.32p) for the Group is calculated by dividing the loss for the period by the weighted average number of ordinary shares in issue of 1,009,923,481 (30 June 2014: 721,190,685; 31 December 2014: 866,743,656).
- 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 2014 and unaudited figures for the six months ended 30 June 2014.