**Company Number 05375156**

# VERONA PHARMA PLC

# INTERIM REPORT

# FOR THE SIX MONTHS ENDED 30 JUNE 2014

**VERONA PHARMA PLC**

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## DIRECTORS, SECRETARY AND ADVISERS

| | |
|---|---|
| Directors | Jan-Anders Karlsson (Chief Executive Officer)<br>Clive Page (Non-Executive Chairman)<br>Claire Poll<br>Trevor Jones<br>Stuart Bottomley<br>Patrick Humphrey |
| Company Secretary | Ben Harber |
| Registered Office | Bradley Court<br>Park Place<br>Cardiff CF10 3DR |
| Company Number | 05375156 |
| Auditors | UHY Hacker Young<br>Quadrant House<br>4 Thomas More Square<br>London E1W 1YW |
| Nominated Adviser and Broker | N+1 Singer<br>One Bartholemew Lane<br>London<br>EC2N 2AX |
| Solicitors | Taylor Wessing LLP<br>5 New Street Square<br>London EC4A 3TW |
| Principal Banker | Royal Bank of Scotland<br>130 Jermyn Street<br>London SW1Y 4UR |
| Registrars | Computershare Investor Services plc<br>PO Box 82, The Pavilions<br>Bridgewater Road<br>Bristol BS99 7NH |

## OPERATIONAL HIGHLIGHTS

*For the six months ended 30 June 2014*

- Development of a novel, commercially scalable, nebulized formulation of RPL554, our lead pipeline candidate. RPL554 is a novel PDE3/PDE4 inhibitor for the treatment of respiratory diseases, including COPD and asthma.
    - Studies have demonstrated very attractive properties compared to previous formulation.
- Commenced preparations for further clinical studies of RPL554 to demonstrate the safety and efficacy of the new formulation in the treatment of COPD patients.
- Data presented on the synergistic bronchodilator effects of RPL554 when used in combination with anti-muscarinic agents and beta2-agonists.

## FINANCIAL HIGHLIGHTS

- Completed a £14.02m (gross) share placing, subscription and open offer in March 2014. All existing institutional shareholders participated together with a number of new healthcare–focused investors.
- Loss after tax for the period of £1.40 million (2013: £1.02 million) or 0.19 pence (2013: 0.31 pence) per ordinary share.
- Net cash outflows from operating activities during the six month period of £1.47m (2013: £1.29m), with cash and cash equivalents as at 30 June 2014 of £12.10 million (2013: £0.93 million).

## INTRODUCTION

Verona Pharma is a biotech company focused on the development of high value, "first-in-class" drugs for the treatment of respiratory diseases. The Company's lead medicine, RPL554, is an innovative inhaled dual phosphodiesterase PDE3/ PDE4 inhibitor with both bronchodilator and anti-inflammatory properties for the treatment of patients with COPD and asthma. We are initially developing RPL554 as a hospital treatment for COPD patients with acute exacerbations. Despite the many recently introduced novel maintenance treatments, patients frequently experience breakthrough symptoms and have to be hospitalized. Perhaps somewhat surprisingly, old short-acting nebulized bronchodilators are still used on the wards and there is clearly a need for novel, effective treatments in this acute hospital setting. We believe RPL554 can become an attractive additional therapy to provide extra clinical benefit in patients with acute exacerbations of COPD and asthma. There is little competition in the form of novel classes of bronchodilator drugs for these acutely ill patients and the Board therefore believes that these are very attractive commercial markets for Verona Pharma.

We believe there is also an opportunity to develop RPL554 as maintenance therapy for mild to moderate COPD and asthma patients, obviously a much larger addressable market. We have previously demonstrated the ability to formulate RPL554 as a dry-powder or as a solution suitable for administration in a DPI or pMDI device (a pre-requisite for orally inhaled drugs for this patient segment) and together with a suitable partner we can undertake further clinical development for this market.

With the new funding of £14m (gross) raised in March 2014, the Company is now well positioned to continue to implement the strategy to accelerate shareholder value creation that was announced at the end of last year. A new nebulized formulation of RPL554 that is suitable for commercial use has now been developed. This will be used in the initial development of RPL554 as a nebulised treatment for hospitalized COPD patients and we anticipate that the combined bronchodilator and anti-inflammatory properties of RPL554 should be beneficial to these acutely ill patients.

Interestingly, 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 and regulators in optimizing treatment of COPD patients at discharge from hospitals and beyond. This provides a unique opportunity for RPL554 that we will explore in further Phase 2 clinical studies.

We are also investigating RPL554 in combination products 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 our 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 LABA/ LAMA bronchodilator inhalers available to COPD patients and could be used both in acute hospital care and in long-term maintenance treatment.

The Board believes that evolving the development strategy for RPL554 to include combination products and new indications, together with strengthening the IP coverage around the programme adds significant value to the Company. It should accelerate access to multi-billion dollar commercial markets and increase the flexibility in the timing for achieving attractive commercial partnerships and prolong patent protection for the emerging franchise.

### RPL554

RPL554 is a novel inhaled dual PDE3 / PDE4 inhibitor. RPL554 is currently being developed as a potential "first-in-class" treatment for patients with chronic respiratory diseases such as COPD and asthma based on its unique and favourable bronchodilator and anti-inflammatory effects.

RPL554 has successfully passed a number of early clinical Phase 1 and 2 studies. These single and multiple dose studies demonstrate that RPL554, when inhaled across a range of doses, is an effective bronchodilator

in patients with COPD or 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.

RPL554 has also been demonstrated to have potent anti-inflammatory effect in a clinical trial in human subjects. This property is unique to RPL554 and 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. 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-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.

A novel nebulized formulation of RPL554 has been developed, suitable for commercial use. A substantive pre-clinical work package is being conducted to switch to this new formulation in future clinical trials. This next series of clinical trials will set out to confirm the safety and efficacy of the new formulation of RPL554 and study its effect when given to COPD patients together with other bronchodilators, in preparation for the start of Phase 2b.

RPL554 is initially being developed for hospital use, as a treatment for COPD patients who have been hospitalized for an acute exacerbation. The objective is to add RPL554 to treatment with standard bronchodilators and to achieve an improved lung function and symptom relief and therefore reduce hospital stay. Interestingly, such an effect would be highly beneficial also to reduce the high re-admission rate of COPD patients 30 days after discharge from a hospital treatment. The increasing awareness of the high cost of these "treatment failures" has triggered multiple treatment improvement plans, but so far with little success. This could become a major commercial opportunity for RPL554.

The synergistic interaction with anti-muscarinic drugs has been repeatedly demonstrated in a series of pre-clinical studies in human airways. RPL554 would therefore be a particularly promising component of a combination therapy with an anti-muscarinic drug like glycopyrrolate. Verona Pharma has started work on co-formulating these compounds for inhaled use both in acute hospital settings and for chronic maintenance therapy.

Finally, it is also planned to examine RPL554 in further respiratory diseases such as acute asthma in the A&E unit and in other pulmonary disorders such as cystic fibrosis and bronchiectasis.

**VRP700**

Cough is the most common symptom of a number of 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. Unfortunately, currently available cough remedies are recognised as being relatively ineffective, often with significant side effects. To the best of our knowledge, there is no novel and effective inhaled therapy for treating the severe, intractable cough associated with these lung diseases in clinical development.

A clinical trial of VRP700 at the University of Florence, Italy, showed a very effective reduction of chronic cough in a small group of patients with various forms of severe lung disease. A second, randomized, double-blind, placebo-controlled clinical study with single-dose administration of VRP700 was completed in patients with IPF at the University of Manchester, UK. This is the first study objectively measuring spontaneous cough in IPF patients. Coughs were not significantly reduced in this study. It is possible that VRP700 could be effective in chronic cough caused by a different lung condition, or possibly by more frequent dosing of the compound over a longer treatment period. Whilst we will not undertake any further in-house development of VRP700, we are exploring opportunities to realise value from this asset.

## NAIPS

The Company continued to support the recent patent filings in the NAIPS programme as a basis for securing ownership and creating value from this earlier stage research program in the longer term.

## FINANCIALS

The loss from operations after tax for the six month period ended 30 June 2014 (the "Period") was £1.40 million (2013: £1.02 million) or 0.19 pence (2013: 0.31 pence) per ordinary share. The loss includes a non-cash share-based payment charge of £0.06 million (2013: £0.03 million) and a research development tax credit of £Nil (2013: £0.29 million).

Research and development expenditure, which was expensed as incurred, amounted to £0.87 million (2013: £0.80 million). Programme expenditures incurred during the Period were as follows: RPL554 programme amounted to £0.57 million (2013: £0.50 million), VRP700 programme amounted to £0.30 million (2013: £0.30 million).

Expenditures in RPL554 increased by £0.07 million, with costs of preparing the new formulation and for clinical studies of RPL554 in the current period being slightly higher than the cost in the prior period.

Administrative expenses for the six months period were £0.53 million (2013: £0.51 million). The increase of £0.02 million over the prior period was primarily due to an increase in share-based payments.

On 24 March 2014, the Company announced that it had raised £14.02 million (gross) from a placing, subscription and open offer. These funds will be used primarily to support the development of RPL554 in severe COPD as well as for corporate and general administrative expenditures.

As at 30 June 2014, the Company had approximately £12.10 million (2013: £0.93 million) in cash and cash equivalents.

## OUTLOOK

The new financing raised in March 2014 enables us to advance the new commercial formulation of RPL554 through clinical studies up to the start of Phase 2b which is expected in 2016. Additional pre-clinical and manufacturing work will be performed to satisfy certain regulatory guidelines. In parallel, we will continue 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 as from October 2014 the US Government will implement a new policy of penalizing hospitals with high 30-day re-admission rates for select conditions, including COPD. In our clinical studies in hospitalized 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 products 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, a clear health-economics benefit from this treatment.

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.

In summary, the Company continues to operate with a strong focus and financial discipline. We remain very positive about progress to date in our lead drug development programme and the opportunities for its further development and commercialisation.

Professor Clive P. Page
**Chairman**

Dr. Jan-Anders Karlsson
**Chief Executive Officer**

**VERONA PHARMA PLC**

**GROUP STATEMENT OF COMPREHENSIVE INCOME**
**FOR THE SIX MONTHS ENDED 30 JUNE 2014**

| | Notes | 6 months ended 30 June 2014 (unaudited) £ | 6 months ended 30 June 2013 (unaudited) £ | Year ended 31 December 2013 (audited) £ |
|---|---|---|---|---|
| Revenue | | - | - | - |
| Cost of sales | | - | - | - |
| **Gross profit/(loss)** | | - | - | - |
| Research and development | | (865,646) | (800,036) | (1,656,490) |
| Administration expenses | | (525,620) | (508,866) | (1,160,294) |
| **Operating loss** | | (1,391,266) | (1,308,902) | (2,816,784) |
| Finance revenue | | 3,220 | 1,875 | 2,632 |
| **Loss before taxation** | | (1,388,046) | (1,307,027) | (2,814,152) |
| Taxation – credit | 2 | - | 289,400 | 289,400 |
| **Total comprehensive loss for the period** | | (1,388,046) | (1,017,627) | (2,524,752) |
| Loss per ordinary share – basic and diluted | 3 | (0.19)p | (0.31)p | (0.74)p |

**VERONA PHARMA PLC**

**GROUP STATEMENT OF FINANCIAL POSITION**
**AS AT 30 JUNE 2014**

| | As at 30 June 2014 (unaudited) £ | As at 30 June 2013 (unaudited) £ | As at 31 December 2013 (audited) £ |
|---|---|---|---|
| **ASSETS** | | | |
| **Non current assets** | | | |
| Plant and equipment | 23,505 | 33,519 | 27,647 |
| Intangible assets – patents | 347,463 | 160,321 | 207,144 |
| Goodwill | 1,469,112 | 1,469,112 | 1,469,112 |
| | 1,840,080 | 1,662,952 | 1,703,903 |
| **Current assets** | | | |
| Trade and other receivables | 324,093 | 208,070 | 249,639 |
| Cash and cash equivalents | 12,099,601 | 930,753 | 603,791 |
| | 12,423,694 | 1,138,823 | 853,430 |
| **Total assets** | 14,263,774 | 2,801,775 | 2,557,333 |
| **EQUITY AND LIABILITIES** | | | |
| **Capital and reserves attributable to equity holders** | | | |
| Share capital | 1,009,923 | 336,175 | 372,598 |
| Share premium | 26,669,298 | 13,434,648 | 14,184,412 |
| Share-based payments reserve | 653,931 | 494,520 | 640,579 |
| Retained losses | (14,474,741) | (11,638,056) | (13,129,576) |
| **Total equity** | 13,858,411 | 2,627,287 | 2,068,013 |
| **Current liabilities** | | | |
| Trade and other payables | 405,363 | 174,488 | 489,320 |
| **Total liabilities** | 405,363 | 174,488 | 489,320 |
| **Total equity and liabilities** | 14,263,774 | 2,801,775 | 2,557,333 |

**VERONA PHARMA PLC**

**GROUP STATEMENT OF CASH FLOWS**
**FOR THE SIX MONTHS ENDED 30 JUNE 2014**

| | 6 months ended 30 June 2014 (unaudited) £ | 6 months ended 30 June 2013 (unaudited) £ | Year ended 31 December 2013 (audited) £ |
|---|---|---|---|
| **Net cash outflow from operating activities** | (1,469,753) | (1,291,199) | (2,343,944) |
| **Cash inflow from taxation** | - | 289,400 | 289,400 |
| **Cash flow from investing activities** | | | |
| Interest received | 3,220 | 1,827 | 2,642 |
| Purchase of plant and equipment | (1,507) | (1,197) | (2,033) |
| Payment for patents | (158,361) | (45,204) | (105,587) |
| **Net cash outflow from investing activities** | (156,648) | (44,574) | (104,978) |
| **Cash flow from financing activities** | | | |
| Financing costs | - | - | - |
| Net proceeds from issue of shares | 13,122,211 | 1,016,256 | 1,802,443 |
| **Net cash inflow from financing activities** | 13,122,211 | 1,016,256 | 1,802,443 |
| **Net increase/(decrease) in cash and cash equivalents** | 11,495,810 | (30,117) | (357,079) |
| Cash and cash equivalents at the beginning of the period | 603,791 | 960,870 | 960,870 |
| **Cash and cash equivalents at the end of the period** | 12,099,601 | 930,753 | 603,791 |
| **Reconciliation of operating loss to net cash outflow from operating activities** | | | |
| Operating loss | (1,391,266) | (1,308,902) | (2,816,784) |
| Share-based payments charge | 56,233 | 25,186 | 186,850 |
| (Increase)/decrease in trade and other receivables | (74,454) | 29 | (41,598) |
| (Decrease)/increase in trade and other payables | (83,957) | (24,837) | 289,995 |
| Depreciation of plant & equipment | 5,649 | 7,162 | 13,870 |
| Amortisation of intangible assets | 18,042 | 10,163 | 23,723 |
| **Net cash outflow from operating activities** | (1,469,753) | (1,291,199) | (2,434,944) |

**VERONA PHARMA PLC**

**GROUP STATEMENT OF CHANGES IN EQUITY**
**FOR THE SIX MONTHS ENDED 30 JUNE 2014**

| | Share capital £ | Share premium £ | Option reserve £ | Retained losses £ | Total £ |
|---|---|---|---|---|---|
| **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)** | 1,009,923 | 26,669,298 | 653,931 | (14,474,741) | 13,858,411 |
| **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 |
| Share issue costs | - | (142,605) | - | - | (142,605) |
| Share-based payments | - | - | 25,186 | - | 25,186 |
| Transfer of previously expensed share-based payment 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 2013** | 307,203 | 12,447,364 | 470,577 | (10,621,672) | 2,603,472 |
| Total comprehensive loss for the year | - | - | - | (2,524,752) | (2,524,752) |
| | 307,203 | 12,447,364 | 470,577 | (13,146,424) | 78,720 |
| Issue of shares | 65,395 | 1,894,767 | - | - | 1,960,162 |
| Share issue costs | - | (157,719) | - | - | (157,719) |
| Share-based payments | - | - | 186,850 | - | 186,850 |
| Transfer of previously expensed share-based payment charge upon lapse of options | - | - | (16,848) | 16,848 | - |
| **Balance at 31 December 2013 (audited)** | 372,598 | 14,184,412 | 640,579 | (13,129,576) | 2,068,013 |

## 1. Publication of non-statutory accounts

i) This interim financial information for the six months ended 30 June 2014 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 10 September 2014. The figures for the year ended 31 December 2013 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 2013 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 2014 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 2013 and expected to be adopted in the financial year ending 31 December 2014.

In the opinion of the Directors, the interim financial information for the period present 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 the 30 June 2014 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 2013 - £Nil; year ended 31 December 2013 - £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.

## 3. Loss per share

i) The basic loss per share of 0.19p (30 June 2013: loss of 0.31p; 31 December 2013: loss of 0.74p) for the Group is calculated by dividing the loss for the period by the weighted average number of ordinary shares in issue of 721,190,685 (30 June 2013: 329,133,121; 31 December 2013: 341,564,623).

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 2013 and unaudited figures for the six months ended 30 June 2013.