



## ValiRx PLC

# Half-year Report

RNS Number : 8701K

ValiRx PLC

27 September 2016

### VALIRX PLC

(*"ValiRx", "the Company" or "the Group"*)

#### HALF YEARLY REPORT FOR THE PERIOD ENDED 30 JUNE 2016

**London, UK.,** 27 September 2016: ValiRx Plc (AIM: VAL), a life science company, which focuses on clinical stage cancer therapeutic development, taking proprietary & novel technology for precision medicines towards commercialisation and partnering, today announces its Half Yearly Report for the period ended 30 June 2016.

#### HIGHLIGHTS

##### Operational Highlights

- Progressive period for ValiRx, which has seen substantial advances made in clinical trials by both therapeutic compounds
- The Phase I/II Clinical Trial of VAL201 confirmed at the end of the period that the compound was well tolerated and safe, with no significant adverse events being reported. Post period studies continue to show preliminary indications of VAL201 efficacy
- VAL401 completed its submission to commence Phase IIb clinical trial in patients with lung cancer. Ethics and regulatory approval to commence patient recruitment was received just after the period-end and now ready to start recruiting
- VAL401 received two patent grants in the period - a US patent grant in April followed by a post period allowance in July of a New Zealand patent grant
- ValiRx successfully engaged with its UK and international life-sciences audiences by exhibiting at both the UK Investor Show in London and at the prestigious AACR conference in New Orleans
- March 2016 - The Company engaged US investor relations firm, Burns McClelland, to help create broader recognition of and enhanced engagement for ValiRx within the US Life Science investor community. This follows the Company's recently established presence in the US and the opening in November 2015 of a ValiRx office in Cambridge, Boston, Massachusetts.

##### Financial Highlights

- Placing to raise £0.5m in February 2016 with existing and new investors
- March 2016 - Convertible Loan Facility agreed with Bracknor to facilitate the expansion of the VAL201 trial into a multi-centre study - Board concluded in July that it would not make further use of the facility

- Loss after taxation increased 55% to £2.12m (H1 2015: £1.37m) due to increase in clinical R&D expenditure on VAL201 and 401;
- Total comprehensive loss for the period of £2.074m (H1 2015: £1.34m); and
- Cash and cash equivalents as at 30 June 2016 of £568,805 (H1 2015: £391,884).

#### Post-Period Highlights

- Sale in July of TRAC Technology Rights for EUR 0.8 million. This sale should be seen within the context of ValiRx's original purchase of the technology for EUR75,000, only months earlier
- Placing in September with existing and new investors successfully raised £1.2 million - Convertible Loan Facility with Yorkville also concluded for up to US\$3.75 million in potential 3 tranches
- VAL301 in development - reformulation of VAL201 for new indication, endometriosis

#### Oliver de Giorgio-Miller, Non-Executive Chairman of ValiRx, commented:

*"ValiRx is making good progress in its clinical trials and is receiving welcome support from both existing and new shareholders as well as from our academic and commercial partners. I am also very pleased to see our subsidiary, ValiSeek, on the cusp of dosing patients and that we can expect to see results in its Phase IIb trial start arriving in the coming months".*

*"Our review of the pre-clinical data obtained with VAL201 has also revealed a major gynaecological indication for the compound, namely endometriosis; this condition is not adequately served with current medications as they are frequently poorly tolerated and/or impair fertility during treatment. VAL301 should show that it is completely devoid of these complications and that it also shows signs of maintaining bone density while treating this chronic debilitating condition".*

*"We are now well into the second half of the year and I am pleased that we have been able to sustain our momentum as we move towards exciting clinical developmental milestones and potential value inflection points as far as our VAL201, 301 and 401 therapeutic compounds are concerned. The funding recently secured provides a cash runway towards reaching these. I look forward to updating the market with our future progress in due course".*

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014.

\*\*\* ENDS \*\*\*

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Jon Belliss

**Notes for Editors***ValiRx Plc*

ValiRx is a biotechnology oncology focussed company specialising in developing novel treatments for cancer and associated biomarkers. It aims to make a significant contribution in "precision" medicine and science, namely to engineer a breakthrough into human health and well-being, through the early detection of cancer and its therapeutic intervention.

The Company's business model focuses on out-licensing therapeutic candidates early in the development process. By aiming for early-stage value creation, the company reduces risk considerably while increasing the potential for realising value. The group is already in licensing discussions with major players in the oncology field.

ValiRx's three classes of drugs in development, which each have the potential for meeting hitherto unmet medical needs by existing methods, have worldwide patent filings and agreed commercial rights. They originate or derive from World class institutions, such as Cancer Research UK and Imperial College.

Until recently, cancer treatments relied on non-specific agents, such as chemotherapy. With the development of target-based agents, primed to attack cancer cells only, less toxic and more effective treatments are now possible. New drugs in this group-such as those in ValiRx's pipeline-promise to greatly improve outcomes for cancer patients.

The Company listed on the Alternative Investment Market ("AIM") of the London Stock Exchange in October 2006 and trades under the ticker symbol: VAL.

**CHAIRMAN'S STATEMENT FOR THE HALF YEAR ENDED 30 JUNE 2016**

The Company continues to make good progress across all areas of our business and I am particularly pleased to see VAL401 and VAL201 on the clinical trial development pathway, with VAL201 patients being dosed and VAL401 patients on the cusp of being dosed. Results from these will shortly be forthcoming thereafter. VAL201's Phase I/II clinical development is proceeding well and as planned in its clinical trial at UCLH. Just after the period end, we were able to commercialise a part of our portfolio, through the sale of TRAC, a gene expression and biomarker technology, at a considerable premium to its purchase price a year earlier. In so doing, we have freed up resource and management time, while retaining a license to the technology for its future use in our therapeutic developments.

**VAL201**

Our lead compound, VAL201, continues to perform well in its Phase I/II Clinical Trial in patients with hormone resistant prostate cancer and we confirmed in June, at the end of the period, that VAL201 was tolerated and safe. Since then VAL201 not only continues to show no drug related significant adverse events, but it also demonstrates early efficacy. These positive efficacy indications also extend to include some subjects at an early stage in their therapeutic dose ranging and elevation safety studies. Furthermore, additional Clinical Trial Centres are now being integrated into the study to assist with the dose expansion stage of the trial.

With the encouraging, independently, generated information that has been gathered during the clinical trial, ValiRx has continued to design the follow-up therapeutic and applicability trial protocols for VAL201 in prostate cancer. This is progressing well and is expected to be completed and in place by the time that the current Phase I/II trial reports.

The Company continues with the design of a trial for VAL201's use in treating the debilitating female condition, endometrioses and other endometrial conditions. The associated partnerships - both commercial and technical - are expected to be in place before the final reporting of the current 'safety and tolerability-focused' Phase I/II clinical trial completes.

**VAL401**

This half-year has been an important period for progressing VAL401 towards the clinic. ValiSeek completed its first submission in the regulatory approval process during the period and was pleased to receive just after the period-end, full regulatory and ethics approval for the clinical trial site at the Medulla Immunotherapy and Chemotherapy Clinic, Tbilisi. This is to test VAL401 as an oral treatment of late stage non-small cell lung adenocarcinoma. Since these regulatory approvals were received, the site initiation visit has been carried out, introducing the team at Clinical Accelerator to the site, and ensuring the protocol and recruitment requirements.

ValiSeek have confirmed the data management plan for the trial of VAL401 and the use of the proprietary "KEM" (Knowledge Extraction and Management) patient stratification technology, to fully exploit complex datasets of small numbers of patients.

ValiSeek received two patent grants for VAL401 in recent months - a US patent grant in April followed by a post period allowance in July of a New Zealand patent grant. The patents strongly endorse the science lying behind the VAL401 compound and courtesy of their IP protection, they add value to shareholder funds and endorse ValiRx's joint venture with ValiSeek, in terms of its international scope and worldwide commercial ambition.

**Outlook**

*We are now well into the second half of the year and I am pleased that we have been able to sustain our momentum as we move towards exciting clinical developmental milestones and potential value inflection points as far as our VAL201, 301 and 401 therapeutic compounds are concerned. The funding recently secured provides a cash runway towards reaching these. I look forward to updating the market with our future progress in due course.*

**Oliver de Giorgio-Miller**

**Non-Executive Chairman**

27 September 2016

**ValiRx Plc****Consolidated statement of comprehensive income**

	Note	Six months ended 30 June 2016 (unaudited) £	Six months ended 30 June 2015 (unaudited) £	Year ended 31 December 2015 (audited) £
<b>Revenue</b>		239,855	153,099	82,603
Cost of sales		(101,184)	(25,639)	(77,875)
<b>Gross profit</b>		138,671	127,460	4,728
Research and development		(638,356)	(859,391)	(1,543,441)
Administrative expenses		(921,318)	(989,846)	(1,694,089)
Other income		-	158,623	203,391
<b>Operating loss</b>		(1,421,003)	(1,563,154)	(3,029,411)
Fair value loss on derivative financial assets		(916,399)	-	463,023
Finance income		6	660	1,074
Finance costs		(229)	(7)	(1,793)
<b>Loss before income taxation</b>		(2,337,625)	(1,562,501)	(2,567,107)
Income tax credit	3	214,982	190,000	391,202
<b>Loss on ordinary activities after taxation</b>		(2,122,643)	(1,372,501)	(2,175,905)
Non-controlling interests		52,055	35,557	57,570

**Loss for the period and total comprehensive income attributable to owners of the parent**

		<u>(2,070,588)</u>	<u>(1,336,944)</u>	<u>(2,118,335)</u>
<b>Loss per share - basic and diluted</b>	<b>4</b>	<u>(0.48)p</u>	<u>(4.80)p</u>	<u>(6.66)p</u>

**Valirx Plc**  
**Consolidated statement of changes in shareholders' equity**

	Share capital £	Share premium £	Retained earnings £	Merger reserve £	Share option reserve £	Reverse acquisition reserve £	Non-controlling interest £	Total £
<i>Unaudited</i>								
Balance at 1 January 2016	8,120,736	10,526,862	(15,637,275)	637,500	203,519	602,413	79,069	4,532,824
Loss for the period	-	-	(2,070,588)	-	-	-	(52,055)	(2,122,643)
On acquisition of subsidiary	-	-	-	-	-	-	32,531	32,531
Issue of shares	14,046	1,238,435	-	-	-	-	-	1,252,481
Movement in period	-	(341,945)	-	-	-	-	-	(341,945)
Share based payment	-	-	-	-	55,792	-	-	55,792
<b>Balance at 30 June 2016</b>	<u>8,134,782</u>	<u>11,423,352</u>	<u>(17,707,863)</u>	<u>637,500</u>	<u>259,311</u>	<u>602,413</u>	<u>59,545</u>	<u>3,409,040</u>
<i>Unaudited</i>								
Balance at 1 January 2015	7,281,806	7,604,732	(13,518,940)	637,500	154,144	602,413	26,374	2,788,029
Loss for the period	-	-	(1,336,944)	-	-	-	(35,557)	(1,372,501)
On acquisition of subsidiary assets	-	-	-	-	-	-	41,876	41,876
Issue of shares	830,770	849,230	-	-	-	-	-	1,680,000
Costs of shares issued	-	(121,022)	-	-	-	-	-	(121,022)
Share based payment	-	-	-	-	49,375	-	-	49,375
<b>Balance at 30 June 2015</b>	<u>8,112,576</u>	<u>8,332,940</u>	<u>(14,855,884)</u>	<u>637,500</u>	<u>203,519</u>	<u>602,413</u>	<u>32,693</u>	<u>3,065,757</u>
<i>Audited</i>								
Balance at 1 January 2015	7,281,806	7,604,732	(13,518,940)	637,500	154,144	602,413	26,374	2,788,029
Loss for the year	-	-	(2,118,335)	-	-	-	(57,570)	(2,175,905)
On acquisition of subsidiary assets	-	-	-	-	-	-	110,265	110,265

Issue of shares	838,930	3,291,070	-	-	-	-	-	4,130,000
Costs of shares issued	-	(368,940)	-	-	-	-	-	(368,940)
Movement in period	-	-	-	-	49,375	-	-	49,375
<b>Balance at 31 December 2015</b>	<b>8,120,736</b>	<b>10,526,862</b>	<b>(15,637,275)</b>	<b>637,500</b>	<b>203,519</b>	<b>602,413</b>	<b>79,069</b>	<b>4,532,824</b>

**Valirx Plc****Consolidated statement of financial position**

	<b>As at 30 June</b>		<b>31 December</b>
	2016 (unaudited) £	2015 (unaudited) £	2015 (audited) £
<b>ASSETS</b>			
<b>Non current assets</b>			
Intangible assets	2,757,107	2,537,881	2,673,363
Property, plant and equipment	17,677	1,359	22,177
	<u>2,774,784</u>	<u>2,539,240</u>	<u>2,695,540</u>
<b>Current assets</b>			
Inventories	28,200	30,107	43,950
Trade and other receivables	948,775	770,961	686,394
Derivative financial assets	546,624	-	1,463,023
Cash and cash equivalents	568,805	391,884	232,465
	<u>2,092,404</u>	<u>1,192,952</u>	<u>2,425,832</u>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Trade and other payables	(1,458,148)	(666,435)	(588,548)
	<u>634,256</u>	<u>526,517</u>	<u>1,837,284</u>
<b>NET CURRENT ASSETS</b>			
	<u>634,256</u>	<u>526,517</u>	<u>1,837,284</u>
<b>NET ASSETS</b>	<u>3,409,040</u>	<u>3,065,757</u>	<u>4,532,824</u>
<b>SHAREHOLDERS' EQUITY</b>			
Share capital	8,134,782	8,112,576	8,120,736
Share premium account	11,423,352	8,332,940	10,526,862
Merger reserve	637,500	637,500	637,500
Reverse acquisition reserve	602,413	602,413	602,413
Share option reserve	259,311	203,519	203,519
Retained earnings	(17,707,863)	(14,855,884)	(15,637,275)
	<u>3,349,495</u>	<u>3,033,064</u>	<u>4,453,755</u>
Non-controlling interest	59,545	32,693	79,069
<b>Total equity</b>	<u>3,409,040</u>	<u>3,065,757</u>	<u>4,532,824</u>

**Valirx Plc****Consolidated cash flow statement**

	<b>Year ended</b>
	<b>31 December</b>
<b>Six months ended 30 June</b>	

	2016 ( <i>unaudited</i> ) £	2015 ( <i>unaudited</i> ) £	2015 ( <i>audited</i> ) £
<b>Operating activities</b>			
Operating loss	(1,421,003)	(1,563,154)	(3,029,411)
Depreciation of property plant and equipment	5,420	-	10,906
Amortisation of intangible assets	59,031	44,938	91,831
Decrease/(increase) in inventories	15,750	(18,957)	(32,800)
(Increase)/decrease in receivables	(47,399)	196,641	94,663
Increase/(decrease) in payables within one year	619,600	(88,640)	(166,527)
Other non-cash movements	(18,584)	11,236	4,847
Share option charge	55,792	49,375	49,375
<b>Cash outflows from operating activities</b>	<b>(731,393)</b>	<b>(1,368,561)</b>	<b>(2,977,116)</b>
<b>Taxation</b>	<b>-</b>	<b>-</b>	<b>387,747</b>
<b>Investing activities</b>			
Interest received	6	660	1,074
Interest paid	(229)	(7)	(1,793)
Payments to acquire intangible assets	(91,781)	(172,010)	(389,926)
Payments to acquire property plant and equipment	(799)	-	(31,670)
<b>Net cash outflow from investing activities</b>	<b>(92,803)</b>	<b>(171,357)</b>	<b>(422,315)</b>
<b>Acquisitions and disposals</b>			
Non-controlling interest	-	-	110,265
<b>Net cash inflow for acquisitions and disposals</b>	<b>-</b>	<b>-</b>	<b>110,265</b>
<b>Financing activities</b>			
Issue of ordinary share capital	502,481	1,600,000	3,050,000
Cost of share issue	(341,945)	(121,022)	(368,940)
Proceeds from convertible loan notes	1,000,000	-	-
<b>Net cash generated from financing activities</b>	<b>1,160,536</b>	<b>1,478,978</b>	<b>2,681,060</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>336,340</b>	<b>(60,940)</b>	<b>(220,359)</b>
Cash and cash equivalents at start of period	232,465	452,824	452,824
<b>Cash and cash equivalents at end of period</b>	<b>568,805</b>	<b>391,884</b>	<b>232,465</b>

## ValiRx Plc

### Notes to the interim financial statements

#### 1 General information

ValiRx Plc is a company incorporated in the United Kingdom, which is listed on the Alternative Investment Market of the London Stock Exchange Plc. The address of its registered office is 24 Greville Street, London EC1N 8SS.

#### 2 Financial information

The interim consolidated financial information for the six months ended 30 June 2016 has not been audited or reviewed and does not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006. The Group's statutory accounts for the year ended 31 December 2015 have been delivered to the Registrar of Companies. The report of the independent auditors on those financial statements was unqualified and did not contain a statement under Sections 498 (2) or (3) of the Companies Act 2006.

The interim financial statements have been prepared in accordance with International Financial Reporting Standards ('IFRS') as adopted by the European Union, IFRIC interpretations and the Companies Act 2006 applicable to companies reporting under IFRS and under the historical cost convention. The accounting policies applied in preparing the interim financial information are consistent with those set out in the statutory accounts of the Company for the year ended 31 December 2015.

The interim consolidated financial statements are presented in pounds sterling because that is the currency of the primary economic environment in which the group operates.

#### 3 Taxation

	Six months ended 30 June 2016 ( <i>unaudited</i> ) £	Six months ended 30 June 2015 ( <i>unaudited</i> ) £	Year ended 31 December 2015 ( <i>audited</i> ) £
United Kingdom corporation tax at 20%			
Current period - R & D Tax credit	(214,982)	(190,000)	(391,202)
<b>Income tax credit</b>	<b>(214,982)</b>	<b>(190,000)</b>	<b>(391,202)</b>

**4 Loss per ordinary share**

The loss and number of shares used in the calculation of loss per share are as follows:

	Six months ended 30 June	Six months ended 30 June	Year ended 31 December
	2016	2015	2015
	(unaudited)	(unaudited)	(audited)
Basic:			
Loss for the financial period	(2,122,643)	(1,372,501)	(2,118,335)
Weighted average number of shares	44,523,138	28,603,733	31,789,529
Loss per share	(4.77)p	(4.80)p	(6.66)p

**5 Dividends**

The directors do not propose to declare a dividend in respect of the period.

**6 Share capital**

	30 June 2016		30 June 2015	
	Number	£	Number	£
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
<b>Allotted, called up and fully paid</b>				
Ordinary shares of 0.1p each	52,383,488	52,385	30,177,214	30,179
Deferred shares of 5.0p each	58,378,365	2,918,918	58,378,365	2,918,918
Deferred shares of 0.9p each	157,945,030	1,421,505	157,945,030	1,421,505
Deferred shares of 12.4p each	30,177,214	3,741,974	30,177,214	3,741,974
		8,134,782		8,112,576
	31 December 2015			
	Number	£		
	(audited)	(audited)		
<b>Allotted, called up and fully paid</b>				
Ordinary shares of 0.1p each	38,338,851	38,339		
Deferred shares of 5.0p each	58,378,365	2,918,918		
Deferred shares of 0.9p each	157,945,030	1,421,505		
Deferred shares of 12.4p each	30,177,214	3,741,974		
		8,120,736		

- On 17 February 2016, the company raised £502,480, before expenses, by way of a placing of 4,187,333 ordinary shares of 0.1p each at a price of 12p per share;
- On 1 April 2016, the Company converted £90,000 of Convertible Loan Notes into 1,184,211 ordinary shares of 0.1p each at a price of 7.6p per share;
- On 18 April 2016, the Company converted £120,000 of Convertible Loan Notes into 1,621,622 ordinary shares of 0.1p each at a price of 7.4p per share;
- On 19 April 2016, the Company converted £200,000 of Convertible Loan Notes into 2,702,703 ordinary shares of 0.1p each at a price of 7.4p per share;
- On 26 April 2016, the Company converted £90,000 of Convertible Loan Notes into 1,184,211 ordinary shares of 0.1p each at a price of 7.6p per share;
- On 18 May 2016, the Company converted £250,000 of Convertible Loan Notes into 3,164,557 ordinary shares of 0.1p each at a price of 7.9p per share;

**7 Copies of interim results**

Copies of the interim results can be obtained from the website [www.valirx.com](http://www.valirx.com). From this site you may access our financial reports and presentations, recent press releases and details about the company and its operations.

This information is provided by RNS  
The company news service from the London Stock Exchange

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