

ValiRx PLC

Half-year Report

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ValiRx PLC
26 September 2017

VALIRX PLC

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

HALF YEARLY REPORT FOR THE PERIOD ENDED 30 JUNE 2017

London, UK., 26 September 2017: 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 2017.

HIGHLIGHTS

Operational Highlights

- Encouraging and positive period for ValiRx, with substantial progress seen across both clinical and pre-clinical portfolio and with the therapeutic compound, VAL401, addressing lung cancer, nearing trial completion
- Phase I/II Clinical Trial of VAL201 has demonstrated consistent safety and tolerability with signs of activity in patients with advanced prostate cancer
- VAL401 clinical trial in patients with lung cancer expanded to 3 sites; recruitment now completed and the trial is expected to complete by year-end 2017
- VAL101 underwent drug optimisation to block/ silence Bcl-2 expression identified inter alia in Pancreatic Cancer cells
- VAL301 is in late pre-clinical phase initially for the treatment of the gynaecological condition, endometriosis - a reformulation of VAL201, which pre-clinical studies suggest does not compromise bone density or fertility

Financial Highlights

- Placing to raise £1.16m in March 2017 with existing and new investors
- ValiRx received R&D Tax Credits amounting to c. £650,000 in August 2017
- Loss before income taxation reduced slightly by 2.6% to £2.25m (H1 2016: £2.31m)
- Total comprehensive loss for the period of £1.99m (H1 2016: £2.07m); and
- Cash and cash equivalents as at 30 June 2017 of £383, 426 (H1 2016: £568,805).

Post-Period Highlights

- Placing in September 2017 with existing and new investors successfully raised £0.5 million
- VAL101 - ValiRx recently reported much improved technical efficacy and commercially viable efficient manufacturing capabilities and that preliminary results for the optimised second generation of the VAL101 molecule are demonstrating gene silencing levels that are similar to the original structure. VAL101's late pre-clinical studies to be accelerated in preparation for the compound's entry into the clinic.

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

"We have seen considerable progress across our therapeutic portfolio in the last 6 months, adding value to the company's assets and bringing us closer to the point where our clinical programmes for VAL201 and VAL401 will deliver meaningful data and will bring the Company closer to finding a partner. I am pleased with the momentum generated as we move towards clinical developmental milestones and potential value inflection points for VAL401 and VAL201 as we approach the year-end. "

"Our portfolio of therapeutic drugs collectively address multi-billion dollar markets and meet significant unmet need. I therefore strongly believe that ValiRx and its assets offer investors or joint venture partners an increasingly attractive and investable proposition as we strengthen our position among frontrunners in the fields of personalised and precision medicine."

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

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Notes for Editors

About ValiRx

ValiRx is a biotechnology oncology focused 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 two 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 AIM Market 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 2017

Trialist reports on VAL201 and VAL401 in clinical trials for the treatment of Advanced Prostate Cancer and Non Small-Cell Lung Cancer remain buoyant as evidence of their safety and tolerability continues to mount and as evidence of their efficacy emerges.

VAL201

What makes VAL201 a potentially major breakthrough therapeutic treatment of Advanced Prostate Cancer is its novel mechanism of action. A number of studies have demonstrated that inhibiting Src activity strongly reduces prostate cancer growth. VAL201 specifically targets the association of androgen receptor with Src, a protein that is important in tumour cell proliferation without suppressing other hormone induced activities. This is in complete contrast to current therapies, which in addition to abolishing the receptor-dependent signalling pathways also inhibit the receptor's other functions leading to impotence, tumour flare and loss of bone mass. No serious adverse events have been reported in the ongoing clinical studies at University College London Hospital ("UCLH") and VAL201 continues to show signs of clinical activity in patients with advanced prostate cancer.

VAL401

The period under review has been a defining period in terms of VAL401's clinical development and the expansion of our drug pipeline. VAL401 is a re-formulation of anti-psychotic drug Risperidone into an orally administered gelatin capsule. The compound has shown pronounced anti-cancer properties in pre-clinical testing and has moved quickly through its Phase II efficacy trial involving patients with locally advanced or metastatic non-small cell lung cancer, who have typically 6 - 12 months of life expectancy. First dosing of patients commenced in November 2016. Since then, further patients and clinical trial sites have been recruited and opened respectively, with initial pharmacokinetic analysis showing that the presence and levels of the active drug and known metabolite in blood samples, are as expected. In June 2017, we announced that the trial had completed its recruitment phase and that ValiSeek had decided there was no requirement to enrol further patients. Since then, data processing and analysis of the results to date has commenced and results from the preliminary datalock are expected this month. The trial remains on track to be completed by year-end following which further data processing and analysis will be performed, thereby defining the clinical activity of VAL401 and its potential positive effect on patient quality of life.

GeneICE/VAL101

Our GeneICE "rebellious gene" technology has shown continued good progress in its late pre-clinical phase, with the programme currently benefitting from a second Eurostars grant for up to €1.6 million. Rebellious genes are genes that are overexpressed when they should not be or are erroneously expressed, e.g. in cancers, inflammatory conditions, Alzheimer's and autoimmune diseases. ValiRx's proprietary GeneICE technology enables the design of compounds for selective silencing of specific genes. The GeneICE lead compound has been designed against a gene expressing Bcl-2 protein, which has been implicated and associated with various cancers. Pre-clinical work during the period under review has been conducted with our partners, DKFZ, Heidelberg and Pharmatest in Finland, to generate a commercially viable molecular structure for VAL101, because whilst the molecule worked in its first generation and that Bcl-2, the gene associated with cancer, was seen to reduce and that cancer cell death occurred, the molecule's structure and manufacture however required optimisation for commercial production. ValiRx was pleased to report earlier this month, much improved technical efficacy and commercially viable efficient manufacturing capabilities and that preliminary results for the optimised second generation of the VAL101 molecule are demonstrating gene silencing levels that are similar to the original structure. As such, ValiRx intends to accelerate VAL101's late pre-clinical studies in preparation for the compound's entry into the clinic.

VAL301

VAL301 is derived from our lead compound, VAL201 and is currently in late-stage pre-clinical development as a non-invasive, effective treatment for the non-cancerous, but hugely debilitating gynaecological condition, Endometriosis. Earlier pre-clinical work on VAL201 has highlighted the compound's potential to protect uterine tissue from the oestrogenic effects that give rise to Endometriosis, with minimal impact on bone density or fertility, which are major drawbacks frequently encountered with the current commonly used drugs for this condition. Our focus now is to complete the pre-clinical package and arrive at the optimal formulation so that the Company obtains the necessary regulatory approvals to enter VAL301 into a clinical trial in 2018.

Outlook

We have seen considerable progress across our therapeutic portfolio in the last 6 months, adding value to the company's assets and bringing us closer to the point where our clinical programmes for VAL201 and VAL401 will deliver meaningful data and will bring the Company closer to finding a partner. I am pleased with the momentum generated as we move towards clinical developmental milestones and potential value inflection points for VAL401 and VAL201 as we approach the year-end.

Our portfolio of therapeutic drugs collectively address multi-billion dollar markets and meet significant unmet need. I therefore strongly believe that ValiRx and its assets offer investors or joint venture partners an increasingly attractive and investable proposition as we strengthen our position among frontrunners in the fields of personalised and precision medicine.

Oliver de Giorgio-Miller

Non-Executive Chairman

26 September 2017

Valirx Plc

Consolidated statement of comprehensive income

Note	Six months ended 30 June 2017 (unaudited) £	Six months ended 30 June 2016 (unaudited) £	Year ended 31 December 2016 (audited) £
Revenue	-	-	-
Cost of sales	-	-	-
Gross profit	-	-	-

Research and development		(723,149)	(638,356)	(2,375,354)
Administrative expenses		(958,340)	(758,445)	(1,794,284)
Operating loss		(1,681,849)	(1,396,801)	(4,169,638)
Fair value loss on derivative financial assets		(81,726)	(916,399)	(1,619,187)
Finance income		489	6	17
Fair value profit on derivative liability		(204,346)	-	375,621
Finance costs		(284,471)	(205)	(338,188)
Loss before income taxation		(2,251,543)	(2,313,399)	(5,751,375)
Income tax credit	3	195,000	214,982	620,104
Loss on ordinary activities after taxation		(2,056,543)	(2,098,417)	(5,131,271)
Discontinued operations (Loss)/profit for the period from discontinued operations		-	(24,226)	182,750
		(2,056,543)	(2,122,643)	(4,948,521)
Non-controlling interests		59,119	52,055	200,518
Loss for the period and total comprehensive income attributable to owners of the parent		(1,997,424)	(2,070,588)	(4,748,003)
Loss per share - basic and diluted	4			
From continuing operations		(1.79)p	(4.60)p	(8.54)p
From discontinued activities		-	(0.05)p	(0.03)p

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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 2017	8,165,650	12,998,102	(20,385,278)	637,500	331,453	602,413	19,619	2,369,459
Loss for the period	-	-	(1,997,424)	-	-	-	(59,119)	(2,056,543)
On acquisition of subsidiary assets	-	-	-	-	-	-	55,303	55,303
Issue of shares	60,557	1,478,947	-	-	-	-	-	1,539,504
Costs of shares issued	-	(110,173)	-	-	-	-	-	(110,173)
Share based payment	-	-	-	-	197,332	-	-	197,332
Balance at 30 June 2017	8,226,207	14,366,876	(22,382,702)	637,500	528,785	602,413	15,803	1,994,882
<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 assets	-	-	-	-	-	-	32,531	32,531
Issue of shares	14,046	1,238,435	-	-	-	-	-	1,252,481
Costs of shares issued	-	(341,945)	-	-	-	-	-	(341,945)
Share based payment	-	-	-	-	55,792	-	-	55,792
Balance at 30 June 2016	<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>Audited</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 year	-	-	(4,748,003)	-	-	-	(200,518)	(4,948,521)
On acquisition of subsidiary assets	-	-	-	-	-	-	141,068	141,068
Issue of shares	44,914	3,060,507	-	-	-	-	-	3,105,421
Costs of shares issued	-	(589,267)	-	-	-	-	-	(589,267)
Movement in period	-	-	-	-	127,934	-	-	127,934
Balance at 31 December 2016	<u>8,165,650</u>	<u>12,998,102</u>	<u>(20,385,278)</u>	<u>637,500</u>	<u>331,453</u>	<u>602,413</u>	<u>19,619</u>	<u>2,369,459</u>

Valirx Plx

Consolidated statement of financial position

	As at 30 June		31 December
	2017	2016	2016
	(unaudited)	(unaudited)	(audited)
	£	£	£
ASSETS			
Non current assets			
Intangible assets	2,948,060	2,757,107	2,824,613
Property, plant and equipment	<u>5,273</u>	<u>17,677</u>	<u>10,553</u>
	<u>2,953,333</u>	<u>2,774,784</u>	<u>2,835,166</u>
Current assets			
Inventories	-	28,200	-
Trade and other receivables	1,537,535	948,775	1,425,439
Derivative financial assets	58,949	546,624	140,675
Cash and cash equivalents	<u>383,426</u>	<u>568,805</u>	<u>560,763</u>
	<u>1,979,910</u>	<u>2,092,404</u>	<u>2,126,877</u>
LIABILITIES			
Current liabilities			
Trade and other payables	1,564,313	1,458,148	1,254,139
Borrowings	1,125,556	-	1,294,299
Derivative liability	<u>248,492</u>	<u>-</u>	<u>44,146</u>
	<u>2,938,361</u>	<u>1,458,148</u>	<u>2,592,584</u>
NET CURRENT (LIABILITIES)/ASSETS	<u>(958,451)</u>	<u>634,256</u>	<u>(465,707)</u>
NET ASSETS	<u>1,994,882</u>	<u>3,409,040</u>	<u>2,369,459</u>

SHAREHOLDERS' EQUITY

Share capital	8,226,207	8,134,782	8,165,650
Share premium account	14,366,876	11,423,352	12,998,102
Merger reserve	637,500	637,500	637,500
Reverse acquisition reserve	602,413	602,413	602,413
Share option reserve	528,785	259,311	331,453
Retained earnings	<u>(22,382,702)</u>	<u>(17,707,863)</u>	<u>(20,385,278)</u>
	1,979,079	3,349,495	2,349,840
Non-controlling interest	<u>15,803</u>	<u>59,545</u>	<u>19,619</u>
Total equity	<u><u>1,994,882</u></u>	<u><u>3,409,040</u></u>	<u><u>2,369,459</u></u>

Valirx Plc**Consolidated cash flow statement**

	Six months ended 30 June		Year ended 31 December
	2017 (<i>unaudited</i>) £	2016 (<i>unaudited</i>) £	2016 (<i>audited</i>) £
Operating activities			
Operating loss	(1,681,489)	(1,396,801)	(4,169,638)
Operating loss -discontinued operation	-	(24,226)	-
Depreciation of property plant and equipment	5,280	5,420	10,560
Amortisation of intangible assets	46,300	59,031	92,275
Decrease in inventories	-	15,750	11,733
Decrease/(increase) in receivables	82,904	(47,399)	(1,071,548)
Increase in payables within one year	284,002	619,600	787,726
Other non-cash movements	(61,922)	(18,584)	(22,454)
Share option charge	197,352	55,792	127,934
Cash outflows from operating activities	<u>(1,127,573)</u>	<u>(731,417)</u>	<u>(4,233,412)</u>
Taxation	-	-	375,926
Investing activities			
Interest received	489	6	17
Interest paid	(18,341)	(205)	(338,188)
Payments to acquire intangible assets	(114,444)	(91,781)	(386,625)
Sale of property plant and equipment	-	(799)	3,470
Net cash outflow from investing activities	<u>(132,296)</u>	<u>(92,779)</u>	<u>(721,326)</u>
Acquisitions and disposals			
Sale of subsidiary undertakings (net of cash)	-	-	857,136
Non-controlling interest	-	-	141,068
Net cash inflow for acquisitions and disposals	<u>-</u>	<u>-</u>	<u>998,204</u>
Financing activities			
Issue of ordinary share capital	1,192,725	502,481	1,695,906
Cost of share issue	(110,173)	(341,945)	(589,267)
New convertible loan notes	-	1,000,000	2,993,113
Costs of convertible loan notes issued	-	-	(190,846)
Net cash generated from financing activities	<u>1,082,552</u>	<u>1,160,536</u>	<u>3,908,906</u>
Net (decrease)/increase in cash and cash equivalents	<u>(177,337)</u>	336,340	328,298
Cash and cash equivalents at start of period	560,763	232,465	232,465
Cash and cash equivalents at end of period	<u><u>383,426</u></u>	<u><u>568,805</u></u>	<u><u>560,763</u></u>

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 3rd Floor, 16 Upper Woburn Place, London WC1H 0BS

2 Financial information

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 2016.

3 Taxation

	Six months ended 30 June	Six months ended 30 June	Year ended 31 December
	2017	2016	2016
	(unaudited)	(unaudited)	(audited)
	£	£	£
United Kingdom corporation tax at 20%			
Current period - R & D Tax credit	(195,000)	(214,982)	(644,497)
Prior years - R & D Tax credit	-	-	24,393
Income tax credit	(195,000)	(214,982)	(620,104)

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
	2017	2016	2016
	(unaudited)	(unaudited)	(audited)
Basic:			
Loss for the financial period from continuing operations	(2,056,543)	(2,098,417)	(5,131,271)
Non controlling interest	59,119	52,055	200,518
	<u>(1,997,424)</u>	<u>(2,046,362)</u>	<u>(4,930,753)</u>
Loss for the financial period - discontinued activities	<u>-</u>	<u>(24,226)</u>	<u>182,750</u>
Weighted average number of shares	114,718,325	44,523,138	57,743,223
Loss per share - continuing operations	(1.79)p	(4.60)p	(8.54)p
Loss per share - discontinued activities	-	(0.05)p	0.32p

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

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- On 6 January 2017, the Company converted US\$150,000 of Convertible Loan Notes (plus accrued interest of US\$15,840) into 2,393,788 ordinary shares of 0.1p each at a price of 5.625p per share;
- On 15 March 2017, the Company raised £1.16 million, before expenses, by way of a placing of 46,509,015 ordinary shares of 0.1p each at a price of 2.5p per share;
- On 15 March 2017, the Company raised £30,000, before expenses, by way of a subscription for 1,200,000 ordinary shares of 0.1p each at a price of 2.5p per share, by certain Directors;
- On 7 June 2017, the Company converted US\$250,000 of Convertible Loan Notes (plus accrued interest of US\$22,724) into 10,453,630 ordinary shares of 0.1p each at a price of 2.0292p per share;

Copies of the interim results can be obtained from the website 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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