

VALIRX PLC

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

HALF YEARLY REPORT FOR THE PERIOD ENDED 30 JUNE 2018

London, UK., 25 September 2018: 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 2018.

HIGHLIGHTS**Operational Highlights**

- Final results from VAL401's Phase II Clinical Trial in patients with lung cancer show verified trial data offering palliative stage patients an improvement in life quality alongside survival prospects with confirmation of acceptance of the Clinical Study Report received post period (announced 06/09/18);
- Receipt of MHRA approval to escalate and extend dosing in VAL201's Phase I/II Clinical Trial to treat prostate cancer – Recruitment of patients for this second phase is continuing - A post period preliminary inspection of the clinical data derived from the original dosing regimen has been completed, which highlights a dose-related impact on patients' physiology and chemistry;
- VAL301 is in late pre-clinical phase initially for the treatment of the gynaecological condition, endometriosis. This treatment will be a reformulation of VAL201, which pre-clinical studies suggest does not compromise bone density or fertility. Final laboratory tests are underway prior to advancing the VAL301 compound into additional toxicology and then clinical trials;
- An optimized, commercially viable, 2nd generation development of the VAL101 molecule has been created. The compound is derived from ValiRx's proprietary GenelCE platform to shut down rebellious genes causing cancer and potentially some neurological disorders. Preparation is underway for the compound's entry into the clinic; and
- The period saw further strengthening of ValiRx's patent portfolio in the US, Europe & New Zealand augmented by a post-period grant of a US Patent for VAL301.

Financial Highlights

- ValiRx received R&D Tax Credits amounting to c. £416,000 in September 2018

- Loss before income taxation increased slightly by 4.75% to £2,155,788 (H1 2017: £2,054,211)
- Total comprehensive loss for the period of £1,914,453 (H1 2017: £1,800,092); and
- Cash and cash equivalents as at 30 June 2018 of £590,615 (H1 2017: £383,426).

Post-Period highlights

- Placing to raise £1.15m of gross proceeds in September 2018 with existing and new investors;
- Detailed discussions are in progress in respect to a pivotal Phase III Clinical Trial for VAL401. Partners external to ValiRx and ValiSeek will have substantial input into the trial design, with first dosing anticipated next year. An Advisory board of UK Key Opinion Leaders expressed confidence in taking VAL401 immediately, alongside standard of care cancer treatment.

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

“The past six months have been a pivotal period for the Company as we have seen our two clinical stage compounds reach respective inflection points on their developmental pathways and our pre-clinical portfolio of future precision drugs have themselves made exciting advances towards the clinic. New technologies and tools continue to revolutionise our understanding of cancer in the development of personalised and ‘precision’ drugs. ValiRx continues to be at the forefront of these new developments in this space and I look forward to patients and shareholders alike benefiting from the Company’s continued efforts to develop ground-breaking drugs and from the successful crystallisation of substantial value”.

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 2018

During the period under review, I am pleased to report that our four therapeutic drugs in development, two of which are in clinical trials, have all taken significant strides forward along their respective clinical and pre-clinical pathways. This is in line with the Company's aim to make a meaningful contribution in "precision" medicine and science, through the early detection of cancer and its personalised therapeutic intervention. By so doing, ValiRx is striving to develop therapeutics that can substantially improve human health and well-being.

VAL401

A particularly pleasing achievement by the Company in the period was its successful completion of the VAL401 Phase II clinical study in patients with late stage non-small cell lung cancer - the most common form of lung cancer. Results from the trial show that palliative stage patients could expect to see improvements in quality of life, with the added benefit of improved survival prospects. The encouraging 60% overall response rate provides a strong foundation for a pivotal Phase III clinical study and the measure of immune competency of the treated patients was also a pleasingly unexpected addition to the results. In summary, we are very excited to see such a good response rate for a condition with huge unmet medical need.

Detailed discussions are in progress in respect to a Phase III Clinical Trial and partners external to ValiRx and ValiSeek will have substantial input into the trial design with first dosing anticipated next year.

VAL201

VAL201 has performed extremely well in its clinical trials and has confirmed to date, that beyond it being well tolerated and safe, it is efficacious and works. The compound had a major trial review of its protocol at the end of 2017, which the regulatory authorities subsequently approved. This modification to the trial protocol allows the Company to escalate or accelerate the dosing regimen of the study, from 4mg to 16mg in a couple of steps. This effectively will see a substantial increase in the dose of VAL201 being administered to patients and allows treatment to more speedily reach its full therapeutic potential and potential anti-cancer impact on patients.

A post period preliminary inspection (announced 06/09/18) of the clinical data derived from the original dosing regimen has been completed regarding all the subjects that have been treated to date. This inspection considered all dosing regimens. In summary, the preliminary observations highlighted a dose-related impact on patients' physiology and chemistry, such as androgen PSA and various cell and protein turnover factors, which are important in the treatment of cancer. These are in line with anticipated outcomes as far as cancer reduction is concerned. Meanwhile, the Company continues to recruit appropriate patients for this second part of the trial.

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. We have established from our pre-clinical studies that VAL201's specific mode of action has the potential to provide a potent therapeutic effect to manage the symptoms of this hormonally-induced disorder, without side effects, including loss of bone density and/or infertility.

In preclinical studies, VAL301 has been shown to reduce endometrial lesions by up to 50% and the compound is well placed as a potential treatment. VAL301 received a US patent grant for its use in endometriosis shortly after the period end and it is currently in final pre-clinical preparation with an ambition to move into the clinic within the next twelve months, dependant on funding and regulatory clearance.

GenelCE/VAL101

Shortly before the period under review, we announced another important breakthrough in the development of an optimised, commercially viable second generation of the VAL101 molecule derived from our proprietary GenelCE platform (announced 07/09/2017). This molecule is based on a technology, which is called GenelCE ('Gene Inactivation by Chromatin Engineering') and is licensed from Imperial College.

Pre-clinical work being conducted with our partners, DKFZ, Heidelberg and Pharmatest in Finland, has generated a commercially viable molecular structure for VAL101. The activity of Bcl-2, the gene associated with cancer, is seen to reduce and cancer cell death was seen to occur. As such, ValiRx is currently accelerating VAL101's late pre-clinical studies in preparation for its entry into the clinic.

Outlook

The past six months have been a pivotal period for the Company as we have seen our two clinical stage compounds reach respective inflection points on their developmental pathways and our pre-clinical portfolio of future precision drugs have themselves made exciting advances towards the clinic. New technologies and tools continue to revolutionise our understanding of cancer in the development of personalised and 'precision' drugs. ValiRx continues to be at the forefront of these new developments in this space and I look forward to patients and shareholders alike benefiting from the Company's continued efforts to develop ground-breaking drugs and from the successful crystallisation of substantial value.

Oliver de Giorgio-Miller

Non-Executive Chairman

25 September 2018

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Consolidated statement of comprehensive income

	Note	Six months ended 30 June 2018 (unaudited) £	Six months ended 30 June 2017 (unaudited) £	Year ended 31 December 2017 (audited) £
			(Note 7)	
Revenue		-	-	-
Cost of sales		-	-	-
Gross profit		-	-	-
Research and development		(851,688)	(723,149)	(1,746,808)
Administrative expenses	7	(920,760)	(761,008)	(1,467,268)
Share option charge		(332,241)	-	-
Other income		-	-	88,773
Operating loss		(2,104,689)	(1,484,157)	(3,125,303)
Fair value loss on derivative financial assets		(46,892)	(81,726)	(23,446)
Finance income		-	489	489
Fair value profit on derivative liability		-	(204,346)	44,146
Finance costs		(207)	(284,471)	(449,868)
Loss before income taxation		(2,151,788)	(2,054,211)	(3,553,982)
Income tax credit	3	206,000	195,000	416,336
Loss on ordinary activities after taxation		(1,945,788)	(1,859,211)	(3,137,646)
Non-controlling interests		31,335	59,119	117,962
Loss for the period and total comprehensive income attributable to owners of the parent		(1,914,453)	(1,800,092)	(3,019,684)
Loss per share - basic and diluted				
From continuing operations	4	(0.51)p	(1.57)p	(2.00)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 2018	8,432,708	16,419,494	(23,378,744)	637,500	464,000	602,413	(24,744)	3,152,627
Loss for the period	-	-	(1,914,453)	-	-	-	(31,335)	(1,945,788)
Issue of shares	104,653	2,354,512	-	-	-	-	-	2,459,165
Costs of shares issued	-	(239,853)	-	-	-	-	-	(239,853)
Exercise of share options and warrants	-	147,394	-	-	(147,394)	-	-	-
Lapse of share options	-	-	2,400	-	(2,400)	-	-	-
Share based payment	-	-	-	-	394,094	-	-	394,094
Balance at 30 June 2018	8,537,361	18,681,547	(25,290,797)	637,500	708,300	602,413	(56,079)	3,820,245
<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	-	-	(1,800,092)	-	-	-	(59,119)	(1,859,211)
On acquisition of subsidiary assets	-	-	-	-	-	-	55,303	55,303
Issue of shares	60,557	1,478,947	-	-	-	-	-	1,539,504
Costs of shares issued	-	(307,505)	-	-	-	-	-	(307,505)
Share based payment	-	-	-	-	197,332	-	-	197,332
Balance at 30 June 2017	8,226,207	14,169,544	(22,185,370)	637,500	528,785	602,413	15,803	1,994,882
<i>Audited</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 year	-	-	(3,019,684)	-	-	-	(117,962)	(3,137,646)
On acquisition of subsidiary assets	-	-	-	-	-	-	73,599	73,599
Issue of shares	267,058	3,866,468	-	-	-	-	-	4,133,526
Costs of shares issued	-	(445,076)	-	-	-	-	-	(445,076)
Lapse of share options	-	-	26,218	-	(26,218)	-	-	-
Share based payment	-	-	-	-	158,765	-	-	158,765
Balance at 31 December 2017	8,432,708	16,419,494	(23,378,744)	637,500	464,000	602,413	(24,744)	3,152,627

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Consolidated statement of financial position

	As at 30 June		31 December
	2018	2017	2017
	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(audited)</i>
	£	£	£
ASSETS			
Non-current assets			
Goodwill	1,602,522	1,584,227	1,602,522
Intangible assets	1,379,876	1,363,833	1,325,283
Property, plant and equipment	-	5,273	-
	2,982,398	2,953,333	2,927,805
Current assets			
Trade and other receivables	746,532	698,038	766,475
Tax receivable	257,244	839,497	424,094
Derivative financial assets	70,338	58,949	117,229
Cash and cash equivalents	590,615	383,426	701,410
	1,664,729	1,979,910	2,009,208
Total assets	4,647,127	4,933,243	4,937,013
SHAREHOLDERS' EQUITY			
Share capital	8,537,361	8,226,207	8,432,708
Share premium account	18,681,547	14,169,544	16,419,494
Merger reserve	637,500	637,500	637,500
Reverse acquisition reserve	602,413	602,413	602,413
Share option reserve	708,300	528,785	464,000
Retained earnings	(25,290,797)	(22,185,370)	(23,378,744)
	3,876,324	1,979,079	3,177,371
Non-controlling interest	(56,079)	15,803	(24,744)
Total equity	3,820,245	1,994,882	3,152,627
LIABILITIES			
Current liabilities			
Trade and other payables	826,882	1,564,313	1,394,266
Borrowings	-	1,125,556	390,120
Derivative liability	-	248,492	-
	826,882	2,938,361	1,784,386
Total equity and liabilities	4,647,127	4,933,243	4,937,013

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Consolidated cash flow statement

	Six months ended 30 June		31 December
	2018 (unaudited) £	2017 (unaudited) £	2017 (audited) £
Cash flows from operating activities			
Operating loss	(2,104,689)	(1,484,157)	(3,125,303)
Depreciation of property plant and equipment	-	5,280	10,553
Amortisation of intangible assets	84,800	46,300	177,134
(Increase)/decrease in receivables	(25,005)	82,904	14,467
(Decrease)/increase in payables within one year	(567,384)	284,002	54,038
Other non-cash movements	43,991	(61,922)	(83,164)
Share option charge	332,342	197,332	-
	(2,235,945)	(930,261)	(2,952,275)
Tax credit received	372,850	-	636,739
Interest paid	(207)	(18,341)	(35,897)
Net cash outflow from operating activities	(1,863,302)	(948,602)	(2,351,433)
Cash flows from investing activities			
Purchase of goodwill	-	(55,303)	(73,599)
Purchase of intangible assets	(139,393)	(114,444)	(206,727)
Non-controlling interests	-	55,303	73,599
Interest received	-	489	489
Net cash outflow from investing activities	(139,393)	(113,955)	(206,238)
Cash flows from financing activities			
Share issue	2,070,000	1,192,725	3,068,406
Costs of shares issued	(178,100)	(307,505)	(286,311)
New convertible loan notes	-	-	263,704
Repayment of convertible loan notes	-	-	(347,481)
Net cash generated from financing activities	1,891,900	885,220	2,698,318
Net (decrease)/increase in cash and cash equivalents	(110,795)	(177,337)	140,647
Cash and cash equivalents at start of period	701,410	560,763	560,763
Cash and cash equivalents at end of period	590,615	383,426	701,410

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 consolidated financial information for the six months ended 30 June 2018 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 2017 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 2017.

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 2018 (unaudited) £	Six months ended 30 June 2017 (unaudited) £	Year ended 31 December 2017 (audited) £
United Kingdom corporation tax at 20%			
Current period - R & D Tax credit	(206,000)	(195,000)	(424,094)
Prior period - R & D Tax credits	-	-	7,758
Income tax credit	(206,000)	(195,000)	(416,336)

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 2018 (unaudited)	Six months ended 30 June 2017 (unaudited)	Year ended 31 December 2017 (audited)
Basic:			
Loss for the financial period	(1,945,788)	(1,859,211)	(3,137,646)
Non-controlling interest	31,335	59,119	117,962
	(1,914,453)	(1,800,092)	(3,019,684)
Weighted average number of shares	384,343,833	114,718,325	151,071,019
Loss per share - continuing operations	(0.51)p	(1.57)p	(2.00)p

The outstanding share options and share warrants would have no dilutive effect on the loss per share.

5 Dividends

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

6 Share capital

	30 June 2018		30 June 2017	
	Number <i>(unaudited)</i>	£ <i>(unaudited)</i>	Number <i>(unaudited)</i>	£ <i>(unaudited)</i>
Allotted, called up and fully paid				
Ordinary shares of 0.1p each	454,962,717	454,963	143,809,745	143,809
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
		<u>8,537,361</u>		<u>8,226,206</u>
	31 December 2017			
	Number <i>(unaudited)</i>	£ <i>(unaudited)</i>		
Allotted, called up and fully paid				
Ordinary shares of 0.1p each	350,310,448	350,311		
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		
		<u>8,432,708</u>		

- On 2 January 2018, the Company raised £1.0 million, before expenses, by way of a placing of 23,529,412 ordinary shares of 0.1p each at a price of 4.25p per share;
- On 3 January 2018, the Company converted US\$520,000 of Convertible Loan Notes (plus accrued interest of US\$1,667) into 25,222,857 ordinary shares of 0.1p each at a price of 1.5429p per share;
- On 8 January 2018, warrants were exercised over 8,000,000 shares and 400,000 shares at exercise prices of 1.25p and 5p respectively, raising gross proceeds of £120,000.
- On 14 May 2018, the Company raised £0.95 million, before expenses, by way of a placing of 47,500,000 ordinary shares of 0.1p each at a price of 2.00p per share;

7 Comparative figures for the unaudited accounts for the six months ended 30 June 2017

As the warrants issued during the six months ended 30 June 2017 were all in consideration of shares issued, the charge should have been taken directly to equity and charged against the share premium as costs in respect of the shares issued rather than the statement of comprehensive income. The effect of this adjustment is to reduce the loss for the six months ended 30 June by £197,332 and to reduce the share premium account by a like amount. There is no impact on the total assets of the Group.

There is no impact on either the audited accounts for the year ended 31 December 2017 or the unaudited accounts for the six months ended 30 June 2018.

8 Copies of interim results

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.