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ValiRx PLC
26 September 2019

VALIRX PLC

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

HALF YEARLY REPORT FOR THE PERIOD ENDED 30 JUNE 2019

London, UK., 26 September 2019: ValiRx Plc (AIM: VAL), a life science company, which focuses on clinical stage cancer therapeutic development, taking proprietary and novel technology for precision medicines towards commercialisation and partnering, today announces its Half Yearly Report for the period ended 30 June 2019 and provides an update e on significant post-period events.

HIGHLIGHTS

Operational Highlights

- MHRA and REC approve a major update to the trial of VAL201 including the appointment of a Principal Investigator to the clinical team, with results from the first clinical trial of the compound being prepared for an independent evaluation following the completion of the current patient group.
- The period saw further strengthening of ValiRx's IP patent portfolio. Grant allowances for VAL301 were permitted for the European Union, China and the Russian Federation, building on an earlier patent granted in 2018 for the US. VAL201 had its IP protection extended during the period, with a patent grant allowed in the US for the use of the compound in the prevention and treatment of metastatic cancer. This allowance builds on previously granted worldwide rights for the use of the compound against prostate cancer.
- ValiRx acquired the IP assets of FIT Biotech OY (announced 2 May 2019) to complement its other drug discovery (drug enhancing) technologies and is currently in discussions with a potential JV partner over further developing certain of the Company's genetic-based diagnostic assets

Financial Highlights

- Loss before income tax narrowed substantially by 56.9% to £927,342 (H1 2018: £2,155,788); largely as a result of a profit on the sale of fixed asset investments and no requirement to manufacture additional VAL201 drug as sufficient quantities were produced in H2 2018;
- Total comprehensive loss for the period of £750,569 (H1 2018: £1,914,453);
- Cash and cash equivalents as at 30 June 2019 of £171,443 (H1 2018: £590,615); and
- Loss per share - basic and diluted reduced by 78.4% to (0.11)p (H1 2018: (0.51)p.

Post-Period highlights

- R&D Tax Credit of £423,000 received in September 2019
- The Company announced (10 September 2019) that in addition to pharmacokinetic and toxicology data, clinical trial results show VAL201 behaves as predicted in reducing prostate cancer progression - evidence that is supported from tumour imaging (MRI and CT) in subjects.
- VAL301's clinical team signed an agreement in July 2019 with Aptus Clinical Ltd ("Aptus"), the UK based, clinical Contract Research Organisation ("CRO"), to effectuate a clinical development plan for VAL301 incorporating a Phase I/II study design concept in Endometriosis.
- Two placings and a subscription raised £1.226m of gross proceeds with existing and new investors. The funds were raised for working capital needs and to progress the development of the Company's therapeutic drug portfolio.

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

"Throughout the reporting period, ValiRx has continued to sustain valuable momentum in terms of progressing its therapeutic assets and along their respective clinical and pre-clinical pathways. We have made important strides forward across both our therapeutic and technology portfolios, with the expectation that these will deliver added-value in the near term for our shareholders."

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 Word 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 2019

Throughout the reporting period, ValiRx has continued to sustain valuable momentum in terms of progressing its therapeutic assets and along their respective clinical and pre-clinical pathways**.**

VAL201

We were very pleased to announce in June 2019 that based on our clinical results for VAL201, a substantial amendment to the clinical trial protocol had received regulatory approval from the Medicines and Healthcare products Regulatory Agency ("MHRA") and the Research Ethics Committee ("REC").

Following approval of this substantial amendment, an authoritative prostate cancer specialist, Dr Mark Linch was appointed Principal Investigator to the clinical trial team at University College London Hospital ("UCLH"). Dr Linch is the Consultant Medical Oncologist specialising in the treatment of prostate and bladder cancer at UCLH and as a recognised specialist, we are pleased to benefit from his deep understanding and experience of the condition.

To date, the results generated by the trial, showed that the compound is safe and can be given to humans at a therapeutic level and beyond. The approval given to relax the restrictions previously applied to the trial, means that a more effective use of VAL201 can be achieved, with respect to concentration and timing and regarding increased flexibility in the administration of the drug. The trial is providing practical information back to the trialling of VAL201, so that the next stage of clinical development, in which ValiRx will endeavour to show how effective the compound actually is, can be entered into with confidence and support from all those involved.

Building on this progress, ValiRx was able to announce in September 2019, that in addition to pharmacokinetic and toxicology data, clinical trial results to date show that VAL201 behaves as predicted in reducing prostate cancer progression - evidence that is supported from tumour imaging (MRI and CT) in subjects. The full data set is currently being reviewed and collated and additional data surrounding the possibility of an effect on metastatic tumour lesions is being collated in the few subjects exhibiting such tumours. This phase I/II trial will be finalised from a regulatory viewpoint with the trial focused on confirming and validating the optimum treatment regime and its particular use in clinical practice. Data relating to the pharmacology, pharmacokinetics and pharmacodynamics will be published as it is collated, verified and submitted.

VAL301

In July 2019 and just after the period end, VAL301's clinical team signed an agreement with Aptus Clinical Ltd ("Aptus"), the UK based, clinical Contract Research Organisation ("CRO"), to effectuate a clinical development plan for VAL301 incorporating a Phase I/II study design concept in endometriosis. With VAL301 being derived from the same active pharmaceutical ingredient as VAL201, the positive results from the VAL201 trial will be used to strengthen the clinical application of the VAL301 development programme and this agreement with Aptus represents an important stage in the preparation of the VAL301 compound for a clinical study.

Pre-clinical studies of the compound indicated that treatment with VAL301 should not affect bone density or fertility, two of the major problems associated with current medical treatments for endometriosis and ValiRx intends to develop VAL301 as a non-invasive, effective and better tolerated treatment for this debilitating condition.

Acquisition of IP & Joint Venture Discussions

In May 2019, ValiRx acquired the IP assets of FIT Biotech OY ("FIT Bio"). FIT Bio had been publicly listed on the First North Finland marketplace and had been developing gene delivery technologies for a number of indications and was positioning its technology as an alternative to biologics, such as vaccines, antibodies and protein-based drugs. Indeed, FIT Bio's principle technology - its Gene Transport Unit platform - had seen an initial product enter into clinical trials.

In addition to the IP assets of FIT Bio, ValiRx currently owns a potentially complementary portfolio of other genetic-based diagnostic assets. The Company is currently in discussions with a potential joint venture partner over the profitable collaboration, development and exploitation of these assets.

Financial review

At period end, ValiRx had net assets of £4,378,572 (2018: £4,647,127) of which £171,443 (2018: £590,615) comprised cash and equivalents. The Company was also pleased to announce (on 24 September 2019) its post period receipt of proceeds from a R&D Tax Credit of £0.423m.

The operating loss for the period narrowed substantially by 49% to £1,071,334 (2018: £2,104,689) reflecting stringent budgeting, while conducting the necessary discussions with the MHRA on VAL201 and with Aptus on VAL301 to advance both assets in clinical trials. The Company's loss before income tax similarly was substantially reduced to £927,342 (H1 2018: £2,151,788) largely as a result of a profit on the sale of fixed asset investments and no requirement to manufacture additional VAL201 drug as sufficient quantities were produced in H2 2018.

The Company continues to carefully monitor its working capital position.

Outlook

The Board is pleased with the progress of the Company in the first half of the year. We have made important strides forward across both our therapeutic and technology portfolios, with the expectation that these will deliver added value in the near term for our shareholders.

Oliver de Giorgio-Miller

Non-Executive Chairman

26 September 2019

Valirx Plc
Consolidated statement of comprehensive income

		Six months ended 30 June		Year ended 31 December
	Note	2019 *(unaudited)* £	2018 *(unaudited)* £	2018 *(audited)* £
Continuing operations				
Research and development		(206,666)	(851,688)	(1,698,791)
Administrative expenses		(864,668)	(920,760)	(2,166,798)
Share option charge		-	(332,241)	-
Operating loss		(1,071,334)	(2,104,689)	(3,865,589)
Fair value loss on derivative financial assets		-	(46,892)	(442,229)
Profit on the sale of fixed asset investments		153,416	-	-
Provision for bad debt		-	-	(506,755)
Finance costs		(9,424)	(207)	(14,565)
Loss before income taxation		(927,342)	(2,151,788)	(4,829,138)
Income tax credit	3	150,000	206,000	461,296
Loss on ordinary activities after taxation		(777,342)	(1,945,788)	(4,367,842)
Non-controlling interests		26,773	31,335	69,020
Loss for the period and total comprehensive income attributable to owners of the parent		(750,569)	(1,914,453)	(4,298,822)
Loss per share - basic and diluted	4	(0.11)p	(0.51)p	(0.94)p

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
	£	£	£	£	£	£	£	£
Unaudited								
Balance at 1 January 2019	8,680,694	19,779,905	(27,461,771)	637,500	885,963	602,413	(93,764)	3,030,940
Loss for the period	-	-	(750,569)	-	-	-	(26,773)	(777,342)
Issue of shares	425,762	1,012,738	-	-	-	-	-	1,438,500
Costs of shares issued	-	(332,285)	-	-	-	-	-	(332,285)
Share based payment	-	(39,268)	-	-	39,268	-	-	-
Balance at 30 June 2019	9,106,456	20,421,090	(28,212,340)	637,500	925,231	602,413	(120,537)	3,359,813
Unaudited								
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
Audited								
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 year	-	-	(4,298,822)	-	-	-	(69,020)	(4,367,842)
Issue of shares	247,986	3,861,177	-	-	-	-	-	4,109,163
Costs of shares issued	-	(500,766)	-	-	-	-	-	(500,766)
Lapse of share options	-	-	215,795	-	(215,795)	-		-
Share based payment	-	-	-	-	637,758	-	-	637,758
Balance at 31 December 2018	8,680,694	19,779,905	(27,461,771)	637,500	885,963	602,413	(93,764)	3,030,940

Valirx Plc

Consolidated statement of financial position

	As at 30 June		31 December
	2019	2018	2018
	(unaudited)	*(unaudited)*	*(audited)*
	£	£	£
ASSETS			
Non-current assets			
Goodwill	1,602,522	1,602,522	1,602,522
Intangible assets	1,813,405	1,379,876	1,623,950
Property, plant and equipment	-	-	-
	3,415,927	2,982,398	3,226,472
Current assets			
Trade and other receivables	180,009	746,532	174,089

Tax receivable	611,193	257,244	461,193
Derivative financial assets	-	70,338	-
Cash and cash equivalents	171,443	590,615	372,872
	962,645	1,664,729	1,008,154
Total assets	4,378,572	4,647,127	4,234,626
SHAREHOLDERS' EQUITY			
Share capital	9,106,456	8,537,361	8,680,694
Share premium account	20,421,090	18,681,547	19,779,905
Merger reserve	637,500	637,500	637,500
Reverse acquisition reserve	602,413	602,413	602,413
Share option reserve	925,231	708,300	885,963
Retained earnings	(28,212,340)	(25,290,797)	(27,461,771)
	3,480,350	3,876,324	3,124,704
Non-controlling interest	(120,537)	(56,079)	(93,764)
Total equity	3,359,813	3,820,245	3,030,940
LIABILITIES			
Current liabilities			
Trade and other payables	804,841	826,882	889,987
Borrowings	213,918	-	313,699
	1,018,759	826,882	1,203,686
Total equity and liabilities	4,378,572	4,647,127	4,234,626

Valirx Plc
Consolidated cash flow statement

	Six months ended 30 June		Year ended 31 December
	2019	2018	2018
	(unaudited)	*(unaudited)*	*(audited)*
	£	£	£
Cash flows from operating activities			
Operating loss	(1,071,334)	(2,104,689)	(3,865,589)
Amortisation of intangible fixed assets	92,012	84,800	142,988
Increase in receivables	(5,920)	(25,005)	(31,996)
Decrease in payables within one year	(85,146)	(567,384)	(504,279)
Other non-cash movements	-	43,991	(957)
Share option charge	-	332,342	482,993
Net cash outflows from operations	(1,070,388)	(2,235,945)	(3,776,840)
Tax credit received	-	372,850	424,197
Interest paid	(1,205)	(207)	(866)
Net cash outflow from operating activities	(1,071,593)	(1,863,302)	(3,353,509)
Cash flows from investing activities			
Purchase of intangible fixed assets	(281,467)	(139,393)	(324,028)
Sale of non-current investments	153,416	-	-
Net cash outflow from investing activities	(128,051)	(139,393)	(324,028)
Cash flows from financing activities			
Share issue	1,226,000	2,070,000	3,720,000
Costs of shares issued	(119,785)	(178,100)	(346,001)
Repayment of loan notes	(108,000)	-	(25,000)
Net cash generated from financing activities	998,215	1,891,900	3,348,999
Net decrease in cash and cash equivalents	(201,429)	(110,795)	(328,538)
Cash and cash equivalents at start of period	372,872	701,410	701,410
Cash and cash equivalents at end of period	171,443	590,615	372,872

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 Stonebridge House, Chelmsford Road, Hatfield Heath, England, CM22 7BD**Financial information**

The interim consolidated financial information for the six months ended 30 June 2019 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 2018 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 2018.

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.

2 Taxation

	Six months ended 30 June 2019 (unaudited) £	Six months ended 30 June 2018 (unaudited) £	Year ended 31 December 2018 (audited) £
United Kingdom corporation tax at 19%			
Current period - R & D Tax credit	(150,000)	(206,000)	(461,193)
Prior period - R & D Tax credits	-	-	(103)
Income tax credit	(150,000)	(206,000)	(461,296)

3 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 2019 (unaudited)	Six months ended 30 June 2018 (unaudited)	Year ended 31 December 2018 (audited)
Basic:			
Loss for the financial period	(777,342)	(1,945,788)	(4,367,842)
Non-controlling interest	26,773	31,335	69,020
	(750,569)	(1,914,453)	(4,298,822)
Weighted average number of shares	691,640,169	384,343,833	458,715,753
Loss per share	(0.11)p	(0.51)p	(0.94)p

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

4 Dividends

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

5 Share capital

	30 June 2019		30 June 2018	
	Number (unaudited)	£ (unaudited)	Number (unaudited)	£ (unaudited)
Allotted, called up and fully paid				
Ordinary shares of 0.1p each	1,024,057,953	1,024,059	454,962,717	454,964
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
		9,106,456		8,537,361

	31 December 2018

	Number	£
Allotted, called up and fully paid	*(unaudited)*	*(unaudited)*
Ordinary shares of 0.1p each	598,296,049	598,297
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
		8,680,694

- On 28 February 2019, the Company raised £0.50 million, before expenses, by way of a placing of 83,333,333 ordinary shares of 0.1p each at a price of 0.60p per share;
- On 1 May 2019, the Company raised £0.426 million, before expenses, under the Subscription Agreement previously reported, by the issue of 71,000,000 at a price of 0.60p per share;
- On 18 June 2019, the Company raised £0.30 million, before expenses, by way of a placing of 150,000,000 ordinary shares of 0.1p each at a price of 0.20p per share;
- On 25 June 2019, the Company issued 121,428,571 ordinary shares of 0.1p each at a price of 0.175p per share in consideration for the termination of the Subscription Agreement at an agreed fee of £212,500.

6 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.

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

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