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ValiRx PLC
29 May 2019

VALIRX PLC

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

FINAL RESULTS FOR THE YEAR ENDED 31 DECEMBER 2018

London, UK, *29 May 2019*: 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 final results for the year ended 31 December 2018.

HIGHLIGHTS

Operational Highlights

- VAL201's Phase I/II Clinical Trial to treat prostate cancer has established that VAL201 is safe and well tolerated at doses up to 4mg/kg, and has seen early evidence of the drug's potential activity in prostate cancer. At the current stage of the trial, ValiRx is establishing the maximum tolerated dose of VAL201, based on the safety and tolerability data that it continues to collate since the MHRA approved the protocol amendment. This is a dose-ranging study, which on trial conclusion, ValiRx will either out-license the VAL201 asset to a major pharmaceutical company or will proceed to a pivotal Phase IIb study.
- Post period, ValiSeek has reported that it has agreed Letters of Intent with one European and one US partner, about the further advancement of VAL401 into the next proposed clinical trial, on a co-financing basis and that ValiSeek will seek external financing towards the next trial (announced 26 March 2019).
- VAL301 is in late pre-clinical phase initially for the treatment of the gynaecological condition, endometriosis. Key attributes of VAL301 are that unlike current treatments for this condition, pre-clinical studies suggest it does not compromise bone density or fertility. In the period, VAL301 received a US patent grant and post period, patent allowances covering China and the Russian Federation, providing protection for the compound in three of the most populous nations in the World;
- Positive results for the VAL101 compound showing it to be effective in inducing apoptosis (programmed cell death) in cancer cell models. The results suggest that VAL101 has significant apoptotic effect on cancer cells. The compound is an optimized, commercially viable, 2nd generation development of the VAL101 molecule.
- The period saw further strengthening of ValiRx's VAL201 patent portfolio with grants in the US & Europe and ValiSeek's VAL401 patent allowance in New Zealand.

Financial Highlights

- Placings during the period of £3.7m (2017: £3.072m)) applied to continue the advancement of the clinical trial of VAL201, the pre-clinical progress of VAL101 & VAL301 and the broadening of the Company's IP portfolio;
- Total comprehensive loss for the year of £4,298,822 (2017: £3,019,684);
- Loss per share from continuing operations of 0.94p (2017: Loss 1.90p);
- Cash and cash equivalents as at 31 December 2018 of £372,872 (2017: £701,410), reflecting additional API and IMP (drug) required to meet dose-escalation study requirement, based on anticipated patient recruitment dosed at 16mg/kg, as opposed to 4mg/kg in 2017;
- Loss before income taxation of £4,829,138 (2017: £3,553,982).

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

"Given the risk-averse funding climate in the reporting period, we sustained momentum in terms of adding value to our assets by advancing VAL201 in the UCLH prostate cancer clinical trial and progressing the pre-clinical advancements of the VAL101 and VAL301 compounds, to bring these closer to the Phase I ready stage. We are also pleased to report post period, that ValiSeek has secured a robust solution and strategy for the advancement of VAL401 and that it has agreed Letters of Intent with two partners to progress VAL401 into its next proposed clinical trial".

"New technologies and tools continue to revolutionise our understanding of cancer in the development of personalised and 'precision' drugs and I was delighted to see just after the period's end, the NHS's Long Term Plan being announced, with the Government now actively discussing and championing, in all but name, our therapeutic and diagnostic approaches".

"Our drug candidates have been subjected to rigorous clinical and pre-clinical testing, the results of which have consistently given the green light to continue their progress. We aim to remain at the forefront of developing new enhanced therapeutics and I look forward keenly to patients and our supportive shareholders alike deriving the full benefit from our efforts".

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

***** ENDS *****

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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 YEAR ENDED 31 DECEMBER 2018

Given the risk-averse funding climate in the reporting period, we sustained momentum in terms of adding value to our assets by advancing VAL201 in the UCLH prostate cancer clinical trial and progressing the pre-clinical advancements VAL101 and VAL301 compounds to bring these closer to Phase I ready stage. We are also pleased to report post period, that ValiSeek has secured a robust solution and strategy for the advancement of VAL401 and that it has agreed Letters of Intent with two partners to progress VAL401 into its next proposed clinical trial.

New technologies and tools continue to revolutionise our understanding of cancer in the development of personalised and 'precision' drugs and I was delighted to see just after the period's end, the NHS's Long-Term Plan being announced, with the Government now actively discussing and championing, in all but name, our therapeutic and diagnostic approaches.

As a company specialising in the development of precision medicines to treat cancer, ValiRx has seen its management invited to present various aspects of their scientific work and share knowledge and experience on both the domestic and international stage. Scientific papers have been given at important peptide and oncology conferences in both Hangzhou, China and Munich, Germany and the Company has also seen management invited to attend a Life Science reception of industry experts at the House of Lords and to contribute to the debate on issues relating to the UK's Life Sciences Industrial Strategy, as they pertain now and into the future.

We have established that VAL201 is safe and well tolerated at doses up to 4mg/kg and have seen very early evidence of the drug's potential activity in prostate cancer. At the current stage of the trial, we are establishing the maximum tolerated dose of VAL201, based on the safety and tolerability data that we continue to collate since the MHRA approved protocol amendment which permits intra-patient dose escalation (up to 16mg/kg), and the potential for a change in the dose administration schedule, upon review by the Cohort Review Committee. This is for the Cohort Review Committee to consider at this stage of the trial, to achieve the primary study objective, estimating the maximum tolerated dose.

The above will be conducted as part of the current dose-ranging study protocol. Going forward, ValiRx will either out-license the VAL201 asset to a major pharmaceutical company or proceed to a pivotal Phase II study.

Alongside the progress seen with the VAL201 compound, our work continues on reformulating VAL201 into VAL301 to treat endometriosis, a painful and debilitating gynaecological condition with high unmet clinical need and we anticipate taking this forward in 2019 to make it Phase I ready.

Post period, ValiSeek, the Company's joint venture company with Tangent Reprofiling Limited (a SEEK Group company), announced in March 2019 that it had agreed Letters of Intent with one European and one US partner, about the further advancement of VAL401 into its next proposed clinical trial, on a co-financing basis with ValiSeek seeking external financing towards the next trial. This is excellent news and an exciting prospect and courtesy of ValiRx's 55.5 per cent. majority equity ownership of ValiSeek, the Company looks forward to benefiting from all commercial returns, according to its shareholding, as per the ValiSeek Joint Venture agreement, announced on 8 April 2014.

Finally, the Company was pleased to report positive VAL101 results (April 2018) and progress with the compound, which has been shown to be effective in inducing apoptosis (programmed cell death) in cancer cell models. The results suggest that VAL101 has significant apoptotic effect on cancer cells. The VAL101 compound has been designed against a gene expressing Bcl-2 protein, which has been implicated and associated with various cancers.

The studies involved a wide range of technical and scientific methodologies demonstrating the enhanced effect of the VAL101 compound on the prevention of cancer growth at cellular biochemical and genomic levels. This excellent outcome follows on from ValiRx's earlier September 2017 update, which highlighted the successful optimisation of the VAL101 molecule, which will now be the compound taken forward towards clinical trials.

Accordingly, ValiRx is progressing this programme towards the clinic in a full partnership with its commercial and academic collaborators in Finland, Germany and Denmark. The Company is adding commercial partners in the US and China in order to support manufacturing and clinical development.

Our financial results show the total comprehensive loss attributable to the Parent Company for the year ended 31 December 2018 of £4,298,822 (2017: £3,019,684) and a loss per share of 0.94p (2017: Loss 1.90p).

2018 has seen tangible and very satisfactory progress. The Company's clinical trials continue to deliver strong progress in their scientific pursuit of developing new therapeutic medicines for the treatment of cancer. ValiRx's clinical products, VAL201 and VAL401, have both reached pivotal milestones on their development pathways and the Company's pre-clinical pipeline is fast approaching human trials.

May I thank all shareholders for their on-going support, and fellow Directors and members of the Group for their loyalty and endeavour in positioning ValiRx at the forefront of developing new enhanced therapeutics and I look forward keenly to patients and our supportive shareholders alike deriving the full benefit from our efforts.

Oliver de Giorgio-Miller

Chairman
29 May 2019

CHIEF EXECUTIVE'S REPORT FOR THE YEAR ENDED 31 DECEMBER 2018

The Company has seen a year of strong progress and I am pleased to report that our therapeutic compounds have all made substantive steps forward towards addressing unmet needs on their respective oncological pathways and in so doing, to develop therapeutics that can substantially improve human health and well-being.

VAL401

Completion of VAL401 Phase ll clinical study in patients with late stage non-small cell lung cancer

The successful completion of the VAL401 Phase ll clinical study in patients with late stage non-small cell lung cancer was an important milestone to reach and a vindication of ValiRx's investment into its subsidiary and joint venture, ValiSeek. With results from the trial showing that palliative stage patients could expect to see improvements in quality of life, in addition to an indication of improved overall survival compared to case-matched control patients, the clinical trial achieved the objectives and scientific breakthrough it had anticipated from its pre-clinical studies. The encouraging 60% overall response rate offers a strong foundation for a pivotal Phase III clinical study, with the added measure of immune competency of the treated patients further bolstering the results.

Non-small cell lung cancer is the most common form of cancer, with huge unmet medical needs. The publication of a peer-reviewed article in European Journal of Drug Metabolism and Pharmacokinetics just after the period end, having been subject to review and scrutiny by independent experts, provides a welcome and respected validation of our efforts to address this condition. Advanced discussions continue with potential partners regarding VAL401's next clinical trial with input being received into the study's design and towards first dosing.

VAL201

Excellent Safety and tolerability data together with early efficacy data lead to enhancement of the VAL201 Dose Escalation Clinical Study

VAL201 continues to perform well in its clinical trials and has confirmed to date, that beyond it being well tolerated and safe, preliminary effectiveness has been shown throughout the trial. The compound had a major trial review of its protocol at the end of 2017, which the Medicines and Healthcare products Regulatory Agency ("MHRA") subsequently approved. This modification to the trial protocol has allowed the Company to escalate or accelerate the dosing regimen of the study, from 4mg to 16mg in a couple of steps. This has seen a substantial increase in the dose of VAL201 being administered to patients and it will allow treatment to more speedily reach its full therapeutic potential and potential anti-cancer impact on patients.

In the intervening period since approval was received to escalate the VAL201 dosing (18/12/17), the Company has geared up the compound supply chain to meet increased demand for the drug, with further screening and recruiting of patients who are eligible to enter the study. The current fifth cohort has now received the escalated dose, and this marks the point at which VAL201 entered the concluding stages of its Phase I/II clinical trial.

Src kinase & Prostate cancer

VAL201 is a potentially major breakthrough therapeutic treatment of Advanced Prostate Cancer due to its novel mechanism of action. A number of studies have demonstrated that Src kinase complete inhibition, strongly reduces prostate cancer growth but may have side effects. VAL201 however, specifically targets the association of androgen receptor with Src, SH3 domain, a signal that is important in tumour cell proliferation without suppressing other Src-AR induced activities. This provides an advantage to current therapies, which in addition to abolishing the division signalling pathways, potentially also inhibit the other Androgen Receptor (AR) functions including metabolism.

VAL301

Endometriosis

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 pre-clinical studies, VAL301 has been shown to reduce endometrial lesions by up to 50% and the compound is well placed as a potential treatment. During the period, VAL301 received a US patent grant for its use in endometriosis and this was followed by patent allowances in Russia and China, post period. Since patent portfolios and trial results represent the main assets and value drivers for small biotechnology companies, VAL301's substantial patent protection exists as a validation of its technology. We continue to have the ambition of moving into the clinic this year, dependant on funding and regulatory clearance.

GeneICE/VAL101

The current VAL101 compound has been designed against a gene expressing Bcl-2 protein, which has been implicated and associated with various cancers. It is now an optimised, commercially viable second generation of the molecule and is derived from our proprietary GeneICE platform, a technology licensed from Imperial College, which is called GeneICE ('Gene Inactivation by Chromatin Engineering').

We were pleased to announce in April 2018, new positive VAL101 results, which are shown to be effective in inducing apoptosis (programmed cell death) in cancer cell models. The results show a superior apoptotic effect in comparison to currently available reagents and the studies involved a wide range of technical and scientific methodologies demonstrating the enhanced effect of the compound on the prevention of cancer growth at cellular biochemical and genomic levels. This is an excellent outcome and positions our programme well as we progress the technology towards the clinic in a full partnership with commercial and academic collaborators in Finland, Germany and Denmark.

Outlook

I am very pleased with the progress we have seen across our drug portfolio during the period under review and am truly excited by those new technologies and tools that are revolutionising our understanding of cancer, many of which come from ValiRx itself. I look forward to patients and shareholders alike benefiting from our on-going efforts to develop new cancer treatments.

Dr Satu Vainikka
Chief Executive
29 May 2019

Consolidated Statement of Profit or Loss and Other Comprehensive Income
for the year ended 31 December 2018

	2018	2017
	£	£
CONTINUING OPERATIONS		
Other operating income	**-**	88,773
Research and development	**(1,698,791)**	(1,746,808)
Administrative expenses	**(2,166,798)**	(1,467,268)
OPERATING LOSS	**(3,865,589)**	(3,125,303)
Fair value loss on derivative financial assets	**(442,229)**	(23,446)
Finance income	**-**	489
Fair value gain on derivative liability	**-**	44,146
Provision for bad debt	**(506,755)**	-
Finance costs	**(14,565)**	(449,868)
LOSS BEFORE INCOME TAX	**(4,829,138)**	(3,553,982)
Income tax credit	**461,296**	416,336
LOSS AFTER INCOME TAX	**(4,367,842)**	(3,137,646)
Non-controlling interest	**69,020**	117,962
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	**(4,298,822)**	(3,019,684)
LOSS PER SHARE		
- BASIC AND DILUTED	**(0.94)p**	(1.90)p

Consolidated Statement of Financial Position
31 December 2018

	2018	2017
	£	£
ASSETS		
NON-CURRENT ASSETS		
Goodwill	**1,602,522**	1,602,522
Intangible assets	**1,623,950**	1,325,283
Property, plant and equipment	**-**	-
Investments	**-**	-
	3,226,472	2,927,805
CURRENT ASSETS		
Trade and other receivables	**174,089**	766,475
Tax receivable	**461,193**	424,094
Derivative financial assets	**-**	117,229
Cash and cash equivalents	**372,872**	701,410

	1,008,154	2,009,208
TOTAL ASSETS	**4,234,626**	4,937,013
EQUITY		
SHAREHOLDERS' EQUITY		
Called up share capital	**8,680,694**	8,432,708
Share premium	**19,779,905**	16,419,494
Merger reserve	**637,500**	637,500
Reverse acquisition reserve	**602,413**	602,413
Share option reserve	**885,963**	464,000
Retained earnings	**(27,461,771)**	(23,378,744)
	3,124,704	3,177,371
Non-controlling interests	**(93,764)**	(24,744)
TOTAL EQUITY	**3,030,940**	3,152,627
LIABILITIES		
CURRENT LIABILITIES		
Trade and other payables	**889,987**	1,394,266
Borrowings	**313,699**	390,120
TOTAL LIABILITIES	**1,203,686**	1,784,386
TOTAL EQUITY AND LIABILITIES	**4,234,626**	4,937,013

Consolidated Statement of Changes in Equity
for the Year Ended 31 December 2018

	Share capital £	Share premium £	Merger reserve £	Reverse acquisition reserve £	Share option reserve £	Non-controlling interest £	Retained earnings £	Total £
Balance at 1 January 2017	8,165,650	12,998,102	637,500	602,413	331,453	19,619	(20,385,278)	2,369,459
Changes in equity								
Loss for the year	-	-	-	-	-	(117,962)	(3,019,684)	(3,137,646)
On acquisition of subsidiary	-	-	-	-	-	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	-
Movement in year	-	-	-	-	158,765	-	-	158,765
Balance at 31 December 2017	8,432,708	16,419,494	637,500	602,413	464,000	(24,744)	(23,378,744)	3,152,627
Changes in equity								
Loss for the year	-	-	-	-	-	(69,020)	(4,298,822)	(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 and warrants	-	-	-	-	(215,795)	-	215,795	-
Movement in year	-	-	-	-	637,758	-	-	637,758
Balance at 31 December 2018	**8,680,694**	**19,779,905**	**637,500**	**602,413**	**885,963**	**(93,764)**	**(27,461,771)**	**3,030,940**

Merger reserve
The merger reserve of £637,500 exists as a result of the acquisition of ValiRx Bioinnovation Limited. The merger reserve represents the difference between the nominal value of the share capital issued by the Company and the fair value of ValiRx Bioinnovation at 3 October 2006, the date of acquisition.

Reverse acquisition reserve
The reverse acquisition reserve exists as a result of the method of accounting for the acquisition of ValiRx Bioinnovation Limited and ValiPharma Limited.

Consolidated Statement of Cash Flows
for the year ended 31 December 2018

	2018	2017
	£	£
Cash flows from operations		
Cash outflow from operations	**(3,776,840)**	(2,952,275)
Interest paid	**(866)**	(35,897)
Tax credit received	**424,197**	636,739
Net cash outflow from operating activities	**(3,353,509)**	(2,351,433)
Cash flows from investing activities		
Purchase of goodwill	**-**	(73,599)
Purchase of intangible fixed assets	**(324,028)**	(206,727)
Non-controlling interests	**-**	73,599
Interest received	**-**	489
Net cash outflow from investing activities	**(324,028)**	(206,238)
Cash flows from financing activities		
New convertible loan notes	**-**	263,704
Repayment of convertible loan notes	**(25,000)**	(347,481)
Share issue	**3,720,000**	3,068,406
Costs of shares issued	**(346,001)**	(286,311)
Net cash inflow from financing activities	**3,348,999**	2,698,318
(Decrease)/increase in cash and cash equivalents	**(328,538)**	140,647
Cash and cash equivalents at beginning of year	**701,410**	560,763
Cash and cash equivalents at end of year	**372,872**	701,410

Reconciliation of operating loss to cash generated from operating activities

	2018	2017
	£	£
Operating loss	**(3,865,589)**	(3,125,303)
Depreciation of property, plant and equipment	**-**	10,553
Amortisation of intangible assets	**142,988**	177,134
(Increase)/decrease in trade and other receivables	**(31,996)**	14,467
(Decrease)/increase in trade and other payables	**(504,279)**	54,038
Other non-cash movements	**(957)**	(83,164)
Share option charge	**482,993**	-
Net cash outflow from operating activities	**(3,776,840)**	(2,952,275)

Notes to the Consolidated Financial Statements
for the year ended 31 December 2018

1 **Basis of preparation**

The financial information set out above does not constitute the Company's statutory accounts for the year ended 31 December 2018 but is derived from those accounts. Statutory accounts for 2018 will be delivered to the Registrar of Companies following the Company's annual general meeting.

2 **Loss per ordinary share**

The earnings and number of shares used in the calculation of loss per ordinary share are set out below:

	2018	2017

	£	£
Loss for the financial period	**(4,367,842)**	(3,137,646)
Non-controlling interest	**69,020**	117,962
Loss attributable to owners of Parent Company	**(4,298,822)**	(3,019,684)
Basic:		
Weighted average number of shares	**458,715,753**	151,071,019
Loss per share	**(0.94p)**	(1.90p)

The loss and the weighted average number of shares used for calculating the diluted loss per share are identical to those for the basic loss per share. The outstanding share options and share warrants would have the effect of reducing the loss per share and would therefore not be dilutive under IAS 33 'Earnings per Share'.

Following the issue of 83,333,333 ordinary shares of 0.1p each in February 2019 and 71,000,000 in April 2019, the number of allotted ordinary shares of 0.1p each in issue was 752,629,382.

3 **Publication of report and accounts**

The report and accounts for the year ended 31 December 2018 will be posted to shareholders shortly and will be available from the Company's website: http://valirx.com/

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