RNS Number : 6568X
ValiRx PLC
31 August 2022

VALIRX PLC

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

HALF YEARLY REPORT FOR THE PERIOD ENDED 30 JUNE 2022

London, UK., 2022: ValiRx Plc (AIM: VAL), a life science company, which focuses on clinical stage cancer therapeutic development and women's health, taking proprietary and novel technology for precision medicines towards commercialisation and partnering, today announces its half yearly report for the period ended 30 June 2022 and provides an update on significant post-period events.

HIGHLIGHTS

Operational Highlights:

- Evaluation agreement signed with University of Barcelona providing future licensing opportunity for peptidomimetic drug candidate for the treatment of uterine and pancreatic cancers
- Continued progression of Evaluation project with Hokkaido University for a peptide drug candidate for the treatment of endometrial, pancreatic and bile duct cancers
- Announced equity issue raising gross proceeds of £2.5 million (post period end) to support continued development of its assets, as well as strengthen its balance sheet with a view to pursuing acquisitive tCRO strategy
- Post period end - successful evaluation of triple negative breast cancer programme with King's College London, now progressing to full in-licensing
- Progression of tCRO strategy working towards identifying a target lab infrastructure acquisition to establish future revenue flows into the Company

Financial Highlights

- Research and developments costs £200,531 (2021: £166,500)
- Administrative expenses £611,370 (2021: £618,228)
- Share-based payment charge £261,052 (2021: £nil)
- Total comprehensive loss for the period of £992,481 (2021: £743,178)
- Loss before income taxation of £1,074,784 (2021: £785,434)
- Loss per share from continuing operations of 1.53p (2021: Loss 1.14p)
- Cash and cash equivalents at 30 June 2022 of £97,699 (2021: £1,239,035) - £2.5m (gross) fundraising post period

Dr Kevin Cox, Non-Executive Chairman of ValiRx, commented:

"Despite a challenging market, I am pleased that we have been able to complete a £2.5m (before expenses) equity raise at the period end with new and existing investors. We now have sufficient funding to continue building the collaborative development pipeline and continue to explore options to create a translational contract research organisation (tCRO)."

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulations (EU) No. 596/2014 as it forms part of UK Domestic Law by virtue of the European Union (Withdrawal) Act 2018 ("UK MAR"). The Directors of the Company take responsibility for this announcement.

***** ENDS *****

For more information, please contact:

ValiRx plc	**Tel: +44 (0) 2476 796496**
	www.valirx.com
Dr S J Dilly	suzanne.dilly@valirx.com
V Formation (Public Relations)	**+44 (0) 115 787 0206**
	www.vformation.biz
Lucy Wharton - Senior PR Executive	
Sue Carr - Director	lucy@vformation.biz
	sue@vformation.biz
Cairn Financial Advisers LLP (Nominated Adviser)	**Tel: +44 (0) 20 7213 0880**
Liam Murray/Jo Turner/Ludovico Lazzaretti	
Cenkos Securities Limited (Joint Broker)	**Tel: +44 (0) 207397 8900**
Russell Kerr / Michael Johnson (Sales)	
Callum Davidson / Giles Balleny (Corporate Finance)	
Turner Pope Investments (TPI) Limited (Joint Broker)	**Tel: +44 (0) 20 3657 0050**
James Pope / Andy Thacker	

Notes for Editors

About ValiRx

ValiRx PLC accelerates the development of innovative medicines that enhance patient experience. We do this by combining intellectual and financial resources to select, progress and partner a balanced portfolio of risk-reduced, early-stage technologies for translation into clinical candidates.

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 2022

Market conditions in the first half of 2022 have been challenging for the majority of public companies, driven in large part by the Russian invasion of Ukraine and the macro-economic impacts of the Covid aftermath. While ValiRx has not been immune to these external factors, we have continued to make significant progress with the strategic changes initiated in 2021.

Despite these challenges, we were pleased to have been able to complete a £2.5m (before expenses) equity raise at the period end with new and existing investors which ensured that we now have a comfortable cash position

that will enable continued progression of the collaborative development pipeline and provide ValiRx with an opportunity to explore a range of options to build our translational contract research organisation (tCRO) with a view to adding further revenue streams to the business.

Understandably, our partners in the clinical development of VAL201, TheoremRx Inc, have faced similar market challenges, with associated delays to their financing process. Nevertheless, at this time we have no reason to believe they will not be successful in due course.

Over the last six months the Company's strategic shift towards a tCRO business model has been further refined and the concept shared widely with institutional investors, receiving very positive feedback and a strong interest to support future acquisitions that fit with the proposed buy-and-build strategy.

Success with the tCRO strategy and the conversion of assets from our evaluation pipeline into full licencing will require ValiRx to add additional resource and experience at all levels of the Company. To this end, we hope to be able to strengthen the Board, and the executive and operational teams in the near future.

Kevin Cox
30 August 2022

CHIEF EXECUTIVE OFFICER'S STATEMENT FOR THE HALF YEAR ENDED 30 JUNE 2022

The first half of 2022 has been notable within ValiRx for making steady, sustained progress on all scientific fronts and continued evolution of our ambitions to build a tCRO.

Our Evaluation Project brought in from Barcelona in February was added to the two evaluation projects brought in towards the end of 2021 from Kings College London and Hokkaido Universities respectively. These projects demonstrate the global reach of our search capability for early-stage drug candidates and the assessment of all three of these has actively progressed during this period.

Post-period, we were delighted to be able to confirm successful completion of the Evaluation stage of the triple negative breast cancer project from Kings College London and our decision to move forward with full in-licencing as announced 13 July 2022. As the first successful Evaluation project within our new strategy, this progression marks a major milestone, increasing the breadth of the ValiRx pipeline. We continue to seek further opportunities to bring under our Evaluation process, as well as continuing to assess the Barcelona and Hokkaido projects for suitability for full in-licencing.

A summary of progress of each project is provided below, forming our quarterly project update.

Scientific Update Summary

VAL201 in prostate cancer

VAL201 is a short peptide being studied for the treatment of prostate cancer. The peptide structure is inspired by the structure of the naturally occurring androgen receptor and is designed to intercept and prevent the binding of the androgen receptor to SRC kinase; an enzyme implicated in cancerous cell growth pathways. By preventing the androgen-mediated activation of SRC kinase, VAL201 can prevent cancerous cell proliferation (or growth) without interfering with other functions of the androgen receptor or SRC kinase. This precision method, mimicking a natural process, proposes a high specificity of cancer treatment, with a lower side effect profile.

Our Phase 1/2 clinical trial treating men with prostate cancer with varying doses of VAL201 concluded in January 2020, with the clinical study report submitted in January 2021.

Sub-licensing VAL201

A Letter of Intent (LOI) to sub-license VAL201 to the US biotech company TheoremRx Inc has been in place since November 2021. On completion of TheoremRx financing, a sub-license will be executed between ValiRx and

TheoremRx enabling TheoremRx to develop VAL201 globally in oncology in exchange for upfront, milestone and royalty payments.

Although TheoremRx has faced challenges relating to the current macro-economic conditions, they have demonstrated good progress towards completion of the financing process, and we remain confident that they have the commercial, scientific and financial experience to honour their commitment to the project.

VAL301 in endometriosis

VAL301, the same peptide ingredient as VAL201, is being investigated for the treatment of women with endometriosis and is in the preclinical stage of development.

VAL301 presents an opportunity to suppress hormone-driven cellular growth in the absence of outright hormone suppression. By interrupting only the hormone driven cell growth while sparing the other hormone activities, infertility and related side effects are potentially avoided.

VAL301 is one of our preclinical pipeline products and this potential benefit of selectivity will be investigated in future clinical trials. The Company announced on 1 May 2020 that a Material Transfer Agreement was signed with an undisclosed Japanese pharmaceutical company, which enables them to carry out their own laboratory-based evaluations.

Independently of the work being carried out in Japan, ValiRx has commissioned further preclinical testing of the peptide to support the mechanism of action in the treatment of endometriosis. This additional work will provide greater insight into the interactions of the peptide with multiple cellular proteins under differing stimulation conditions as well as considering formulation aspects of the project.

If successful, this new preclinical data may trigger the positioning of VAL301 into a new ValiRx subsidiary to facilitate further commercial development and partnering of this programme.

VAL401 in adenocarcinoma

VAL401 was originally developed for treating lung cancer. VAL401 completed an exploratory Phase II trial in late-stage cancer patients in 2017. The data indicated that some patients treated with VAL401 benefited from an improvement in quality of life, particularly in measures of pain, nausea, anxiety and insomnia; and a statistically significant improvement in overall survival from time of diagnosis when compared to case matched control patients from the same clinic. Following discussions with clinical key opinion leaders, it was suggested that patients with pancreatic cancer could derive great benefit from a product like VAL401 due to improvements to severe abdominal pain, lack of appetite and nausea related to the disease.

ValiRx continues to seek partners to advance VAL401 into the next stages of development and has engaged an external business development agency to assist in identifying and approaching potential partners.

BC201 in Covid-19

BC201 uses the peptide ingredient of VAL201 to diminish the excessive immune response and consequently reduce severe symptoms of Covid-19.

The theoretical action of the peptide is two-fold: by blocking the Androgen Receptor mediated activity of SRC Kinase, the peptide down-regulates the expression of TMPRSS2 a transmembrane protein believed to be required for Coronavirus cell entry; and by directly dampening the immune response. This latter mechanism has potential for use against sepsis and autoimmune conditions in addition to the current Covid-19 programme of work.

On 2 June 2020, the Company announced that it had entered into a collaboration agreement with Oncolytika Limited and Black Cat Bio Limited to consider the potential for VAL201 to develop BC201.

ValiRx provides samples of VAL201 to enable the testing programme and access to the clinical data but has no commitment to support the project financially. Subject to a successful outcome, ValiRx will receive 40% of any licensing income generated by the project.

Evaluation Projects

Kings College London, triple negative breast cancer

Successfully completing the Evaluation Stage, this peptide drug candidate will now be licensed into a subsidiary company of ValiRx in order to progress through preclinical development. Terms were negotiated at the time of entering the evaluation and are now being finalised to enable the in-license to be completed.

Hokkaido University, endometrial, pancreatic and bile duct cancers

This peptide-based programme targets a novel mechanism of action, binding a target that is identified as being over-expressed in endometrial, pancreatic and bile duct cancers. A programme of work is underway to ensure that the peptide can be synthesised to industry standards using industry standard techniques; formulated to access the protein target; that the biological activity is as expected, with sufficient anti-cancer activity within the safe dosing limits; and whether the range of cancer (or other disease) types can be expanded.

Barcelona University, uterine and pancreatic cancers

This peptidomimetic drug candidate targets a novel binding pocket of KRAS, a protein that is well recognised to be important in cancer cell processes. A programme of work is underway to confirm the lead optimisation data and mechanism of action through a series of in silico and in vitro techniques; to synthesise and standardise the drug candidate molecule; to confirm the anti-cancer activity and safety profile; and to assess whether there is scope to expand the range of diseases to be targeted for treatment by the candidate.

Dr S J Dilly

30 August 2022

ValiRx Plc
Consolidated statement of comprehensive income

	Note	Six months ended 30 June 2022 (unaudited) £	Six months ended 30 June 2021 (unaudited) £	Year ended 31 December 2021 (audited) £
Continuing operations				
Other operating income		-	702	26,952
Research and development		(200,531)	(166,500)	(303,789)
Administrative expenses		(611,370)	(618,228)	(1,216,391)
Share-based payment charge		(261,052)	-	(184,611)
Operating loss		**(1,072,953)**	(784,026)	(1,677,839)
Finance costs		(1,831)	(1,408)	(2,765)
Loss before income taxation		(1,074,784)	(785,434)	(1,680,604)
Income tax credit	2	70,000	35,000	133,413
Loss on ordinary activities after taxation		**(1,004,784)**	(750,434)	(1,547,191)

Non-controlling interests		12,303	7,256	28,979
Loss for the period and total comprehensive income attributable to owners of the parent		**(992,481)**	(743,178)	(1,518,212)
Loss per share - basic and diluted				
From continuing operations	3	**(1.53)p**	(1.14)p	(2.34)p

ValiRx Plc
Consolidated statement of financial position

		As at 30 June		31 December
		2022 *(unaudited)* £	2021 *(unaudited)* £	2021 *(audited)* £
ASSETS				
NON-CURRENT ASSETS				
Goodwill		1,602,522	1,602,522	1,602,522
Intangible assets		1,007,770	1,233,184	1,108,116
Property, plant and equipment		-	-	-
Right-of-use assets		9,278	17,136	13,278
		2,619,570	2,852,842	2,723,916
CURRENT ASSETS				
Trade and other receivables		79,291	27,414	72,925
Tax receivable		203,413	35,000	133,413
Cash and cash equivalents		97,699	1,239,035	593,672
		380,403	1,301,449	800,010
TOTAL ASSETS		**2,999,973**	4,154,291	3,523,926
SHAREHOLDERS' EQUITY				
Share capital		9,669,995	9,669,995	9,669,995
Share premium account		24,519,456	24,401,856	24,490,618
Merger reserve		637,500	637,500	637,500
Reverse acquisition reserve		602,413	602,413	602,413
Share option reserve		723,433	484,088	491,219
Retained earnings		(33,284,988)	(31,606,191)	(32,292,507)
		2,867,809	4,189,661	3,599,238
Non-controlling interest		(197,170)	(163,144)	(184,867)

TOTAL EQUITY	**2,670,639**	4,026,517	3,414,371
LIABILITIES			
NON-CURRENT LIABILITIES			
Borrowings	28,056	40,473	35,654
Lease liabilities	2,486	9,576	5,681
	30,542	50,049	41,335
CURRENT LIABILITIES			
Trade and other payables	281,955	60,506	50,835
Borrowings	9,747	9,527	9,627
Lease liabilities	7,090	7,692	7,758
	298,792	77,725	68,220
TOTAL LIABILITIES	**329,334**	127,774	109,555
TOTAL EQUITY AND LIABILITIES	**2,999,973**	4,154,291	3,523,926

ValiRx Plc
Consolidated statement of changes in shareholders' equity

	Share capital £	**Share premium** £	**Retained earnings** £	**Merger reserve** £	**Share-based payment reserve** £	**Reverse acquisitior reserve** £
Unaudited						
Balance at 1 January 2022	9,669,995	24,490,618	(32,292,507)	637,500	491,219	602,413
Loss for the period	-	-	(992,481)	-	-	-
Lapse of share warrants	-	28,838	-	-	(28,838)	-
Share-based payment movement	-	-	-	-	261,052	-
Balance at 30 June			**(33,284,988)**			**602,413**

2022	**9,669,995**	**24,519,456**		**637,500**	**723,433**	
Unaudited						
Balance at 1 January 2021	9,669,828	24,380,356	(30,919,728)	637,500	540,803	602,413
Loss for the period	-	-	(743,178)	-	-	-
Issue of shares	167	21,500	-	-	-	-
Lapse of share options	-	-	56,715	-	(56,715)	-
Balance at 30 June 2021	9,669,995	24,401,856	(31,606,191)	637,500	484,088	602,413
Audited						
Balance at 1 January 2021	9,669,828	24,380,356	(30,919,728)	637,500	540,803	602,413
Loss for the year	-	-	(1,518,212)	-	-	-
Issue of shares	167	21,500	-	-	-	-
Lapse of share options	-	88,762	145,433	-	(234,195)	-
Share-based payment movement	-	-	-	-	184,611	-
Balance at 31 December 2021	9,669,995	24,490,618	(32,292,507)	637,500	491,219	602,413

ValiRx Plc
Consolidated cash flow statement

	Six months ended 30 June		Year ended 31 December
	2022 *(unaudited)* £	2021 *(unaudited)* £	2021 *(audited)* £
Cash flows from operating activities			
Operating loss	(1,072,953)	(784,026)	(1,677,839)
Amortisation of intangible fixed assets	102,850	104,843	221,072
Depreciation of right-of-use assets	4,000	3,859	7,717
(Increase)/decrease in receivables	(6,366)	39,321	(6,190)
Increase/(decrease) in payables within one year	231,120	(50,836)	(60,507)
Share option charge	261,052	-	184,611
Net cash outflows from operations	**(480,297)**	(686,839)	(1,331,136)
Tax credit received	-	71,346	71,346

Interest paid	(1,702)	(701)	(782)
Net cash outflow from operating activities	**(481,999)**	(616,194)	(1,260,572)
Cash flows from investing activities			
Purchase of intangible fixed assets	(2,504)	(8,839)	-
Net cash outflow from investing activities	**(2,504)**	(8,839)	-
Cash flows from financing activities			
Share issue	-	21,667	21,667
Repayment of lease liabilities	(4,500)	(4,500)	(9,000)
Bank loan	(6,970)	-	(5,324)
Net cash (used in)/generated from financing activities	**(11,470)**	17,167	7,343
Net decrease in cash and cash equivalents	**(495,973)**	(607,866)	(1,253,229)
Cash and cash equivalents at start of period	593,672	1,846,901	1,846,901
Cash and cash equivalents at end of period	**97,699**	1,239,035	593,672

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, Essex CM22 7BD.

Financial information

The interim financial information for the six months ended 30 June 2022 and 2021 have not been audited or reviewed and do not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006. The comparative financial information for the year ended 31 December 2021 has been derived from the audited financial statements for that period. A copy of those statutory financial statements for the year ended 31 December 2021 has been delivered to the Registrar of Companies. The report of the independent auditors on those financial statements was unqualified, drew attention to a material uncertainty relating to going concern 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 Accounting Standards in conformity with the requirements of the Companies Act 2006 as they apply to the financial statements of the Company for the six months ended 30 June 2022 and as applied in accordance with the provisions of the Companies Act 2006 and under the historical cost convention or fair value where appropriate. They have also been prepared on a basis consistent with the accounting policies expected to be applied for the year ending 31 December 2022 and which are also consistent with those set out in the statutory accounts of the Group for the year ended 31 December 2021.

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

2 Taxation

	Six months ended 30 June 2022 (unaudited) £	Six months ended 30 June 2021 (unaudited) £	Year ended 31 December 2021 (audited) £
United Kingdom corporation tax at 20%			
Current period - R & D Tax credit	(70,000)	(35,000)	(133,413)
Income tax credit	(70,000)	(35,000)	(133,413)

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 2022 (unaudited) £	Six months ended 30 June 2021 (unaudited) £	Year ended 31 December 2021 (audited) £
Basic:			
Loss for the financial period	(1,004,784)	(750,434)	(1,547,191)
Non-controlling interest	12,303	7,256	28,979
	(992,481)	(743,178)	(1,518,212)
Weighted average number of shares	65,049,156	65,004,957	65,004,957
Loss per share	(1.53)p	(1.14)p	(2.34)p

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 exercise prices of the outstanding share options and share warrants are above the average market price of the shares and would therefore not be dilutive under IAS 33 'Earnings per Share.

4 Dividends

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

5 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.

Caution regarding forward looking statements

Certain statements in this announcement, are, or may be deemed to be, forward looking statements. Forward looking statements are identified by their use of terms and phrases such as ''believe'', ''could'', "should" ''envisage'', ''estimate'', ''intend'', ''may'', ''plan'', ''potentially'', "expect", ''will'' or the negative of those, variations or comparable expressions, including references to assumptions. These forward-looking statements are not based on historical facts but rather on the Directors' current expectations and assumptions regarding the Company's future growth, results of operations, performance, future capital and other expenditures (including the amount, nature and sources of funding thereof), competitive advantages, business prospects and opportunities. Such forward looking statements reflect the Directors' current beliefs and assumptions and are based on information currently available to the Directors.

Such statements are based on current expectations and assumptions and are subject to a number of risks and uncertainties that could cause actual events or results to differ materially from any expected future events or results expressed or implied in these forward-looking statements. Persons receiving and reading this announcement should not place undue reliance on forward-looking statements. Unless otherwise required by applicable law, regulation or accounting standard, the Company does not undertake to update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

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.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our Privacy Policy.

END

IR BLGDIBXXDGDG