RNS Number : 9079K
ValiRx PLC
07 September 2021

7 September 2021

ValiRx PLC ("ValiRx" or the "Company")
Half Year report for period to 30 June 2021 and
Investor Presentation

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 2021.

Financial Highlights

- Research and developments costs £166,500 (2020: £99,879)
- Administrative expenses £618,228 (2020: £791,866)
- Total comprehensive loss for the period of £743,178 (2020: £805,082)
- Loss before income taxation of £785,434 (2020: £884,523)
- Loss per share from continuing operations of 1.14p (2020: Loss 4.43p)
- Cash and cash equivalents at 30 June 2021 of £1,239,035 (2020: £258,753)

Investor Presentation
ValiRx plc is pleased to announce that Suzanne Dilly (CEO), Dr Kevin Cox (Non-Executive Chairman) and Mark Treharne (Corporate Development Manger) will provide a live Investor update presentation via the Investor Meet Company platform on **28th Sep 2021 at 1:00pm BST**.

The presentation is open to all existing and potential shareholders. Questions can be submitted pre-event via your Investor Meet Company dashboard up until 9am the day before the meeting or at any time during the live presentation.

Investors can sign up to Investor Meet Company for free and add to meet ValiRx plc via:

https://www.investormeetcompany.com/valirx-plc/register-investor

Investors who already follow **ValiRx plc** on the Investor Meet Company platform will automatically be invited.

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

*** ENDS ***

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Callum Davidson/Giles Balleny (Corporate Finance)	

Notes for Editors

About ValiRx

ValiRx accelerates the development of treatments in oncology and women's health to improve patient lives. We provide the scientific, financial and commercial framework towards enabling rapid translation of innovative science into clinical development.

With our extensive and proven experience in research and drug development, we select and incubate promising novel drug candidates and guide them through an optimised process of development, from pre-clinical studies to clinic and investor-ready assets.

Integrating science and business

We connect diverse disciplines across scientific, technical and commercial domains, with the aim of achieving a more streamlined, less costly, drug development process. We work closely with our selected collaborators and leverage the combined expertise required for science to advance.

Lead candidates from our portfolio are out-licensed or partnered with investors through ValiRx subsidiary companies for further clinical development and commercialisation. https://www.valirx.com/

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

The first half of 2021 has been a period of intense activity for ValiRx, involving discussions with potential partners for out-licensing our clinical projects and in-licensing preclinical projects. While we have confidence that these will result in a beneficial outcome, none of these have reached the stage where they can be announced. We know this lack of news can be frustrating for shareholders but we take the view that announcements should be substantive and not just about making a noise.

The Company remains stable and our cash position is strong and sufficient to support our therapeutic development strategy.

The last six months has also been a period of learning for ValiRx. Learning how to maintain momentum with the effects of Covid still restricting normal business processes; learning how best to identify and progress new early-stage drug development projects with academia; and learning of the gaps in knowledge and capability that generally exist in the development of novel and innovative treatments particularly in Women's Health.

We are confident that ValiRx's proposition of 'connected innovation' can add value to the earlier development of novel compounds in our chosen markets. Our strategy is evolving and, with an increasing focus on Women's Health, we believe our growth can be enhanced through targeted investments that build on the skills and capabilities we already offer to prospective partners.

We have retained Cenkos as our broker to work with us on this process. We believe their breadth of skills will assist in delivering the strategy and securing the necessary funding for investment in value-adding capabilities that both accelerate the translation of women's health treatments and deliver value to all our shareholders.

I look forward to continued progress with our existing projects and the opportunity to build on our concept of connected innovation.

Kevin Cox, Non-executive Chairman
7 September 2021

CEO's Statement

I am pleased that we are now building from a position of financial stability and look to build growth in value through the acquisition of new assets to expand and progress our pipeline of therapeutic candidates in both Women's Health and Oncology.

We are looking to establish a greater foothold in the arena of Women's Health, building on the existing overlap in oncology. Developing therapeutics in Women's Health brings some specific and varied challenges and we believe that enabling innovative new therapeutic candidates and technologies to address these challenges provides an opportunity for ValiRx to provide much needed therapeutics alongside company growth.

We continue to liaise with a wide range of university departments and biotech companies to assess the development of early-stage therapeutic programmes to incorporate into our translational pipeline. This translation from academic project to industry-ready drug candidate, and the translation from preclinical studies into clinical testing are crucial activities to de-risk development programmes and make assets attractive for external investors and industry partners. The opportunity for academic innovators to stay involved with their science, and develop their own capabilities, has been acknowledged as an attractive differentiating feature of our approach to innovation. Indeed, we believe it is crucial to maintain continuity of scientific understanding for successful delivery of our projects.

Our conversations with university representatives have highlighted some of the challenges faced by academic innovators during the commercialisation process, demonstrating a need for support earlier in development than initially anticipated. As we consider how best to support these programmes to fulfil a much-needed solution for better therapeutics, we are also considering whether specialised techniques and capabilities could be developed to improve translation.
This evolving strategy sits alongside the work we have been progressing on both the pipeline and existing projects, as summarised below.

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.

Developments after the VAL201-001 clinical trial

Since the results of the VAL201 Phase I/II clinical trial were released in 2020, several further analyses and commercial development activities have been taking place.

In February 2021, ValiRx entered into a new agreement with Physiomics PLC (AIM:PYC) ("Physiomics"), an oncology consultancy using mathematical models to support the development of cancer treatment regimens and personalised medicine solutions.

Under the terms of the new agreement, ValiRx will benefit from Physiomics' experience in modelling the effects of prostate cancer treatment, as well the use of the latest version of its Virtual Tumour™ technology, which will be applied to derive valuable information from the additional data generated by the completed clinical trial of VAL201. Physiomics will also support ValiRx in modelling the use of the VAL201 peptide in endometriosis (VAL301) and Coronavirus (BC201).

Physiomics has developed a quantitative systems pharmacology approach that uses pre-clinical and clinical data to model the activity of a drug candidate. This data can be used to explore the mechanism of action, disease impact and optimal dosing strategies.

The data from the VAL201 Phase I/II clinical trial has been considered by independent experts who have helped to define the likely patient populations for the next clinical trial, and to clarify the market landscape.

VAL201 is under license to ValiRx from Cancer Research Technology (a division of Cancer Research UK) and they are supporting the Company in negotiation with potential licensees who will progress VAL201 into the next stages of development if the correct commercial terms can be agreed by all parties.

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.

Currently one of our preclinical pipeline products, this potential benefit 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 is carrying out laboratory-based evaluations using their own processes to determine whether to enter a licensing agreement with ValiRx for further development of the project.

Alongside 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 provides greater insight into the interactions of the peptide with multiple cellular proteins which can be applied to all disease applications being considered with the VAL201 peptide.

The Company continues to actively pursue options with other interested parties during the period of evaluation by the Japanese company.

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. Consequently, the next trial for VAL401, expected to be a Phase 2/3 clinical trial, will include pancreatic cancer patients with the aim to help exemplify both the therapeutic and palliative effects of VAL401.

As VAL401 is the reformulation of a widely used generic drug, with a well-documented safety profile and targeting an underserved disease with low survival rates, we expect regulators to have a favourable view on approval subject to successful completion of the next clinical trial.

ValiRx continues to seek partners to advance VAL401 into the next stages of development. Several external parties are assisting in this activity, with Black Cat Bio seeking financing to execute a trial, and an external development agency has been engaged to seek corporate partners.

BC201 in Covid-19

BC201 is a combination of the peptide ingredient of VAL201/VAL301 with complementary active components to dampen this 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 is postulated to down-regulate the expression of TMPRSS2 a transmembrane protein believed to be required for Coronavirus cell entry; and by directly dampening the immune response.

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 be used in conjunction with other components for treatment of patients suffering a hyperimmune response after Coronavirus SARS-CoV2 infection.

Black Cat Bio Limited is co-ordinating the project overall, with project management of specific elements contributed by ValiRx and Oncolytika. ValiRx will provide samples of VAL201 to enable the testing program. Subject to a successful outcome, ValiRx will receive 40% of any licensing income generated by the project.

Preclinical experiments to date have included: measuring the impact of the expression of receptor TMPRSS2, which is important for the virus to enter the cell after treatment; activity of Neutrophil Extracellular Traps after stimulation and treatment by the peptide; and viral infectivity/replication.

Suzanne Dilly, Chief Executive Officer
7 September 2021

Consolidated statement of comprehensive income

	Note	Six months ended 30 June 2021 (unaudited) £	Six months ended 30 June 2020 (unaudited) £	Year ended 31 December 2020 (audited) £

Continuing operations				
Research and development		(166,500)	(99,879)	(230,115)
Administrative expenses		(618,228)	(791,866)	(1,431,587)
Other income		702	10,453	11,077
Operating loss		(784,026)	(881,292)	(1,650,625)
Discount on settlement of financial liability		-	-	122,000
Finance costs		(1,408)	(3,231)	(14,880)
Loss before income taxation		(785,434)	(884,523)	(1,543,505)
Income tax credit	2	35,000	60,000	75,182
Loss on ordinary activities after taxation		(750,434)	(824,523)	(1,468,323)
Non-controlling interests		7,256	19,441	25,075
Loss for the period and total comprehensive income attributable to owners of the parent		(743,178)	(805,082)	(1,443,248)
Loss per share - basic and diluted				
From continuing operations	3	(1.14)p	(4.43)p	(3.81)p

Consolidated statement of financial position

	As at 30 June		31 December
	2021	2020	2020
	(unaudited)	*(unaudited)*	*(audited)*
	£	£	£
ASSETS			
NON-CURRENT ASSETS			
Goodwill	1,602,522	1,602,522	1,602,522
Intangible assets	1,233,184	1,489,598	1,329,188
Property, plant and equipment	-	-	-
Right-of-use assets	17,136	-	20,995
	2,852,842	3,092,120	2,952,705
CURRENT ASSETS			
Trade and other receivables	27,414	100,805	66,735
Tax receivable	35,000	351,787	71,346
Cash and cash equivalents	1,239,035	258,753	1,846,901
	1,301,449	711,345	1,984,982
TOTAL ASSETS	4,154,291	3,803,465	4,937,687
SHAREHOLDERS' EQUITY			
Share capital	9,669,995	9,641,009	9,669,828
Share premium account	24,401,856	21,598,766	24,380,356
Merger reserve	637,500	637,500	637,500
Reverse acquisition reserve	602,413	602,413	602,413
Share option reserve	484,088	992,252	540,803
Retained earnings	(31,606,191)	(30,534,899)	(30,919,728)
	4,189,661	2,937,041	4,911,172
Non-controlling interest	(163,144)	(150,254)	(155,888)
TOTAL EQUITY	4,026,517	2,786,787	4,755,284

LIABILITIES			
NON-CURRENT LIABILITIES			
Borrowings	40,473	50,000	44,486
Lease liabilities	9,576	-	13,439
	50,049	50,000	57,925
CURRENT LIABILITIES			
Trade and other payables	60,506	772,897	111,342
Borrowings	9,527	193,781	5,514
Lease liabilities	7,692	-	7,622
	77,725	966,678	124,478
TOTAL LIABILITIES	127,774	1,016,678	182,403
TOTAL EQUITY AND LIABILITIES	4,154,291	3,803,465	4,937,687

Consolidated statement of changes in shareholders' equity

	Share capital £	Share premium £	Retained earnings £	Merger reserve £	Share-based payment reserve £	Reverse acquisition reserve £	Non-controlling interest £	Total £
Unaudited								
Balance at 1 January 2021	9,669,828	24,380,356	(30,919,728)	637,500	540,803	602,413	(155,888)	4,755,284
Loss for the period	-	-	(743,178)	-	-	-	(7,256)	(750,434)
Issue of shares	167	21,500	-	-	-	-	-	21,667
Lapse of share warrants	-	-	56,715	-	(56,715)	-	-	-
Balance at 30 June 2021	9,669,995	24,401,856	(31,606,191)	637,500	484,088	602,413	(163,144)	4,026,517
Unaudited								
Balance at 1 January 2020	9,417,225	20,596,143	(29,729,817)	637,500	830,449	602,413	(130,813)	2,223,100
Loss for the period	-	-	(805,082)	-	-	-	(19,441)	(824,523)
Issue of shares	223,784	1,260,384	-	-	-	-	-	1,484,168
Costs of shares issued	-	(95,958)	-	-	-	-	-	(95,958)
Share-based payment movement	-	(161,803)	-	-	161,803	-	-	-
Balance at 30 June 2020	9,641,009	21,598,766	(30,534,899)	637,500	992,252	602,413	(150,254)	2,786,787
Audited								
Balance at 1 January 2020	9,417,225	20,596,143	(29,729,817)	637,500	830,449	602,413	(130,813)	2,223,100
Loss for the year	-	-	(1,443,248)	-	-	-	(25,075)	(1,468,323)
Issue of shares	252,603	3,993,579	-	-	-	-	-	4,246,182
Costs of shares issued	-	(245,675)	-	-	-	-	-	(245,675)
Exercise of warrants	-	50,447	-	-	(50,447)	-	-	-
Lapse of share options	-	-	253,337	-	(253,337)	-		-
Share-based payment movement	-	(14,138)	-	-	14,138	-	-	-
Balance at 31 December 2020	9,669,828	24,380,356	(30,919,728)	637,500	540,803	602,413	(155,888)	4,755,284

Consolidated cash flow statement

	Six months ended 30 June		Year ended 31 December
	2021 *(unaudited)* £	2020 *(unaudited)* £	2020 *(audited)* £
Cash flows from operating activities			
Operating loss	(784,026)	(881,292)	(1,650,625)
Amortisation of intangible fixed assets	104,843	83,723	227,338
Depreciation of right-of-use assets	3,859	-	2,157
Decrease/(increase) in receivables	39,321	(10,722)	23,348
(Decrease)/increase in payables within one year	(50,836)	(325,019)	(957,274)
Loss on disposal of intangible assets	-	118,000	154,968
Net cash outflows from operations	(686,839)	(1,015,310)	(2,200,088)
Tax credit received	71,346	-	295,623
Interest paid	(701)	(3,231)	(6,252)
Net cash outflow from operating activities	(616,194)	(1,018,541)	(1,910,717)
Cash flows from investing activities			
Purchase of intangible fixed assets	(8,839)	(73,114)	(93,287)
Proceeds from sale of intangible assets	-	2,000	2,000
Net cash outflow from investing activities	(8,839)	(71,114)	(91,287)
Cash flows from financing activities			
Share issue	21,667	1,400,000	4,132,714
Costs of shares issued	-	(95,958)	(245,675)
Repayment of lease liabilities	(4,500)	-	(2,500)
Bank loan	-	50,000	50,000
Repayment of loan notes	-	-	(80,000)
Net cash generated from financing activities	17,167	1,354,042	3,854,539
Net (decrease)/increase in cash and cash equivalents	(607,866)	264,387	1,852,535
Cash and cash equivalents at start of period	1,846,901	(5,634)	(5,634)
Cash and cash equivalents at end of period	1,239,035	258,753	1,846,901

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 2021 and 2020 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 2020 has been derived from the audited financial statements for that period. A copy of those statutory financial statements for the year ended 31 December 2020 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 2021 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 2021 and which are also consistent with those set out in the statutory accounts of the Group for the year ended 31 December 2020.

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 2021 *(unaudited)* £	**Six months ended 30 June** 2020 *(unaudited)* £	**Year ended 31 December** 2020 *(audited)* £
United Kingdom corporation tax at 19%			
Current period - R & D Tax credit	(35,000)	(60,000)	(71,346)
Prior period - R & D Tax credits	-	-	(3,836)
Income tax credit	(35,000)	(60,000)	(75,182)

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 2021 *(unaudited)*	**Six months ended 30 June** 2020 *(unaudited)*	**Year ended 31 December** 2020 *(audited)*
Basic:			
Loss for the financial period	(750,434)	(824,523)	(1,468,323)
Non-controlling interest	7,256	19,441	25,075
	(743,178)	(805,082)	(1,443,248)
Weighted average number of shares	65,004,957	18,191,261	37,898,019
Loss per share	(1.14)p	(4.43)p	(3.81)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.

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