RNS Number : 8818F
ValiRx PLC
27 September 2024

VALIRX PLC

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

HALF YEARLY REPORT FOR THE PERIOD ENDED 30 JUNE 2024

London, UK., 2024: 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 2023 and provides an update on significant post-period events.

HIGHLIGHTS

Operational Highlights

- First US customer signed for Inaphaea tCRO® in multistage deal
- Development of Inaphaea Biobank to include 2D and 3D Patient derived cell models
- Signature of collaboration service agreements for Inaphaea with DefiniGen
- Overarching evaluation agreement signed with Dundee University with first project on pro-senescence initiated
- Second new evaluation project signed with Imperial College centred on drug resistant ovarian cancer
- Cytolytix evaluation in prostate cancer with Open University

Financial Highlights

- Research and developments costs (excluding employee costs) £121,490 (2023: £207,721)
- Administrative expenses £947,565 (2023: £925,866)
- Share-based payment charge £18,994 (2023: £17,733)
- Loss before income taxation of £1,052,006 (2023: £1,152,325)
- Total comprehensive loss for the period of £970,908 (2023: £1,035,424)
- Loss per share from continuing operations of 0.74p (2023: Loss 1.03p)
- Cash and cash equivalents at 30 June 2024 of £809,147 (2023: £891,246)

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 *****

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Notes for Editors
About ValiRx

ValiRx is a life science company focused on early-stage cancer therapeutics and women's health, accelerating the translation of innovative science into impactful medicines to improve patient lives.

ValiRx provides the scientific, financial, and commercial framework for enabling rapid translation of innovative science into clinical development.

Using its extensive and proven experience in research and drug development, the team at ValiRx selects and incubates promising novel drug candidates and guides them through an optimised process of development, from pre-clinical studies to clinic and investor-ready assets.

ValiRx connects diverse disciplines across scientific, technical, and commercial domains, with the aim of achieving a more streamlined, less costly, drug development process. The team works closely with carefully selected collaborators and leverages the combined expertise required for science to advance.

Lead candidates from ValiRx's portfolio are outlicensed or partnered with investors through ValiRx subsidiary companies for further clinical development and commercialisation.

ValiRx listed on the AIM Market of the London Stock Exchange in October 2006 and trades under the ticker symbol: VAL.

For further information, visit: www.valirx.com

CHAIRMAN'S STATEMENT FOR THE HALF YEAR ENDED 30 JUNE 2024

During the period significant changes have occurred to the management of the Company. Stella Panu stepped down and I joined the board as a non-executive director along with Adrian de Courcey. Suzanne Dilly stepped down as CEO after 10 years of service to the Company, and Mark Eccleston was appointed as her replacement. With Kevin Cox standing down as a director and Chairman I have now recently been appointed as chairman. Additionally, Cathy Tralau-Stewart, has been appointed to the executive board whilst continuing her duties as CSO.

The primary objective for these board changes was to bring additional commercial and business development experience to the Company as ValiRx looks to refocus its commercial strategy. As well as a renewed commitment to the development of therapeutic assets, ValiRx also intends to realise the potential of the assets within its translational Contract Research Organisation ("tCRO®") subsidiary, Inaphaea BioLabs Limited ("Inaphaea"). As part of a strategic review, Inaphaea expanded its business development activities into the immune oncology space and began to target the US markets, having previously focussed mainly in the domestic and European markets. ValiRx signed its first immune-oncology service contract in June 2024 with a multi-stage service agreement which leveraged the primary asset of Inaphaea, its Patient Derived Cell bank and associated data in conjunction with the deep technical expertise of its scientific team to develop a detailed proposal for the US based client.

Throughout the first half of the year, the Inaphaea team have worked diligently to develop the cell bank offering, not only for services, but also to service growing interest in the cells and their derivatives as products. Inaphaea's collaborative partnered capabilities now include in-silico toxicity testing and in-vitro toxicity testing.

ValiRx is renewing its focus on asset development as it sees this as its core purpose. The R&D team continue their work on two new evaluation projects from Dundee University and Imperial College alongside the ongoing Stingray evaluation whilst we are evaluating the results of the Barcelona collaboration with the academic team. We remain focussed on building a strong portfolio of evaluation projects and directing funds to the most positive projects as we seek the best assets to in-license into our next Special Purpose Vehicle (SPV). Work on new Cytolytix formulations in an increased range of cancers is ongoing and builds on new collaborations with non-dilutive funding from the Open University through its Knowledge transfer Voucher scheme.

The commercial and technical progress made in the first half of 2024 has been positive despite funding restrictions and difficult market conditions, which remain challenging. The Company anticipates additional short-term income from both service and product offerings through Inaphaea and we will continue to leverage our biobank resources and collaboration partnerships to advance ValiRx's development programs as efficiently as possible.

Alongside its ongoing fiscal prudence, the Company will implement further cost savings through streamlining and resource management to ensure its cash is focused on supporting its development assets.

Martin Gouldstone
26 September 2024

CHIEF EXECUTIVE OFFICER'S STATEMENT FOR THE HALF YEAR ENDED 30 JUNE 2024

In my first Chief Executive's Interim report, I am reporting on the final period overseen by the previous CEO Dr Suzanne Dilly.

Over the first half of 2024 Inaphaea has delivered on two key objectives.

The first is to service the expanding internal ValiRx pipeline. This has been achieved through provision of rapid and flexible initial assessment for each of the evaluation projects as well as a significant amount of development work for Cytolytix. In addition, the partner network established as part of the tCRO® service offering has been utilised for peptide formulation of CL X001 and in-silico toxicity screening of the Stingray compounds.

As part of its second objective, revenue generation, Inaphaea broadened its marketing activities into the US. The Bio International Convention generated 23 leads as part of an expanding deal pipeline. In the same month, the first US customer signed up with a multi-stage, revenue generating contract leveraging both RNA-sequence data and bespoke screening using Inaphaea's Patient Derived Cell (PDC) bank. The deal was enabled by the scientific

insight and technical expertise of the Inaphaea team and addresses the rapidly growing immune-oncology sector of the market. The specialist services required by the client builds on the PDC cells to provide both 2 dimensional and 3-dimensional cell systems grown in co-culture with human immune cells to model human disease states.

Evaluation projects:

Barcelona University

Work on the KRAS(2) program, carried out under our over-arching evaluation agreement with Barcelona University, was completed on time in June 2024 andthe results are being evaluated with the academic team.

Post period, on reflection of the initial promising results, the development programme was deemed to be still at an early stage, and the Company has decided to return the project to the university researchers for further development, with no further financial commitment from the Company currently in place.

The University of Barcelona is currently receiving grant funding for both "KRAS1" and "KRAS2" projects and the broader collaboration agreement will enable the Company to review the data produced during these grant periods as well as other programmes of interest within the research group, for commercial potential until the expiry of the agreement in 2027. This is in line with ValiRx's objective of directing funds to assets most likely to progress rapidly and deliver value for its shareholders.

Stingray

Several compounds have been provided by Stingray across multiple series and initial work has been carried out to assess efficacy against a range of cell lines, including Inaphaea's Patient Derived Cells. In-silico screening has been performed with our partner Ignota Labs to identify potential toxicity issues which will be addressed during a round of chemical optimisation.

Two further evaluations projects were initiated in the first half of 2024.

Dundee University

The Company entered into an over-arching evaluation agreement with Dundee University and the first asset to be evaluated is a class of pro-senescence inducing compounds. Senescence in a state in which cells stop dividing and pro-senescence drugs can be used in combination with "senolytic" compounds or immune activation in order to remove the senescent cells. As such, pro-senescence drugs offer natural partnering opportunities for commercialisation. Several compounds across multiple series provided by Dundee have been screened using an assay developed at Dundee and transferred to our tCRO® Inaphaea. This process is being used to identify the best compound to take forward into in-silico screening to better understand the mechanism of action.

Imperial College

Chemical synthesis of the lead molecules was commissioned in March 2024 and preliminary efficacy testing has been performed at Inaphaea. A drug-resistant cancer cell line is being developed at Inaphaea to support the project which has cis-platin resistant ovarian cancer as its primary indication.

Further Evaluation Projects

The Company maintains active surveillance of opportunities across a range of established collaborators, through partnering meetings and from direct approaches. It is essential to maintain an active pipeline to account for high attrition within the evaluation process. Further negotiations are underway with a view to securing up to 2 new programmes by year end.

Clinical Stage Assets

VAL201 currently remains subject to the Letter of Intent ("LoI") with TheoremRx Inc, who maintain they are focussed on securing the financing to enable the VAL201 sub-license to complete.

VAL401 is currently under an option agreement with Ambrose Healthcare which will expire at the end of 2024. Ambrose remains committed to progress VAL401 through remaining clinical development and commercialisation and the Company looks forward to progressing this asset in the second half of the year.

Preclinical Stage Assets

CLX001 has been developed into freeze dried nanoformulation, an essential step for continued evaluation. Biological activity has been confirmed in Inaphaea's lab using a range of cell lines. Cytolytix also received funding for a pilot study in prostate cancer cells via a collaboration with the Open University. Encouragingly, the results demonstrated increased activity of CLX001 under low oxygen conditions often seen within tumours. This collaboration has led to additional non-dilutive grant funding applications in prostate cancer and is a good opportunity to expand evaluation of our therapeutic approaches outside of our internal women's health focus.

Additional formulation options are being examined with the aim of identifying application specific versions to target various routes of administration. Once the lead formulation has been confirmed as being biologically active, a full programme of preclinical development including manufacturing, toxicology, disease impact and regulatory activities will be pursued.

Opportunities for early partnering are being explored for Cytolytix, with active commercial development to promote the project to potential industry partners.

ValiRx is prioritising its resources towards completing the current round of evaluation programmes and selecting the next asset to in-license, in order to best direct the efforts of our lab team.

VAL301 *in vitro* preclinical testing is currently on hold whilst we clarify the position around VAL201.

BC201 assessment in the collaboration between Black Cat Bio Limited and Oncolytika has also been put on hold.

Dr Mark Eccleston
26 September 2024

ValiRx Plc
Consolidated statement of comprehensive income

	Note	Six months ended 30 June 2024 (unaudited) £	Six months ended 30 June 2023 (unaudited) £	Year ended 31 December 2023 (audited) £
Continuing operations				
Revenue		-	-	9,600
Cost of sales		-	-	(1,440)
Gross profit		-	-	8,160
Continuing operations				

Research and development		(121,490)	(207,721)	(383,362)
Administrative expenses		(947,565)	(925,866)	(1,886,401)
Share-based payment charge		(18,994)	(17,733)	(36,936)
Operating loss		(1,088,049)	(1,151,320)	(2,298,539)
Other income		30,000	-	-
Loss before interest		(1,058,049)	(1,151,320)	(2,298,539)
Finance income		6,291	-	-
Finance costs		(248)	(1,005)	(4,419)
Loss before income taxation		(1,052,006)	(1,152,325)	(2,302,958)
Income tax credit	2	52,290	90,000	175,173
Loss on ordinary activities after taxation		(999,716)	(1,062,325)	(2,127,785)
Non-controlling interests		28,808	26,901	90,084
Loss for the period and total comprehensive income attributable to owners of the parent		(970,908)	(1,035,424)	(2,037,701)
Loss per share - basic and diluted				
From continuing operations	3	(0.74)p	(1.03)p	(2.01)p

ValiRx Plc
Consolidated statement of financial position

	As at 30 June		31 December
	2024 *(unaudited)* £	2023 *(unaudited)* £	2023 *(audited)* £
ASSETS			
NON-CURRENT ASSETS			
Goodwill	1,602,522	1,602,522	1,602,522
Intangible assets	623,262	818,097	718,814
Property, plant and equipment	231,901	274,744	242,625
Right-of-use assets	-	1,702	-
Investments	30,000	-	-
	2,487,685	2,697,065	2,563,961
CURRENT ASSETS			

Inventory	69,002	-	69,002
Trade and other receivables	99,190	201,368	147,618
Tax receivable	227,463	282,671	175,173
Cash and cash equivalents	809,147	891,246	174,684
	1,204,802	1,375,285	566,477
TOTAL ASSETS	3,692,487	4,072,350	3,130,438
SHAREHOLDERS' EQUITY			
Share capital	9,737,295	9,707,266	9,707,266
Share premium account	29,422,094	27,873,048	27,870,548
Merger reserve	637,500	637,500	637,500
Reverse acquisition reserve	602,413	602,413	602,413
Share-based payment reserve	1,101,157	1,062,960	1,082,163
Retained earnings	(37,652,248)	(35,679,063)	(36,681,340)
	3,848,211	4,204,124	3,218,550
Non-controlling interest	(343,431)	(251,440)	(314,623)
TOTAL EQUITY	3,504,780	3,952,684	2,903,927
LIABILITIES			
NON-CURRENT LIABILITIES			
Borrowings	6,653	16,818	11,857
	6,653	16,818	11,857
CURRENT LIABILITIES			
Trade and other payables	170,712	90,830	204,441
Borrowings	10,342	10,264	10,213
Lease liabilities	-	1,754	-
	181,054	102,848	214,654
TOTAL LIABILITIES	187,707	119,666	226,511
TOTAL EQUITY AND LIABILITIES	3,692,487	4,072,350	3,130,438

ValiRx Plc
Consolidated statement of changes in shareholders' equity

	Share capital	Share premium	Retained earnings	Merger reserve	pa r
	£	£	£	£	
Unaudited					
Balance at 1 January 2024	9,707,266	27,870,548	(36,681,340)	637,500	1,(
Loss for the period	-	-	(970,908)	-	
Issue of shares	30,029	1,771,715	-	-	
Costs of shares issued	-	(220,169)	-	-	
Share-based payment movement	-		-	-	
Balance at 30 June 2024	9,737,295	29,422,094	(37,652,248)	637,500	1,(
Unaudited					
Balance at 1 January 2023	9,695,120	26,772,630	(34,643,639)	637,500	
Loss for the period	-	-	(1,035,424)	-	
Issue of shares	12,146	1,287,854	-	-	
Costs of shares issued	-	(129,025)	-	-	
Share-based payment movement	-	(58,411)	-	-	
Balance at 30 June 2023	9,707,266	27,873,048	(35,679,063)	637,500	1,(
Audited					
Balance at 1 January 2023	9,695,120	26,772,630	(34,643,639)	637,500	
Loss for the year	-	-	(2,037,701)	-	
Issue of shares	12,146	1,323,854	-	-	
Costs of shares issued	-	(167,525)	-	-	
Movement in year	-	(58,411)	-	-	
Balance at 31 December 2023	9,707,266	27,870,548	(36,681,340)	637,500	1,(

ValiRx Plc
Consolidated cash flow statement

	Six months ended 30 June		Year ended 31 December
	2024 *(unaudited)* £	2023 *(unaudited)* £	2023 *(audited)* £
Cash flows from operating activities			
Operating loss	(1,058,049)	(1,151,320)	(2,298,539)
Depreciation of property plant and equipment	38,636	13,558	48,556
Amortisation of intangible fixed assets	95,552	100,803	200,086
Depreciation of right-of-use assets	-	3,859	5,561
Increase in inventory	-	-	(69,002)
Decrease/(increase)in receivables	48,428	(67,552)	(13,803)
(Decrease)/increase in payables within one year	(33,729)	(21,103)	128,508
Share-based payment charge	18,994	17,733	36,936
Net cash outflows from operations	(890,168)	(1,104,022)	(1,961,697)
Tax credit received	-	-	192,671
Interest paid	(248)	(432)	(3,325)
Net cash outflow from operating activities	(890,416)	(1,104,454)	(1,772,351)
Cash flows from investing activities			
Purchase of intangible fixed assets	-	(15,000)	(15,000)
Purchase of investments	(30,000)	-	-
Purchase of property plant and equipment	(27,912)	(288,302)	(291,181)
Interest received	6,291	-	-
Net cash outflow from investing activities	(51,621)	(303,302)	(306,181)
Cash flows from financing activities			
Share issue	1,801,744	1,300,000	1,300,000
Costs of shares issued	(220,169)	(129,025)	(167,525)
Repayment of lease liabilities	-	(4,500)	(6,774)
Bank loan	(5,075)	(4,950)	(9,962)
Net cash generated from financing activities	1,576,500	1,161,525	1,115,739

Net increase/(decrease)in cash and cash equivalents	634,463	(246,231)	(962,793)
Cash and cash equivalents at start of period	174,684	1,137,477	1,137,477
Cash and cash equivalents at end of period	809,147	891,246	174,684

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.

The principal activity of Valirx Plc and its subsidiaries is the development of oncology therapeutics and companion diagnostics.

Financial information

The interim financial information for the six months ended 30 June 2024 and 2023 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 2023 has been derived from the audited financial statements for that period. A copy of those statutory financial statements for the year ended 31 December 2023 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 statementshave 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 2023 and as applied in accordance with the provisions of the Companies Act 2006and 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 2024 and which are alsoconsistent with those set out in the statutory accounts of the Group for the year ended 31 December 2023.

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	**Six months ended 30 June**	**Year ended 31 December**
	2024 *(unaudited)* £	2023 *(unaudited)* £	2023 *(audited)* £
United Kingdom corporation tax at effective rate of tax of25% (2023: 23.5%)			
Current period - R & D Tax credit	(62,000)	(90,000)	(175,173)
Prior period - R & D Tax credits	9,710	-	-
Income tax credit	(52,290)	(90,000)	(175,173)

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 2024 (unaudited)	Six months ended 30 June 2023 (unaudited)	Year ended 31 December 2023 (audited)
Basic:	£	£	£
Loss for the financial period	(999,716)	(1,062,325)	(2,127,785)
Non-controlling interest	28,808	26,901	90,084
	(970,908)	(1,035,424)	(2,037,701)
Weighted average number of shares	131,193,709	100,808,008	101,570,021
Loss per share	(0.74)p	(1.03)p	(2.01)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.

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