



VALIRX PLC

(“ValiRx”, “the Company” or “the Group”)

HALF YEARLY REPORT FOR THE PERIOD ENDED 30 JUNE 2023

London, UK., 2023: ValiRx Plc (AIM: VAL), a life science company, focussing on early-stage cancer therapeutics and women's health, today announces its Half Yearly Report for the period ended 30 June 2023 and provides an update on significant post-period events.

HIGHLIGHTS

Operational

- Launch of wholly owned subsidiary, Inaphaea BioLabs Limited (“Inaphaea”), with post-period event of first external sales
- Acquisition of scientific assets of Imagen Therapeutics Limited (“Imagen Therapeutics”)
- Signature of collaboration service agreements for Inaphaea with Physiomics PLC (“Physiomics”), OncoBone Limited (“OncoBone”), and post-period with Agility Life Sciences Limited (“Agility”)
- Expansion of evaluation agreement with the University of Barcelona to enable study of a second KRAS project and to establish standard terms for future agreements

Financial

- Research and developments costs £207,721 (2022: £200,531)
- Administrative expenses £925,866 (2022: £611,370)
- Share-based payment charge £17,733 (2022: £261,052)
- Total comprehensive loss for the period of £1,035,424 (2022: £992,481)
- Loss before income taxation of £1,152,325 (2022: £1,074,784)
- Expenditure in H1 includes one-off costs associated with the set-up of Inaphaea and acquisition of Imagen assets
- Loss per share from continuing operations of 1.03p (2022: Loss 1.53p)
- Cash and cash equivalents at 30 June 2023 of £891,246 (2022: £97,699)
- Post period receipt of the FY22 R&D tax credits of £192,671 (2021: £133,413)

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.

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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 2023

Having shifted the tCRO® strategy towards a build-and-buy approach in the latter part of 2022, the primary activity in the first half of 2023 has been to establish in-house, cell-based testing capabilities to support both our collaborative development pipeline and generate income through third-party business.

The outcome of this has been the launch of a wholly owned subsidiary, Inaphaea, which has been set up and become operational at a fraction of the cost of acquiring a company with existing infrastructure. The business is already developing a strong pipeline of potential customers and successfully completed its first deal quickly after launch, a testament to the hard work of all those involved in the lab set up, business development and operations.

The launch of Inaphaea and subsequent successful acquisition of the scientific assets of Imagen Therapeutics was made possible through the funds raised in 2022 and the placing and broker offer in January 2023.

Following its launch, Inaphaea has continued to build the tCRO® concept by developing collaborations with companies that provide complementary capabilities, such as Physiomics, Oncobone and, more recently, Agility Life Sciences. Their services, when aligned with the cell-based testing of Inaphaea, present a very compelling service offering to companies seeking to translate preclinical assets into clinical candidates, including ValiRx's own development pipeline.

The ValiRx R&D team are continuing to build a risk-balanced portfolio of novel science in oncology and women's health, with a number of potential candidates in late-stage discussions. Building and funding a strong portfolio of evaluation projects also means that not all the science will meet our rigorous selection criteria, as evidenced by the conclusion of the Hokkaido project as announced on 16 June 2023. The benefit of such decisions is that funds can be re-directed towards projects that may have a greater chance of success and value creation for shareholders, such as the expansion of the Barcelona evaluation agreement to investigate new drug candidates in oncology, as announced on 7 June 2023.

The continued progress of ValiRx during the first half of 2023 has been encouraging. However, this has been against the backdrop of challenging market conditions, with the biotechnology sector in general suffering from a change in sentiment in a post-Covid world. Although there are expectations of additional income from Inaphaea, the Company will be managing its resources in the most efficient manner to maintain momentum over the next period.

Kevin Cox

Chairman

24 August 2023

CHIEF EXECUTIVE OFFICER'S STATEMENT FOR THE HALF YEAR ENDED 30 JUNE 2023

The key event for ValiRx in the first half of 2023 was the launch of our service-providing subsidiary, Inaphaea. A wholly owned subsidiary, Inaphaea is intended to be central to our designs for a translational Contract Research Organisation (tCRO®) offering capabilities to the ValiRx internal pipeline projects as well as to third party, fee-for-service clients.

Initially offering a cell-based assay capability, Inaphaea's intention is to incorporate and validate a suite of in vitro and in silico testing technologies to enhance the central ethos of building strong preclinical evidence to de-risk the later stages of drug development. Focussing on reproducibility, translatability (suitability for later and clinical stages of development), and humanisation of preclinical science, Inaphaea's tCRO® offering is intended to occupy a high value segment of the market.

In June 2023, the establishment of Inaphaea's initial service offering was substantially accelerated by the acquisition of the scientific assets of Imagen Therapeutics. These assets included several high specification items of equipment, providing Inaphaea with capabilities around partial automation and live imaging during cell-based assays. Additionally, a biobank of patient derived cancer cells, consisting of over 500 unique samples was included, enabling Inaphaea to take the first step towards improving humanisation and relevance of the cell-based assays on offer. Soon after, the first external customer was signed up, with an initial multi-stage, defined project taking place between July and September.

In order to build out the service offering within Inaphaea, several collaboration agreements have already been set up, with others currently proposed and under negotiation. This includes the collaboration with Physiomics to offer biological modelling and advanced data analysis; with Agility to offer pre-formulation and formulation assessments and with OncoBone to enable Inaphaea to be incorporated into their virtual CRO offering. Inaphaea has also successfully listed on the Scientist.com database to increase visibility to a larger field of potential clients.

Throughout this period work has also continued to advance the ValiRx internal pipeline of research, with current projects progressing to expected milestones, and new projects sought. These are detailed individually below.

Evaluation Projects:

Hokkaido University

The project under Evaluation from Hokkaido University completed its evaluation period in June 2023. The data did not support the launch of the full in-licensing process for this project at this time, so we returned all the data to the originating academics along with our suggestions for their further development. We intend to maintain a relationship with the University to assess other programmes, or to re-assess this programme in the future.

Barcelona University

On completion of the evaluation programme from the University of Barcelona, we were delighted to share the news that the University has been awarded further funding to develop the project in their own group. Barcelona University has a number of research groups working on areas of interest to ValiRx, and we have agreed an overarching agreement that states standard terms on which we can commence evaluations on subsequent projects; with the first of these being a further KRAS project. KRAS(2) consists of a lead series of molecules that bind to a different proposed binding domain of KRAS, with our evaluation considering the activity of a selection of molecules from the lead series.

Further Evaluation Projects

With an ambition to secure 3-4 new evaluation projects every year, we have been focussing substantial effort on identifying and qualifying further assets that meet our criteria to build a diversified preclinical project pipeline.

Clinical Stage Assets

VAL201 remains subject to the Letter of Intent ("LoI") with TheoremRx Inc, and we maintain good lines of communications with the TheoremRx team to ensure that they are focussed on securing the financing which will enable the VAL201 sub-license to complete.

In June 2023, we announced the carve-out of the Greater China region from the exclusivity clause in the TheoremRx letter of intent. This enables us to re-commence active marketing of the project in this region in order to explore additional lines of revenue.

VAL401 is subject to an intensive business development programme with an external provider of partnering services who are exploring options around partners focussed on oncology and supportive care.

Preclinical Stage Assets

CLX001 was placed in the single asset subsidiary company, Cytolytix Limited ("Cytolytix") in Q4 2022, and has undergone a programme of formulation development during the first half of 2023. The peptide active ingredient requires a nanoformulation to ensure that the peptide is delivered to cancer cells at appropriate levels and to stabilise the active ingredient within the therapeutic agent with the lead formulation now proposed and undergoing testing in the Inaphaea facility.

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.

VAL301 *in vitro* preclinical optimisation is ongoing within the Inaphaea tCRO® facility, with variations of the molecule being studied for impact on growth rates of estrogen dependent cells under a variety of stimulatory conditions. These assays will determine whether an alternative molecular structure can improve the potential for disease modifying impact for endometriosis, as well as offering the potential for new patent filings to refresh the intellectual property portfolio surrounding the project.

BC201 remains in assessment in the collaboration between Black Cat Bio Limited and Oncolytika, with preclinical assessments considering the impact of the active ingredient against viral infections and immune responses.

Dr S J Dilly

CEO

24 August 2023

ValiRx Plc

Consolidated statement of comprehensive income

	Six months ended 30 June	Six months ended 30 June	Year ended 31 December
Note	2023 (unaudited) £	2022 (unaudited) £	2022 (audited) £
Continuing operations			
Research and development	(207,721)	(200,531)	(551,233)
Administrative expenses	(925,866)	(611,370)	(1,502,355)
Share-based payment charge	(17,733)	(261,052)	(539,791)
	<u>(1,151,320)</u>	<u>(1,072,953)</u>	<u>(2,593,379)</u>
Operating loss	(1,151,320)	(1,072,953)	(2,593,379)
Finance costs	(1,005)	(1,831)	(5,456)
	<u>(1,152,325)</u>	<u>(1,074,784)</u>	<u>(2,598,835)</u>
Loss before income taxation	(1,152,325)	(1,074,784)	(2,598,835)
Income tax credit	90,000	70,000	192,671
	<u>(1,062,325)</u>	<u>(1,004,784)</u>	<u>(2,406,164)</u>
Loss on ordinary activities after taxation	(1,062,325)	(1,004,784)	(2,406,164)
Non-controlling interests	26,901	12,303	39,676
	<u>(1,035,424)</u>	<u>(992,481)</u>	<u>(2,366,488)</u>
Loss for the period and total comprehensive income attributable to owners of the parent	(1,035,424)	(992,481)	(2,366,488)
Loss per share - basic and diluted			
From continuing operations	(1.03)p	(1.53)p	(3.06)p

ValiRx Plc

Consolidated statement of financial position

	As at 30 June		31 December
	2023	2022	2022
	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(audited)</i>
	£	£	£
ASSETS			
NON-CURRENT ASSETS			
Goodwill	1,602,522	1,602,522	1,602,522
Intangible assets	818,097	1,007,770	903,900
Property, plant and equipment	274,744	-	-
Right-of-use assets	1,702	9,278	5,561
	2,697,065	2,619,570	2,511,983
CURRENT ASSETS			
Trade and other receivables	201,368	79,291	133,815
Tax receivable	282,671	203,413	192,671
Cash and cash equivalents	891,246	97,699	1,137,477
	1,375,285	380,403	1,463,963
TOTAL ASSETS	4,072,350	2,999,973	3,975,946
SHAREHOLDERS' EQUITY			
Share capital	9,707,266	9,669,995	9,695,120
Share premium account	27,873,048	24,519,456	26,772,630
Merger reserve	637,500	637,500	637,500
Reverse acquisition reserve	602,413	602,413	602,413
Share-based payment reserve	1,062,960	723,433	986,816
Retained earnings	(35,679,063)	(33,284,988)	(34,643,639)
	4,204,124	2,867,809	4,050,840
Non-controlling interest	(251,440)	(197,170)	(224,539)
TOTAL EQUITY	3,952,684	2,670,639	3,826,301
LIABILITIES			
NON-CURRENT LIABILITIES			
Borrowings	16,818	28,056	22,070
Lease liabilities	-	2,486	-
	16,818	30,542	22,070
CURRENT LIABILITIES			
Trade and other payables	90,830	281,955	111,933
Borrowings	10,264	9,747	9,962
Lease liabilities	1,754	7,090	5,680
	102,848	298,792	127,575
TOTAL LIABILITIES	119,666	329,334	149,645
TOTAL EQUITY AND LIABILITIES	4,072,350	2,999,973	3,975,946

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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
	£	£	£	£	£	£	£	£
<i>Unaudited</i>								
Balance at 1 January 2023	9,695,120	26,772,630	(34,643,639)	637,500	986,816	602,413	(224,539)	3,826,301
Loss for the period	-	-	(1,035,424)	-	-	-	(26,901)	(1,062,325)
Issue of shares	12,146	1,287,854	-	-	-	-	-	1,300,000
Costs of shares issued	-	(129,025)	-	-	-	-	-	(129,025)
Share-based payment movement	-	(58,411)	-	-	76,144	-	-	17,733
Balance at 30 June 2023	9,707,266	27,873,048	(35,679,063)	637,500	1,062,960	602,413	(251,440)	3,952,684
<i>Unaudited</i>								
Balance at 1 January 2022	9,669,995	24,490,618	(32,292,507)	637,500	491,219	602,413	(184,867)	3,414,371
Loss for the period	-	-	(992,481)	-	-	-	(12,303)	(1,004,784)
Lapse of share options and warrants	-	28,838	-	-	(28,838)	-	-	-
Share-based payment movement	-	-	-	-	261,052	-	-	261,052
Balance at 30 June 2022	9,669,995	24,519,456	(33,284,988)	637,500	723,433	602,413	(197,170)	2,670,639
<i>Audited</i>								
Balance at 1 January 2022	9,669,995	24,490,618	(32,292,507)	637,500	491,219	602,413	(184,867)	3,414,371
Loss for the year	-	-	(2,366,488)	-	-	-	(39,676)	(2,406,164)
Issue of shares	25,125	2,462,250	-	-	-	-	-	2,487,375
Costs of shares issued	-	(209,076)	-	-	-	-	-	(209,076)
Lapse of share options and warrants	-	28,838	15,356	-	(44,194)	-	-	-
Movement in year	-	-	-	-	539,791	-	4	539,795
Balance at 31 December 2022	9,695,120	26,772,630	(34,643,639)	637,500	986,816	602,413	(224,539)	3,826,301

ValiRx Plc

Consolidated cash flow statement

	Six months ended 30 June		Year ended 31 December
	2023 <i>(unaudited)</i> £	2022 <i>(unaudited)</i> £	2022 <i>(audited)</i> £
Cash flows from operating activities			
Operating loss	(1,151,320)	(1,072,953)	(2,593,379)
Depreciation of property plant and equipment	13,558	-	-
Amortisation of intangible fixed assets	100,803	102,850	204,216
Depreciation of right-of-use assets	3,859	4,000	7,717
(Increase) in receivables	(67,552)	(6,366)	(60,886)
(Decrease)/increase in payables within one year	(21,103)	231,120	61,098
Share-based payment charge	17,733	261,052	539,791
Net cash outflows from operations	(1,104,022)	(480,297)	(1,841,443)
Tax credit received	-	-	133,413
Interest paid	(432)	(1,702)	(4,215)
Net cash outflow from operating activities	(1,104,454)	(481,999)	(1,712,245)
Cash flows from investing activities			
Purchase of intangible fixed assets	(15,000)	(2,504)	-
Purchase of property plant and equipment	(288,302)	-	-
Net cash outflow from investing activities	(303,302)	(2,504)	-
Cash flows from financing activities			
Share issue	1,300,000	-	2,487,375
Costs of shares issued	(129,025)	-	(209,076)
Repayment of lease liabilities	(4,500)	(4,500)	(9,000)
Bank loan	(4,950)	(6,970)	(13,249)
Net cash generated from/(used in) financing activities	1,161,525	(11,470)	2,256,050
Net (decrease)/increase in cash and cash equivalents	(246,231)	(495,973)	543,805
Cash and cash equivalents at start of period	1,137,477	593,672	593,672
Cash and cash equivalents at end of period	891,246	97,699	1,137,477

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 Group 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 2023 and 2022 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 2022 has been derived from the audited financial statements for that period. A copy of those statutory financial statements for the year ended 31 December 2022 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 2023 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 2023 and which are also consistent with those set out in the statutory accounts of the Group for the year ended 31 December 2022.

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
	2023	2022	2022
	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(audited)</i>
	£	£	£
United Kingdom corporation tax at 25% (2022: 19%)			
Current period - R & D Tax credit	<u>(90,000)</u>	<u>(70,000)</u>	<u>(192,671)</u>
Income tax credit	<u><u>(90,000)</u></u>	<u><u>(70,000)</u></u>	<u><u>(192,671)</u></u>

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	Six months ended 30 June	Year ended 31 December
	2023	2022	2022
	(<i>unaudited</i>)	(<i>unaudited</i>)	(<i>audited</i>)
	£	£	£
Basic:			
Loss for the financial period	(1,062,325)	(1,004,784)	(2,406,164)
Non-controlling interest	26,901	12,303	39,676
	<u>(1,035,424)</u>	<u>(992,481)</u>	<u>(2,366,488)</u>
Weighted average number of shares	100,808,008	65,049,156	77,301,896
Loss per share	<u>(1.03)p</u>	<u>(1.53)p</u>	<u>(3.06)p</u>

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.