RNS Number : 5741B
ValiRx PLC
05 June 2023

5 June 2023

ValiRx PLC ("ValiRx" or the "Company")

Full Year Results and Notice of AGM

London, UK - ValiRx Plc (AIM: VAL), a life science company focusing on early-stage cancer therapeutics and women's health, announces its audited results for the year ended 31 December 2022.

Highlights

Operational Highlights:

- Successful completion of Evaluation Agreement with Kings College, London, resulting in the incorporation of Cytolytix Limited in August 2022 to develop CLX001.
- Initiation of Evaluation Agreement with the University of Barcelona.
- Progression of the Evaluation Project with Hokkaido University.
- Evolution of strategy to build a translational Contract Research Organisation (tCRO) from Buy and Build to Build and Buy with the set up and launch of our laboratory facility in MediCity and incorporation of Inaphaea BioLabs Limited ("Inaphaea") in January 2023.
- Director appointment of Stella Panu as Non-Executive Director.
- Senior appointments of Cathy Tralau-Stewart as Chief Scientific Officer and Zai Ahmad as Preclinical Project Manager.
- Post-period appointments of the scientific team at Inaphaea of Melissa Barr, Dominic Lowen and Amelia Hatfield (Lead Scientist, Senior Scientist and Scientist respectively) and Andrew Carnegie (Head of Strategic Commercial Development).

Financial Highlights:

- Research and developments costs of £551,233 for the year ended 31 December 2022 as compared to £303,789 in 2021, an increase of £285,964 reflecting the increase in expenditure on research for the Evaluation Projects, VAL301 and the initiation of Cytolytix.
- Administrative expenses of £1,502,355 for the year ended 31 December 2022 as compared to £1,216,391 in 2021, an increase of £285,964.
- Total comprehensive loss for the year ended 31 December 2022 of £2,366,488 as compared to £1,518,212 in 2021, an increase of £848,276 and a loss per share of 3.06p as compared to 2.34p in 2021.
- Cash balance at 31 December 2022 of £1,137,477 as compared to £593,672 in 2021.
- Cash raised through an equity placing in July 2022 of £2.5M in total before costs; and post-period cash raised through an equity placing in January 2023 of approximately £1.3M in total before costs.
- Tax credit accrued through R&D in 2022 of £192,617; payment expected in Q3 2023 as compared to £133,413 received in Q3 2022 for R&D conducted in 2021.

The Company's Annual General Meeting ("AGM") will be held at 11:00am on 28 June 2023 at the offices of DAC Beachcroft LLP at The Walbrook Building, 25 Walbrook, London EC4N 8AF. A copy of the Company's annual report

and accounts, together with the Notice of AGM, will today be posted to all shareholders and will shortly be available on the Company's website www.valirx.com.

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.

For more information, please contact:

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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 out licensed 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 Report for the year ended 31 December 2022

ValiRx achieved a major milestone in October 2022 with the formation of Cytolytix Limited, a majority owned subsidiary and SPV to aid the development of an exciting new technology to treat triple negative breast cancer. We believe this collaboration with Kings College London will serve as the model for future evolution of our collaborative development pipeline.

Two other projects with academics from Hokkaido and Barcelona University have also been in the evaluation phase throughout the year and, subject to a successful conclusion of our experiments, will also be incorporated into SPVs.

Nevertheless, successful evaluation of new science cannot be guaranteed and it remains important to build a risk balanced portfolio of projects to maintain a steady flow of new assets for further development.

To this end, we were very pleased to welcome Dr Cathy Tralau-Stewart to the team in September last year as interim CSO (now permanent). Cathy has brought a wealth of experience in assessing novel science, particularly from academic institutions, and has taken the lead in identifying, securing and developing a range of novel assets that help to manage development risks.

We were also delighted to have appointed Stella Panu as a new Board member. Stella has brought deep experience in both corporate finance and M&A and is helping the team to drive forward the tCRO® strategy, with the aim of generating near term income for ValiRx.

During 2022 it became clear that initiating the tCRO® through a buy-and-build strategy was going to be a significant challenge as the valuations of suitable acquisition candidates for a core laboratory facility, on which to build the tCRO®, were excessive and unlikely to create sufficient shareholder value. With Stella's guidance and Suzy's CRO expertise, the previous buy-and-build approach has been modified to focus on establishing our own core laboratory, incorporating the necessary technologies to support ValiRx's in-house pipeline and attract 3rd party business. We believe this will enable ValiRx to build the tCRO® with lower risk and lower cost, leading to more efficient use of capital.

Having successfully established the tCRO®, transferred our in-house projects and secured new customers, we will continue to seek opportunities to acquire capabilities and technologies that complement the overall vision of improving translational research and transition ValiRx into an income generating and profitable company.

Efforts continue to out-licence our clinical assets VAL201 and VAL401 but, disappointingly, we have not yet concluded out-licencing deals. The Letter of Intent with TheoremRx for VAL201 continues to be exclusive at this time as we still expect their funding efforts will progress to a conclusion, albeit more slowly than anticipated.

The shift of the tCRO® strategy towards a build-and-buy strategy and the delays to TheoremRx funding necessitated a placing in 2022, which successfully raised £2.5m, including a broker option. These funds and the recent post-period raise of £1.3m now places ValiRx in a strong position to continue to build both our in-house pre-clinical development pipeline and the tCRO® throughout the next period.

As ever, we would like to thank all shareholders, both old and new, for your continued support as ValiRx navigates its transition towards a profitable future.

Kevin Cox
Chairman
5 June 2023

Chief Executive's Report for the year ended 31 December 2022

2022 was a key year for ValiRx in building the team for the next stage of growth within our strategy. Welcoming a new Board member and two new senior scientific executives within 2022, and post-period, three laboratory based scientists and commercial expert, enabled a sense of growth and development. Building a culture within the new team of pride in achieving excellent science, whether that science is within our in-house portfolio, within our university collaborative evaluations or for our service users; the culture of innovation, ideas and communication runs centrally.

The year was marked with extremes of highs and lows, with the delay to the finalisation of the sub-license of VAL201 to TheoremRx balanced against the high points of the launch of Cytolytix, initiation of the Barcelona Evaluation project and development of our tCRO® concept.

The Letter of Intent signed with TheoremRx was expected to convert to a full sub-license of VAL201 within the early part of 2022, subject only to TheoremRx completing their financing round. While we appreciate that 2022 has presented an unexpectedly more challenging financial market than anticipated, we feel acutely the frustration of this continued delay, but remain satisfied that if sufficiently financed, TheoremRx present a good partnership opportunity for the VAL201 project.

The launch of majority-owned Cytolytix to house the CLX001 project for the treatment of triple negative breast cancer was the highlight of 2022. After a 9 month evaluation period consisting of manufacturing assessment, in vitro and in vivo testing, the nano-formulated peptide licensed from Kings College, London, proved to be commercially and scientifically appropriate for further development.

As the first project to successfully graduate our evaluation process, CLX001 is our flagship example of how we work with academics to bring innovative science into industry.

This case study is helping to set the standard for further evaluations, collaborations and relationships from across the globe.

The second evaluation project to run to completion in 2022 was the peptide for the treatment of pancreatic and uterine cancers, licensed from Hokkaido University. After a 12 month period of evaluation, we requested an extension of the period after substantial manufacturing process challenges were resolved. This evaluation period is now expected to complete in June 2023.

A third parallel evaluation project was brought in during 2022 from Barcelona University, targeting the KRAS protein proposing to treat pancreatic and endometrial cancers, demonstrating the global distribution of our university outreach programme.

Further development of the translational Contract Research Organisation (tCRO®) strategy has seen an evolution from our initial buy-and-build strategy to a more steady build-and-buy proposal. The tCRO® build intends to create a unique service offering by combining our experience as a virtual biotech user of such services with our expertise in translating data into meaningful biological outcomes.

Built with commercial expectations in the foundations of the tCRO®, we believe our service offering will fill a niche area within the Women's Health and Oncology service market landscape to serve small and mid-sized biotechs in an industrially-focussed, high quality, data-driven manner.

Our build-and-buy approach has seen the Company lease lab facilities in a well-established biotech incubator hub, MediCity (Nottingham, UK) and post-period, launch Inaphaea BioLabs Limited as our subsidiary tCRO®. Using this lab as our foundation, we can build upon this, with intent to acquire technologies and techniques to operate alongside as well as within these headquarters. The collaboration with Physiomics PLC, announced post-period, to use their mathematical modelling and analysis techniques in an integrated services offering ensures that Inaphaea is able to offer a key capability to complement our data generation, which we believe
will be highly valued by our service users.

Outlook

2022 was a year to strengthen our strategic position, ensuring growth is maintained from the foundations laid over the past three years. Our renewed pre-clinical development strategy is proving successful with Cytolytix leading the way to demonstrate our capabilities and we look forward to seeing that progress into the first stages of pre-clinical development during 2023.

Our target is to identify four evaluation projects to enter the pipeline every year, and with our new CSO now available to help source these opportunities we anticipate this number being achieved for 2023, building from the three during 2021-2022.

The post-period launch of our tCRO, Inaphaea BioLabs Limited, provides the opportunity for ValiRx to generate revenue streams from the service side of the Company, with these expected to commence in 2023. We anticipate that as Inaphaea builds a reputation for delivering high quality, well thought-out, well conducted science, the potential for revenues will build over time.

Financial overview

Our financial results show the total comprehensive loss for the year ended 31 December 2022 of £2,366,488 (2021: £1,518,212) and a loss per share of 3.06p (2021: Loss - 2.34p).

Research and developments costs were £551,233 for the year ended 31 December 2022 as compared to £303,789 in 2021, an increase of £247,444. In addition, total wage costs of £254,050 (2021: £216,238) were expended on research and development during the year.

Administrative expenses were £1,502,355 (2021: £1,216,391) for the year ended 31 December 2022 an increase of £285,964.

Cash at the bank at 31 December 2022 was £1,137,477 compared to £593,672 in 2021.

I would like to thank the staff and Board members for all their contributions and shareholders for their continued support. We look forward to implementing our evolving strategy while continuing to maintain our culture of openness and transparency to all stakeholders.

Dr S J Dilly
Chief Executive Officer
5 June 2023

Consolidated Statement of Profit or Loss and Other Comprehensive Income for the year ended 31 December 2022

	2022	2021
	£	£
CONTINUING OPERATIONS		
Other operating income	**-**	26,952
Research and development	**(551,233)**	(303,789)
Administrative expenses	**(1,502,355)**	(1,216,391)
Share-based payment charge	**(539,791)**	(184,611)

OPERATING LOSS	**(2,593,379)**	(1,677,839)
Finance costs	**(5,456)**	(2,765)
LOSS BEFORE INCOME TAX	**(2,598,835)**	(1,680,604)
Income tax credit	**192,671**	133,413
LOSS AFTER INCOME TAX	**(2,406,164)**	(1,547,191)
Non-controlling interest	**39,676**	28,979
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	**(2,366,488)**	(1,518,212)
LOSS PER SHARE - BASIC AND DILUTED	**(3.06p)**	(2.34p)

Consolidated Statement of Financial Position for the year ended 31 December 2022

	2022	2021
	£	£
ASSETS		
NON-CURRENT ASSETS		
Goodwill	**1,602,522**	1,602,522
Intangible assets	**903,900**	1,108,116
Property, plant and equipment	**-**	-
Right-of-use assets	**5,561**	13,278
	2,511,983	2,723,916
CURRENT ASSETS		
Trade and other receivables	**133,815**	72,925
Tax receivable	**192,671**	133,413
Cash and cash equivalents	**1,137,477**	593,672
	1,463,963	800,010
TOTAL ASSETS	**3,975,946**	3,523,926
EQUITY		
SHAREHOLDERS' EQUITY		
Called up share capital	**9,695,120**	9,669,995
Share premium	**26,772,630**	24,490,618
Merger reserve	**637,500**	637,500
Reverse acquisition reserve	**602,413**	602,413
Share option reserve	**986,816**	491,219
Retained earnings	**(34,643,639)**	(32,292,507)
	4,050,840	3,599,238
Non-controlling interests	**(224,539)**	(184,867)
TOTAL EQUITY	**3,826,301**	3,414,371
LIABILITIES		
NON-CURRENT LIABILITIES		
Borrowings	**22,070**	35,654

Lease liabilities	**-**	5,681
	22,070	41,335
CURRENT LIABILITIES		
Trade and other payables	**111,933**	50,835
Borrowings	**9,962**	9,627
Lease liabilities	**5,680**	7,758
	127,575	68,220
TOTAL LIABILITIES	**149,645**	109,555
TOTAL EQUITY AND LIABILITIES	**3,975,946**	3,523,926

Consolidated Statement of Changes in Equity for the year ended 31 December 2021

	Share capital	Share premium	Merger reserve	Reverse acquisition reserve	Share-based payment reserve	Non-controlling interest	Retained earnings	Total
	£	£	£	£	£	£	£	£
Balance at 1 January 2021	9,669,828	24,380,356	637,500	602,413	540,803	(155,888)	(30,919,728)	4,755,284
Changes in equity								
Loss for the year	-	-	-	-	-	(28,979)	(1,518,212)	(1,547,191)
Issue of shares	167	21,500	-	-	-	-	-	21,667
Lapse of share options and warrants	-	88,762	-	-	(234,195)	-	145,433	-
Movement in year	-	-	-	-	184,611	-	-	184,611
Balance at 31 December 2021	**9,669,995**	**24,490,618**	**637,500**	**602,413**	**491,219**	**(184,867)**	**(32,292,507)**	**3,414,371**
Changes in equity								
Loss for the year	-	-	-	-	-	(39,676)	(2,366,488)	(2,406,164)
Issue of shares	25,125	2,462,250	-	-	-	-	-	2,487,375
Cost of shares issued	-	(209,076)	-	-	-	-	-	(209,076)
Lapse of share options and warrants	-	28,838	-	-	(44,194)	-	15,356	-
Movement in year					539,791	4	-	539,795
Balance at 31 December 2022	**9,695,120**	**26,772,630**	**637,500**	**602,413**	**986,816**	**(224,539)**	**(34,643,639)**	**3,826,301**

Consolidated Statement of Cash Flows for the year ended 31 December 2022

	Notes	**2022**	2021
		£	£
Cash flows from operations			
Cash outflow from operations	1	**(1,841,443)**	(1,331,136)

Interest paid		**(4,215)**	(782)
Tax credit received		**133,413**	71,346
Net cash outflow from operating activities		**(1,712,245)**	(1,260,572)
Cash flows from financing activities			
Bank loan repayment		**(13,249)**	(5,324)
Repayment of lease liabilities		**(9,000)**	(9,000)
Share issue		**2,487,375**	21,667
Costs of shares issued		**(209,076)**	-
Net cash inflow from financing activities		**2,256,050**	7,343
Increase/(decrease) in cash and cash equivalents		**543,805**	(1,253,229)
Cash and cash equivalents at beginning of year	2	**593,672**	1,846,901
Cash and cash equivalents at end of year	2	**1,137,477**	593,672

Notes to the Consolidated Statement of Cash Flows for the year ended 31 December 2022

1. RECONCILIATION OF OPERATING LOSS TO CASH GENERATED FROM OPERATIONS

	2022	2021
	£	£
Operating loss	**(2,593,379)**	(1,677,839)
Amortisation and impairment of intangible assets	**204,216**	221,072
Depreciation of right-of-use assets	**7,717**	7,717
Increase in trade and other receivables	**(60,886)**	(6,190)
Increase/(decrease) in trade and other payables	**61,098**	(60,507)
Share-based payments charge	**539,791**	184,611
Net cash outflow from operations	**(1,841,443)**	(1,331,136)

2. CASH AND CASH EQUIVALENTS

The amounts disclosed on the Statement of Cash Flows in respect of cash and cash equivalents are in respect of these Statement of Financial Position amounts:

	31 December 2022	**1 January 2022**
	£	**£**
Cash and cash equivalents	**1,137,477**	593,672

	31 December 2021	1 January 2021
	£	£
Cash and cash equivalents	593,672	1,846,901

Notes to the Consolidated Financial Statements for the year ended 31 December 2021

1. STATUTORY INFORMATION

ValiRx Plc is a company incorporated in the United Kingdom, which is listed on the AIM market of the London Stock Exchange Plc. The address of its registered office is Stonebridge House, Chelmsford Road, Hatfield Heath, CM22 7BD.

The registered number of the Company is 03916791.

The principal activity of the Group is the development of oncology therapeutics and companion diagnostics.

The presentation currency of the financial statements is the Pound Sterling (£).

The above information has been extracted from the annual report and accounts for the year ended 31 December 2022 and, accordingly, references and page numbers may not be complete. Shareholders should read the report and accounts in full which will shortly be available from the Company's website.

2. ACCOUNTING POLICIES

Basis of preparation

The Group's financial statements have been prepared in accordance with UK adopted International Accounting Standards in conformity with the requirements of the Companies Act 2006 as they apply to the financial statements of the Group for the year ended 31 December 2022. The principal accounting policies adopted by the Group and by the Company are set out in note 2. The Group financial statements have been prepared under the historical cost convention or fair value where appropriate.

The Group financial statements have been prepared under the historical cost convention or fair value where appropriate.

Going concern

As part of their going concern review the Directors have followed the guidelines published by the Financial Reporting Council entitled "Guidance on the Going Concern Basis of Accounting and Reporting on Solvency Risks-Guidance for directors of companies that do not apply the UK Corporate Governance Code".

The Group and Parent Company are subject to a number of risks similar to those of other development stage pharmaceutical companies. These risks include, amongst others, generation of revenues in due course from the development portfolio and risks associated with research, development, testing and obtaining related regulatory approvals of its pipeline products. Ultimately, the attainment of profitable operations is dependent on future uncertain events which include obtaining adequate financing to fulfil the Group's commercial and development activities and generating a level of revenue adequate to support the Group's cost structure.

The current economic environment is challenging, and the Group has reported an operating loss for the year. These losses are expected to continue in the current accounting year to 31 December 2023.

The Directors have prepared detailed financial forecasts and cash flows looking beyond 12 months from the date of the approval of these financial statements. In developing these forecasts, the Directors have made assumptions based upon their view of the current and future economic conditions that are expected to prevail over the forecast period. The Directors estimate that the cash of £1,137,477 held by the Group as at 31 December 2022 together with cash received in January 2023 will be sufficient to support the current level of activities for at least the next 12 months. The Directors are continuing to explore sources of finance available to the Group and based upon initial discussions with a number of existing and potential investors they have a reasonable expectation that they will be able to secure sufficient cash inflows for the Group to continue its activities beyond the 12 months from the date of approval of these financial statements.

The Company carries out regular fund-raising exercises in order that it can provide the necessary working capital for the Group. Further funds may be required to finance the Group's work programme. The Board expects to continue to raise additional funding as and when required to cover the Group's development, primarily from the issue of further shares.

In January 2023, the Company raised approximately £1.3m, before expenses, through the issue of new ordinary shares.

In the event that additional financing is not secured when it is required, the Group would need to consider:

- reducing and/or deferring discretionary spending on one or more research and development programmes; and/or
- restructuring operations to change its overhead structure.

Basis of consolidation

The Group financial statements consolidate the financial statements of the Company and all its subsidiaries ("the Group"). Subsidiaries include all entities over which the Group has the power to govern financial and operating policies. The existence and effect of potential voting rights that are currently exercisable or convertible are considered when assessing whether the Group controls another entity. Subsidiaries are consolidated from the date on which control commences until the date that control ceases. Intra-group balances and any unrealised gains and losses on income or expenses arising from intra-group transactions, are eliminated in preparing the consolidated financial statements.

On 3 October 2006, ValiRx Bioinnovation Limited ('Bioinnovation') acquired 60.28% of the issued share capital of ValiPharma Limited ('ValiPharma') in exchange for shares in Bioinnovation. Concurrently, the Company, ("ValiRx"), acquired the entire issued share capital of Bioinnovation in a share for share transaction. As a result of these transactions, the former shareholders of ValiPharma became the majority shareholders in ValiRx. Accordingly, the substance of the transaction was that ValiPharma acquired ValiRx in a reverse acquisition. Under IFRS 3 "Business Combinations", the acquisition of ValiPharma has been accounted for as a reverse acquisition.

In May 2008 the Company acquired the remaining 39.72% of the issued share capital of ValiPharma, which is now wholly owned by the Group. This acquisition was accounted for using the acquisition method of accounting.

In November 2013 ValiSeek Limited was formed to enable the Company to enter into a joint venture agreement. The Company has a 55.5% holding in the issued share capital of ValiSeek.

In October 2022 the Company acquired 60% of the issued share capital of Cytolytix Limited.

3. LOSS PER SHARE

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

	2021	2020
	£	£
Loss for the financial period	**(2,406,164)**	(1,547,191)
Non-controlling interest	**39,676**	28,979
Loss attributable to owners of Parent Company	**(2,366,488)**	(1,518,212)
Basic:		
Weighted average number of shares	**77,301,896**	65,004,957
Loss per share	**(3.06p)**	(2.34p)

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

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. While management believes that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments affecting the Company will be those that it anticipates.

Factors that could cause actual results to differ materially from those in the forward-looking statements include risks relating to unanticipated costs, liabilities or delays; failure or delays in research and development programs; the safety and efficacy of the Company's product candidates and the likelihood of clinical data to be positive and of such product candidates to be approved by the applicable regulatory authorities; unanticipated changes relating to competitive factors in the Company's industry; risks relating to the Company's capitalisation, resources and ownership structure, the availability of sufficient resources for company operations and to conduct or continue planned clinical development programs; the outcome of any legal proceedings; risks related to the ability to correctly estimate operating expenses; risks related to the ability to project future cash utilisation and reserves needed for contingent future liabilities and business operations; risks related to the changes in market prices of the Company's ordinary shares; the Company's ability to hire and retain key personnel; changes in law or regulations affecting the Company; international, national or local economic, social or political conditions that could adversely affect the Company and its business; conditions in the credit markets; risks associated with assumptions the Company makes in connection with its critical accounting estimates and other judgments.

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