RNS Number : 4463O
ValiRx PLC
15 May 2024

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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 2023.

Highlights

Operational Highlights:

- Initiation of Evaluation Agreement with StingRay Bio and expanded evaluation agreement with Barcelona University
- Post-period initiation of evaluation agreements with Imperial College London and Dundee University
- Launch of subsidiary Inaphaea BioLabs to conduct internal laboratory based evaluation experiments and to offer external services; with first revenue generating client contract signed
- Acquisition of scientific assets of Imagen Therapeutics, including a biobank of patient derived cell models

Financial Highlights:

- Research and developments costs of £383,362 for the year ended 31 December 2023 as compared to £551,233 in 2022, a decrease of £167,871
- Administrative expenses of £1,886,401 for the year ended 31 December 2023 as compared to £1,502,355 in 2022, an increase of £384,046 reflecting increased spending in the set-up of the laboratory facility
- Total comprehensive loss for the year ended 31 December 2023 of £2,037,701 as compared to £2,366,488 in 2022, a decrease of £328,787 and a loss per share of 2.01p as compared to 3.06p in 2022
- Cash balance at 31 December 2023 of £174,684 as compared to £1,137,477 in 2022

Material uncertainty relating to going concern

The Auditors have drawn attention to the policy on Going Concern within note 2 to the financial statements, which indicates that the accounts have been prepared on the going concern basis. The Board has referred to the fact that the Group and Parent Company are reliant on future fund raisings to continue their activities as budgeted. Should future fund raisings be unsuccessful, this may cast significant doubt on the Group and parent Company's ability to continue as a going concern. The Auditors opinion is not modified in respect of this matter. The Auditor's report contained in the Company's Annual Report is set out in full in note 4 further below.

Notice of AGM

The Company's Annual General Meeting ("AGM") will be held at 1:00 pm on 20 June 2024 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, have been 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 2023

The last few years are widely acknowledged to have been challenging for the biotech industry across the board and specifically for publicly listed companies. Investor interest has significantly retreated, most likely driven by a combination of geo-political events and the dramatic rise in interest rates to tackle high inflation.

Not surprisingly, ValiRx has not been immune to these external factors, further exacerbated by slower than expected progress in key projects, such as VAL201 out-licencing and, to a lesser extent, protracted negotiations on university-derived evaluation agreements.

The funds secured in January 2023 have enabled ValiRx to progress our development pipeline and, importantly, to initiate the build-and-buy strategy to establish our translational contract research organisation (tCRO®), branded as Inaphaea Biolabs.

Since its incorporation in January 2023, Inaphaea has leased, equipped and validated a new laboratory in Nottingham, recruited a highly qualified team and is beginning to build a strong market presence in translational testing services. Critically, the funding secured earlier in the year also placed ValiRx in a strong position to respond rapidly to the offer for sale of the liquidated assets of Imagen Therapeutics. This was a highly competitive process and a quick response was imperative.

The acquired assets comprise a wide range of relevant analytical equipment and a biobank of patient -derived cancer cells (PDCs) accumulated by Imagen over a number of years. Ownership of the PDC biobank has given Inaphaea a clear competitive advantage and will become a corner stone of the tCRO® concept. Work is now underway to identify which cancers are of greatest market interest to be able to prioritise full characterisation of the appropriate cells for use in the provision of services and product sales. In addition, all ValiRx in-house development projects have been transferred into Inaphaea and benefitting from access to the PDCs. This has also resulted in considerable cost savings relative to the use of external contractors.

After extensive business development activities for VAL401, we were pleased to have entered into a letter of intent with Ambrose Healthcare for development of this unique compound. With a focus on rare diseases and patients managed in hospitals, we believe the team at Ambrose have the right skills and experience to progress VAL401 into clinical studies when the necessary funding has been secured.

In summary, despite significant challenges facing the biotech sector in 2023, we were pleased to have secured sufficient investment to progress the dual track strategy of developing a risk-balanced pre-clinical pipeline and building a tCRO®, Inaphaea Biolabs, to generate 3rd party income.

With the recently announced Board changes, we look forward to continuing commercial progress in 2024 and establishing Inaphaea as a leader in the use of PDCs to enhance the translation of novel pre-clinical assets into clinical development.

Kevin Cox
Chairman
13 May 2024

Chief Executive's Report for the year ended 31 December 2023

In this, my final Chief Executive's Report, I would like to take the opportunity to reflect on progress by the Group not just over the past year, but to include the context of the previous four years.

With the launch of Inaphaea BioLabs in Q1 of 2023, we progressed the ambitions of the ValiRx group to move away from a wholly virtual biotech company and towards a balanced, early-stage discovery and preclinical biotechnology group. Although the virtual model was preferred for the Group as a "single asset" group, as the expansion and risk diversification of the preclinical pipeline continues, the value of controlling our own laboratory facility increases proportionally. These early-stage assets need standardised experimental procedures conducting for initial assessment and for advancing the biological understanding of the drug candidate molecules. Access to both the expertise within Inaphaea and the facilities enables a time and cost-efficient turnaround.

The addition of the scientific assets from Imagen Therapeutics provided an opportunity to launch our translational Contract Research Organisation (tCRO®) with a truly valuable biobank of patient derived tumour cell models (PDCs) - covering samples from over 500 tissue collections, grown into cell models.

Work continues on the development, characterisation and optimisation of these samples, but within months of on-boarding the biobank, Inaphaea had secured the first service contract from an external client to screen a focussed library of drug candidates against a PDC sample to seek anti-cancer activity. Considerable interest has also been shown in the use of samples from our biobank by other researchers, and we have developed commercial frameworks to offer these samples under a range of different use categories, including for preclinical research, for commercial incorporation into medical devices and for provision in further specialist third party CRO assays.

The PDCs provide the capability to produce experimental procedures in the Inaphaea facility that more closely model the human disease state compared to fully immortalised cell lines. We minimise the use of non-human growth factors and optimise selective growth conditions to ensure we retain both the cancerous cells and, where appropriate, a proportion of the supportive surrounding cells in the samples. These techniques enable us to provide a differentiated and more translational service.

The tCRO® concept is built on the premise of providing a coherent network of translational science, bridging a number of technologies to create a more complete picture of the biological activity of a drug candidate. As part of our process to further build the tCRO® service offering, we have commenced assembling a range of related services via collaborative services agreements with third party service providers. These providers have been selected specifically with their relationship to the Inaphaea services in mind, and are trusted partners with whom we would collaborate (and in many cases have done so) on our own projects, and hence we recommend them to our clients.

The benefits of the collaborative services approach are many - from the client perspective, the ability to access all the services seamlessly under a single service agreement creates efficiency and, for Inaphaea, we can have confidence that the upstream or downstream processes have been conducted in a manner and with partners that we are confident in working with. Additional synergism is seen through combined marketing, business development, and of course, our exposure to their established client bases.

So, although we are building the Inaphaea customer base from a clean page, we have the advantage of our collaborators networks to build on.

The pipeline of client prospects within Inaphaea is looking strong, with a steady build of prospects throughout the second half of 2023. Although the nature of our industry is of long-term research budget planning with associated long lead times, our current pipeline of prospects is progressing well. As the catalogue of characterised PDCs is developed we expect this to grow further with product license as well as service opportunities.

The in-house research evaluation pipeline was boosted by two programmes within 2023, with the Barcelona agreement being expanded to encompass an additional project, as well as an evaluation project initiated in Q4 on an asset from StingRay Bio. The latter demonstrates our intent to work with innovators in all capacities; we are not restricted to the university sector to source innovative projects for development. We look forward to progressing both of these projects to meet the timelines for a decision on in-licensing within 2024.

Post period two additional programmes from Dundee University and Imperial College London have been secured into evaluation agreements, with Dundee agreeing to an over-arching agreement to encompass future projects. On reflection of our current pipeline of new projects, consisting of Cytolytix plus four active evaluation agreements we have made significant steps towards bringing a balanced pipeline to the Group.

The assets currently in the new pipeline include a mixture of peptides and small molecules; cover a range of cancer types, and have a range of characteristics of validated, novel or unknown target activities. Although all early stage developments, this risk diversification across multiple programmes enables a genuine scientific assessment of all, and a greater chance of success with subsequent returns of value to shareholders. With preclinical attrition rates in oncology programmes thought to be as high as 90%, further growth of the pipeline is required to truly balance the risk and avoid the risks of any single project being inappropriately prioritised or of being continued beyond the natural point of attrition.

The announcement of the Option Agreement for VAL401 with Ambrose Healthcare was a key milestone in 2023, with the maximum Option term concluding within 2024. Ambrose's commitment to progress VAL401 through remaining clinical development and commercialisation is an exciting development and I am looking forward to progressing this partnership.

VAL201 remains under the Letter of Intent with TheoremRx and we noted towards the conclusion of 2023 their progression towards a merger with Nasdaq company EUDA, which marked a significant step forward in publicly revealing their progression towards financing.

Outlook

2024 will see another year of significant evolution, with the changes to the Board composition providing an opportunity to harness new expertise and skills into the Group, enabling further honing of the strategy to promote growth and development across all strands of the portfolio.

While 2023 witnessed the launch of the Inaphaea BioLabs facility, with the Group shifting from being a wholly virtual biotech group to have in-house capability to conduct our experiments in-house; we view 2024 as the stepping stone to consolidate that growth. Anticipating conversion of the pipeline of commercial opportunity into further sales within Inaphaea in 2024 thus demonstrating the value of Inaphaea for both internal project progression and revenue generation.

The evaluation project pipeline will also continue to expand, with two further evaluation agreements executed post period, and research on these is already underway in our facility. Further negotiations are ongoing for additional projects, with a target of 1-2 further within 2024, with some of those negotiation expected to carry into 2025.

Financial overview

Our financial results show the total comprehensive loss for the year ended 31 December 2023 of £2,037,701 (2022: £2,366,488) and a loss per share of 2.01p (2022: Loss - 3.06p).

Research and developments costs were £383,362 for the year ended 31 December 2023 as compared to £551,233 in 2022, a reduction of £167,871. In addition, total wage costs of £462,862 (2022: £254,050) were expended on research and development during the year.

Administrative expenses were £1,886,401 (2022: £1,502,355) for the year ended 31 December 2023 an increase of £384,046.

Cash at the bank at 31 December 2023 was £174,684 compared to £1,137,477 in 2022.

I would like to thank the staff and Board members for all their contributions and shareholders for their continued support. With further evolution and progression of the Company strategy under the new

management team; the Company offers potential for change and prospects for Company growth into the future.

Dr S J Dilly
Chief Executive Officer
13 May 2024

Consolidated Statement of Profit or Loss and Other Comprehensive Income for the year ended 31 December 2023

	2023	2022
	£	£
CONTINUING OPERATIONS		
TURNOVER	**9,600**	
Cost of sales	**(1,440)**	
GROSS PROFIT	**8,160**	
Research and developments	**(383,362)**	(551,233)
Administrative expenses	**(1,886,401)**	(1,502,355)
Share-based payment charge	**(36,936)**	(539,791)
OPERATING LOSS	**(2,298,539)**	(2,593,379)
Finance costs	**(4,419)**	(5,456)
LOSS BEFORE INCOME TAX	**(2,302,958)**	(2,598,835)
Income tax credit	**175,173**	192,671
LOSS AFTER INCOME TAX	**(2,127,785)**	(2,406,164)
Non-controlling interest	**90,084**	39,676
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	**(2,037,701)**	(2,366,488)
LOSS PER SHARE - BASIC AND DILUTED	**(2.01p)**	(3.06p)

Consolidated Statement of Financial Position for the year ended 31 December 2023

	2023	2022
	£	£
ASSETS		
NON-CURRENT ASSETS		
Goodwill	**1,602,522**	1,602,522
Intangible assets	**718,814**	903,900
Property, plant and equipment	**242,625**	-
Right-of-use assets		5,561
	2,563,961	2,511,983
CURRENT ASSETS		
Inventory	**69,002**	-
Trade and other receivables	**147,618**	133,815
Tax receivable	**175,173**	192,671
Cash and cash equivalents	**174,684**	1,137,477
	566,477	1,463,963

TOTAL ASSETS	**3,130,438**	3,975,946
EQUITY		
SHAREHOLDERS' EQUITY		
Called up share capital	**9,707,266**	9,695,120
Share premium	**27,870,548**	26,772,630
Merger reserve	**637,500**	637,500
Reverse acquisition reserve	**602,413**	602,413
Share option reserve	**1,082,163**	986,816
Retained earnings	**(36,681,340)**	(34,643,639)
	3,218,550	4,050,840
Non-controlling interests	**(314,623)**	(224,539)
TOTAL EQUITY	**2,903,927**	3,826,301
LIABILITIES		
NON-CURRENT LIABILITIES		
Borrowings	**11,857**	22,070
Lease liabilities		-
	11,857	22,070
CURRENT LIABILITIES		
Trade and other payables	**204,441**	111,933
Borrowings	**10,213**	9,962
Lease liabilities	**-**	5,680
	214,654	127,575
TOTAL LIABILITIES	**226,511**	149,645
TOTAL EQUITY AND LIABILITIES	**3,130,438**	3,975,946

Consolidated Statement of Changes in Equity for the year ended 31 December 2023

	Share capital	Share premium	Merger reserve	Reverse acquisition reserve	Share-based payment reserve	Non-controlling interest	Retained earnings	Total
	£	£	£	£	£	£	£	£
Balance at 1 January 2022	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**

Changes in equity								
Loss for the year	-	-	-	-	-	(90,084)	(2,037,701)	(2,127,785)
Issue of shares	12,146	1,323,854	-	-	-	-	-	1,336,000
Cost of shares issued	-	(167,525)	-	-	-	-	-	(167,525)
Movement in year	-	(58,411)	-	-	95,347	-	-	36,936
Balance at 31 December 2023	**9,707,266**	**27,870,548**	**637,500**	**602,413**	**1,082,163**	**(314,623)**	**(36,681,340)**	**2,903,927**

Consolidated Statement of Cash Flows for the year ended 31 December 2023

	Notes	2023 £	2022 £
Cash flows from operations			
Cash outflow from operations	1	**(1,961,697)**	(1,841,443)
Interest paid		**(3,325)**	(4,215)
Tax credit received		**192,671**	133,413
Net cash outflow from operating activities		**(1,772,351)**	(1,712,245)
Cash flows from investing activities			
Purchase of intangible fixed assets		**(15,000)**	-
Purchase of property, plant and equipment		**(291,181)**	-
Net cash inflow from financing activities		**(306,181)**	-
Cash flows from financing activities			
Bank loan repayment		**(9,962)**	(13,249)
Repayment of lease liabilities		**(6,774)**	(9,000)
Share issue		**1,300,000**	2,487,375
Costs of shares issued		**(167,525)**	(209,076)
Net cash inflow from financing activities		**1,115,739**	2,256,050
Increase/(decrease) in cash and cash equivalents		**(962,793)**	543,805
Cash and cash equivalents at beginning of year	2	**1,137,477**	593,672
Cash and cash equivalents at end of year	2	**174,684**	1,137,477

Notes to the Consolidated Statement of Cash Flows for the year ended 31 December 2023

1. **RECONCILIATION OF OPERATING LOSS TO CASH GENERATED FROM OPERATIONS**

	2023 £	2022 £
Operating loss	**(2,298,539)**	(2,593,379)

Amortisation and impairment of intangible assets	**200,086**	204,216
Depreciation of right-of-use assets	**5,561**	7,717
Depreciation of property, plant and equipment	**48,556**	
Increase in inventory	**(69,002)**	
Increase in trade and other receivables	**(13,803)**	(60,886)
Increase/(decrease) in trade and other payables	**128,508**	61,098
Share-based payments charge	**36,936**	539,791
Net cash outflow from operations	**(1,961,697)**	(1,841,443)

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 2023	**1 January 2023**
	£	**£**
Cash and cash equivalents	**174,684**	1,137,477

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

Notes to the Consolidated Financial Statements for the year ended 31 December 2023

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 2023 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 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 2023. 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.

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 2024.

The Directors have prepared detailed financial forecasts and cashflows 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 £174,684 held by the Group as at 31 December 2023 together with cash receivable in January 2024 (see below) 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 2024, the Company raised approximately £1.8m, 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 2023 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:

	2023	2022
	£	£
Loss for the financial period	**(2,127,785)**	(2,406,164)
Non-controlling interest	**90,084**	39,676
Loss attributable to owners of Parent Company	**(2,037,701)**	(2,366,488)
Basic:		
Weighted average number of shares	**101,570,021**	77,301,896
Loss per share	**(2.01p)**	(3.06p)

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'.

4. REPORT OF THE INDEPENDENT AUDITORS TO THE MEMBERS OF VALIRX PLC

Opinion

We have audited the financial statements of ValiRx Plc (the 'Parent Company') and its subsidiaries (the 'Group') for the year ended 31 December 2023 which comprise the Group Statement of Comprehensive Income, the Group and Company Statements of Financial Position, the Group Statement of Cash Flows, the Group and Company Statements of Changes in Equity and the related notes, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and UK adopted International Accounting Standards, in conformity with the requirements of the Companies Act 2006.

In our opinion:

- the financial statements give a true and fair view of the state of the Group's and of the Parent Company's affairs as at 31 December 2023 and of the Group's loss for the year then ended;
- 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;
- the Parent Company financial statements have been properly prepared in accordance with UK adopted International Accounting Standards in conformity with the requirements of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We are independent of the Group and Parent Company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Emphasis of Matter

We draw attention to the value of goodwill in the Consolidated Statement of Financial Position and the value of investments in the Company Statement of Financial Position. The value of investments represents the historic cost of acquisition of investments less provisions for impairment. The value of goodwill arises on consolidation and represents the excess between the value of the underlying subsidiary on acquisition and the cost of investment, less provisions for impairment.

Management's assessment of impairment includes a review of the net present value of future potential cashflows of the underlying assets. The basis of these valuations include a number of variables within the calculations that are subjective and based on professional judgments of expectations and estimates. This also includes the expected potential around the success of the future development and commercialisation of the Group's products, VAL 201 and VAL 401.

While we have assessed management's judgements and application of estimates in their calculations and consider these to be reasonable, as set out in the key audit risks below, there are several factors that could result

in a material change in the valuation of the underlying investments which could result in an impairment of the investments and associated goodwill.

Our opinion is not modified in respect of this matter.

Conclusions relating to going concern

Material uncertainty relating to going concern

We draw your attention to the policy on Going Concern within note 2 to the financial statements, which indicates that the accounts have been prepared on the going concern basis. The Board has referred to the fact that the Group and Parent Company are reliant on future fund raisings to continue their activities as budgeted. Should future fund raisings be unsuccessful, this may cast significant doubt on the Group and parent Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

Key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

The key audit matters identified were:

Impairment of goodwill and intangibles

Area of focus

The Group has goodwill of £1.60 million and intangible assets of £0.72 million.

IAS 36 requires at least annual impairment assessments in relation to goodwill, indefinite-lived intangible assets and intangible assets that are not yet ready for use, with more regular assessments should an impairment trigger be identified.

The determination of recoverable amount, being the higher of value-in-use and fair value less costs of disposal, requires judgement on the part of management in identifying and then estimating the recoverable amount for the relevant CGUs.

Recoverable amounts are based on management's view of future cash flow forecasts and external market conditions such as future pricing and the most appropriate discount rate.

Management engaged an expert to assist them in performing an annual impairment assessment which included the assumptions and estimates around the success of the future development and commercialisation of its products VAL 201 and VAL 401. Changes in these assumptions might give rise to a change in the carrying value of intangibles and goodwill.

How our audit addressed the area of focus

We obtained the report prepared by the expert and gained an understanding of the key assumptions and judgements underlying the assessment. We assessed the appropriateness of the methodology applied and tested the mathematical accuracy of the models.

We obtained an understanding of the stage of product development and management's expected timelines for product commercialisation, including updates on the achievement of expected milestones.

We determined the judgement made by the Directors that no impairment was required, and that the disclosures made in the financial statements to be reasonable.

Going concern

area of focus

Refer to note 2 of the financial statements for the Directors' disclosures of related accounting policies, judgements and estimates. The Directors have concluded that they have a reasonable expectation that the Group will have sufficient cash resources and cash inflows to continue its activities for not less than twelve months from the date of approval of these financial statements and have therefore prepared these financial statements on a going concern basis.

The Group had cash and cash equivalents of £174,684 as at 31 December 2023.

Management produces a cash flow forecast based on the board plans.

The key judgements within the cash flow forecast that we particularly focused on were:

- The continued availability of funding.
- The likely recovery of other receivables.
- Cash flows expected from research and development tax credits.- Flexibility of development programme.

How our audit addressed the area of focus

We assessed the reasonableness and support for the judgments underpinning management's forecast, as well as the sensitivity of projections to these judgements.

We reviewed management's financing plans and considered the reasonableness of the assumptions within management's proposed cost reduction actions, should future fund raisings be lower than anticipated.

Our conclusion on management's use of the going concern basis of accounting is included in the going concern section of the report above.

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Our conclusion on management's use of the going concern basis of accounting is included in the going concern section of the report above.

Our application of materiality

When establishing our overall audit strategy, we set certain thresholds which help us to determine the nature, timing and extent of our audit procedures and to evaluate the effects of misstatements, both individually and on the financial statements as a whole.

We consider materiality to be the magnitude by which misstatements, including omissions, could influence the economic decisions of reasonable users that are taken on the basis of the financial statements.

In order to reduce the probability that any misstatement exceeds materiality to an appropriately low level, we use a lower materiality level, performance materiality, to determine the extent of testing needed. Importantly, misstatements below these levels will not necessarily be evaluated as immaterial as we also take account of the nature of identified misstatements, and the particular circumstances of their occurrence, when evaluating their effect of the financial statements as a whole.

Based on our professional judgment, we determined materiality for the financial statements as a whole and performance materiality as follows:

Group and Parent Company materiality were set at £168,200 and £125,000 respectively, based on 8% of loss before tax and amortisation. In our professional judgement, this benchmark is considered appropriate as it reflects the ongoing operational requirements of the business to develop and build the business.

Group and Parent Company performance materiality were set at £126,200 and £93,700 respectively, based on 75% of materiality. In setting the level of performance materiality, we consider a number of factors including the control environment, our testing strategy, the total value of known and likely misstatement (based on past experience and other factors) and management's attitude towards proposed adjustments.

Component materiality

For the purposes of our Group audit opinion, we set materiality for each significant component of the Group based on a percentage of Group materiality, dependent on the size and our assessment of the risk of material misstatement of that component.

Reporting thresholds

We agreed with the Audit Committee that we would report to them all unadjusted audit differences in excess of £5,000, as well as differences below this threshold that, in our view, warranted reporting on qualitative grounds.

An overview of the scope of our audit

The audit was scoped to ensure that the audit team obtained sufficient and appropriate audit evidence in relation to significant operations of the Group during the year ended 31 December 2023. In particular, we looked at areas involving significant accounting estimates and judgement by the Directors. We also addressed the risk of management override of internal controls, including an evaluation of whether there was evidence of bias by the Directors that represented a risk of material misstatement due to fraud.

As part of our planning, we assessed the risk of material misstatement including those that required significant auditor consideration at the component and group level. Procedures were designed and performed to address the risk identified and for the most significant assessed risks of material misstatement, the procedures performed are outlined above in the key audit matters section of this report.

Other information

The Directors are responsible for the other information. The other information comprises the information in the Annual Report but does not include the financial statements and our Report of the Auditors thereon.

Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements, or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Opinions on other matters prescribed by the Companies Act 2006

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the Group Strategic Report and the Report of the Directors for the financial year for which the financial statements are prepared is consistent with the financial statements; and

- the Group Strategic Report and the Report of the Directors have been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception

In the light of the knowledge and understanding of the Group and the Parent Company and its environment obtained in the course of the audit, we have not identified material misstatements in the Group Strategic Report or the Report of the Directors.

We have nothing to report in respect of the following matters where the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept by the Parent Company, or returns adequate for our audit have not been received from branches not visited by us; or
- the Parent Company financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of Directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

Responsibilities of Directors

As explained more fully in the Statement of Directors' Responsibilities set out on page 42, the Directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the Directors determine necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Directors are responsible for assessing the Group's and the Parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the Group or the Parent Company or to cease operations, or have no realistic alternative but to do so.

Auditors' responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a Report of the Auditors that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud, is detailed below.

We are not responsible for preventing irregularities. The primary responsibility for the prevention and detection of fraud rest with both those charged with governance of the entity and management.

Our approach to identifying and assessing the risks of material misstatement in respect of irregularities, including fraud and non-compliance with laws and regulations included, but was not limited to, the following:

- the engagement partner ensured that the engagement team collectively had the appropriate competence, capabilities and skills to identify or recognise non-compliance with applicable laws and regulations;
- we identified the laws and regulations applicable to the company through discussions with the Directors and other management, and from our commercial knowledge and experience of the medical research and development sector;
- we focused on specific laws and regulations which we considered may have a direct material effect on the financial statements or the operations of the company, including the Companies Act 2006, taxation legislation and data protection, anti-bribery, employment and health and safety legislation;
- we assessed the extent of compliance with the laws and regulations identified above through making enquiries of management and inspecting legal correspondence; and
- identified laws and regulations were communicated within the audit team regularly and the team remained alert to instances of non-compliance throughout the audit.

We assessed the susceptibility of the Company's financial statements to material misstatement, including obtaining an understanding of how fraud might occur, by:

- making enquiries of management as to where they considered there was susceptibility to fraud, their knowledge of actual, suspected and alleged fraud; and

- considering the internal controls in place to mitigate risks of fraud and non-compliance with laws and regulations.

To address the risk of fraud through management bias and override of controls, we:

- performed analytical procedures to identify any unusual or unexpected relationships;
- tested journal entries to identify unusual transactions;
- assessed whether judgements and assumptions made in determining the accounting estimates were indicative of potential bias; and
- investigated the rationale behind significant or unusual transactions.

In response to the risk of irregularities and non-compliance with laws and regulations, we designed procedures which included, but were not limited to:

- agreeing financial statement disclosures to underlying supporting documentation;
- reading the minutes of meetings of those charged with governance;
- enquiring of management as to actual and potential litigation and claims; and
- reviewing correspondence with HMRC, relevant regulators including the Health and Safety Executive, and the company's legal advisors.

Due to the inherent limitations of an audit, there is a risk that we will not detect all irregularities, including those leading to a material misstatement in the financial statements or non-compliance with regulation. This risk increases the more that compliance with a law or regulation is removed from the events and transactions reflected in the financial statements, as we will be less likely to become aware of instances of non-compliance. The risk is also greater regarding irregularities occurring due to fraud rather than error, as fraud involves intentional concealment, forgery, collusion, omission or misrepresentation.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at www.frc.org.uk/auditorsresponsibilities. This description forms part of our Report of the Auditors.

Use of our report

This report is made solely to the Company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in a Report of the Auditors and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's members as a body, for our audit work, for this report, or for the opinions we have formed.

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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