

Stock Data

Share Price:	6.50p
Market Cap:	£8.65m*
Shares in issue:	133.31m*
52-week high/low:	15.00p/5.10p
*Post-Placing, Subscription and assuming maximum number of Retail Offer shares	

Company Profile

Sector:	Health Care
Ticker:	VAL
Exchange:	AIM

Activities

ValiRx plc ('ValiRx', 'VAL' or 'the Group') accelerates the development of treatments in cancer and women's health to improve patient lives. It provides the scientific, financial and commercial framework to enable the rapid translation of innovative science into clinical development.

www.valirx.com/

5-year share price performance



Source: [LSE](https://www.lse.com)

Past performance is not an indication of future performance.

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ValiRx plc

Following yesterday's market close, ValiRx announced a conditional equity placing plus conditional Directors/PDMR subscription (together 'the Placing') to raise c.£1.61 million (gross), through the allotment of new ordinary shares to new and existing holders at an issue price of 6p each. In addition to the Placing, the Group is also undertaking a separate conditional Retail Offer (the 'Retail Offer') to existing shareholders via the Bookbuild platform to raise up to £0.25 million (gross) at the same price (being a 23% discount to 12 December 2023's closing), taking the total fundraising to as much as £1.86m (gross). The Board is seeking the necessary shareholder approval for issuance of the Placing Shares and Retail Offer Shares at a General Meeting scheduled for 4 January 2024. Dealings in the newly issued Shares are expected to commence, on or around 8 January 2024. The net proceeds of the Placing will be used both to accelerate exploitation of assets acquired from Imagen Therapeutics and to advance the Group's preclinical product pipeline.

The Retail Offer was launched at 4:30 P.M. yesterday (being, 13 December 2023) and is open for applications up to midday on 19 December 2023. Announcement of the result of the Retail Offer and final quantum raised is expected on or around 20 December 2023.

Use of Funds

The Group has raised c.£1.61 million (gross) through a conditional equity placing which included c.£30,000 (gross) from a conditional Director/PDMR equity subscription. Subject to take up of the Retail Offer, the total gross proceeds of the fundraising could rise to as much as c.£1.86 million (gross). The Board intends to use the new fundraising for the following, with any surplus being applied to general working capital purposes:

ValiRx - Use of Net Proceeds

Exploitation and integration of BioBank materials from the Imagen assets acquisition	£0.6m
Commercial development/Brand establishment within Inaphaea	£0.2m
R&D: new Evaluation Projects (estimated 3-4 projects)	£0.2m
R&D: ongoing Evaluation Projects (StingRay, KRAS and VAL301)	£0.2m
R&D: ongoing and intended SPV (Cytolytix)	£0.4m

Source: ValiRx, [RNS of 13 December 2023](https://www.rns.com)

Past year has seen ValiRx's business plan advanced decisively

ValiRx now occupies a distinctive position amongst its international contract research peer group. Its tCRO® facility offers experimental systems more closely related to human biology that demonstrate high reproducibility, thereby increasing confidence in translation into clinical studies. Inaphaea Biolabs' Medicity (Nottingham) laboratory is now fully equipped, staffed and validated to undertake external cell-based experiments. Management has also assessed a range of new/complementary technologies/facilities for incorporation into its wider offering (including a strategic collaboration with Physiomics, the acquisition of Imagen's assets/tradename and agreement

with OncoBone to introduce virtual CRO planning and evaluation services).

Beyond the first, landmark Master Services Agreement and Project Statement of Work secured with a UK-based biotech company on 19 July 2023, ValiRx's Board have identified a target list of further potential customers, with awareness being raised through industry events, social media, etc. Having already collected a substantial number of detailed enquiries from industry participants, the Board considers the Group's tCRO® operations will be capable of becoming sufficiently profitable and cash generative (with up to a 20% operating margin in the medium to longer term) to support its future in-house development projects. Inaphaea's set-up and running costs of c.£0.5 million comprised investment in the new lease, staffing, operational capability and equipment for in-house use, support for the launch of the tCRO® service plus an initial runway of overheads for twelve months.

By unlocking the vast potential of academic innovation, Inaphaea employs the power of advanced data generation, bio-analytics and interpretation, with a view to integrating the currently fragmented niche service offering to generate deep biological understanding to de-risk clinical trials. In so doing, it will deploy clinical development expertise to implement preclinical understanding. Following the successful acquisition of Imagen Therapeutics Limited's assets on 14 June 2023, Inaphaea's evolution is likely to be further accelerated through a longer term buy-and-build strategy, intended to generate new market opportunities, expand its core skillsets and heighten operational efficiencies.

Yet this is just one of the strategic goals ValiRx has achieved since it last raised new equity funding on 13 January 2023. The past six months, for example also oversaw expansion of its existing Evaluation project with Barcelona University and a new Evaluation Agreement with StingRay Bio Limited, under which ValiRx will test a series of small molecules for development as oncology therapeutic candidates. Most recently, on 5 December 2023, 55.5%-owned Valiseek Limited entered into an exclusive Option Agreement to license VAL401, a reformulation of the established anti-psychotic drug risperidone, with Ambrose Healthcare Limited, a private UK specialist pharmaceutical company.

ValiRx Recent Operational Activity

June 2023	• Expansion of Evaluation Agreement with Barcelona University
June 2023	• Acquisition of scientific assets from liquidators of Imagen Therapeutics, including PDC biobank
Sep 2023	• First External customers using Inaphaea BioLabs screening services
Nov 2023	• New Evaluation Agreement initiated with StingRay Bio Limited
Dec 2023	• Ambrose Healthcare signed Option Agreement over VAL401

Source: ValiRx, Investor Presentation December 2023

Coming year now funded to deliver significant progress

With the bulk of today's fundraising already earmarked to accelerate exploitation of assets acquired from Imagen Therapeutics in tandem with advancing its preclinical product pipeline, 2024 looks to be a very busy period for ValiRx.

Central to Inaphaea's client offering, for example, is provision of a clear USP through access to >500 patient-derived sample cells available through signed product licenses with annual renewal fees. Originally secured through the purchase of Imagen's assets and technologies, significant new investment is planned to process and characterise existing recent cell line samples derived from patient tumours.

ValiRx recognises that any such cells that are currently sourced commercially are typically available as ‘immortalised’ lines (i.e., tumorous cells that do not stop dividing or cells that have been artificially manipulated to proliferate indefinitely and can, thus, be cultured over several generations). In many cases these are decades old, with patients not having been treated under current regimes, with questionable ethical origin and no longer seen to be acting true to the original condition. By being able to offer recent alternative samples that have been subject to minimal processing amid humanised growth conditions, ValiRx will be able to provide customers with a highly relevant, unique and ‘close-to-human’ screening service within a well characterised biological environment for testing drug candidates. Dependent of customer response and needs, there is opportunity to broaden the portfolio offering to further include specific conditions (i.e., endometriosis), derivative lines (for drug resistance, etc.) and/or 3D complex cultures.

Beyond this and planned investment in Inaphaea’s overall commercial development and brand establishment, research, development and promotion of new/ongoing Evaluation projects as well as the Cytolytix SPV should ensure heavy news flow for the coming year:

ValiRx – Potential 2024 News Flow

•Progress reports from TheoremRx on VAL201 development
•Progress reports from Ambrose Healthcare towards VAL401 exercise of license
•Signing 2-4 more evaluations
•Decision points on current evaluations – Barcelona and StingRay; potential for new SPV
•Cytolytix progress updates
•Additional Inaphaea customers and regular trading updates

Source: ValiRx, Investor Presentation December 2023

Cash runway now appears sufficient to carry it well into 2025

Full year 2023E Group net losses along with the cost of establishing/facilitating Inaphaea Biolabs (including the acquisition of Imagen Therapeutics), resulted in an average estimated cash burn of a little over £200,000/month for the period. If one now prudently assumes further, albeit somewhat reduced, Group net losses for 2024E, during which time it utilises the newly raised net funding to accelerate exploitation and integration of its acquired BioBank materials in tandem with commercial development/brand establishment within Inaphaea while also advancing its preclinical product pipeline in the absence of further cash acquisition(s), the Group now appears to have runway sufficient to carry it into Q2 2025.

Between now and then, of course, various upside scenarios suggest this period could become significantly extended. This could be derived through securing higher volumes of fee-paying service customers for Inaphaea, potential signing of licensing agreements with external parties willing to pay upfront charges and fund ongoing development of the Group’s preclinical and/or clinical assets which, in turn, could also attract continuing milestones instalments. Any such outcome could be both transformative for ValiRx’s balance sheet while also proving its business model.

(Please note that TPI’s projections are based on financial modelling and there is no guarantee that such projections will ever be realised, therefore please do not base investment decisions on this information alone. Also please note that past performance is not a reliable indicator of future results.)

Project Pipeline focussed initially on cancer and women's health

The Group provides the scientific, financial and commercial framework to enable rapid translation of innovative science into clinical development. It selects and incubates promising novel drug candidates and guides them through an optimised process specifically structured to minimise risk and maximise the chances of successful development, with a view to guiding them through preclinical studies to clinic and investor-ready assets.

ValiRx – Pipeline Strategy

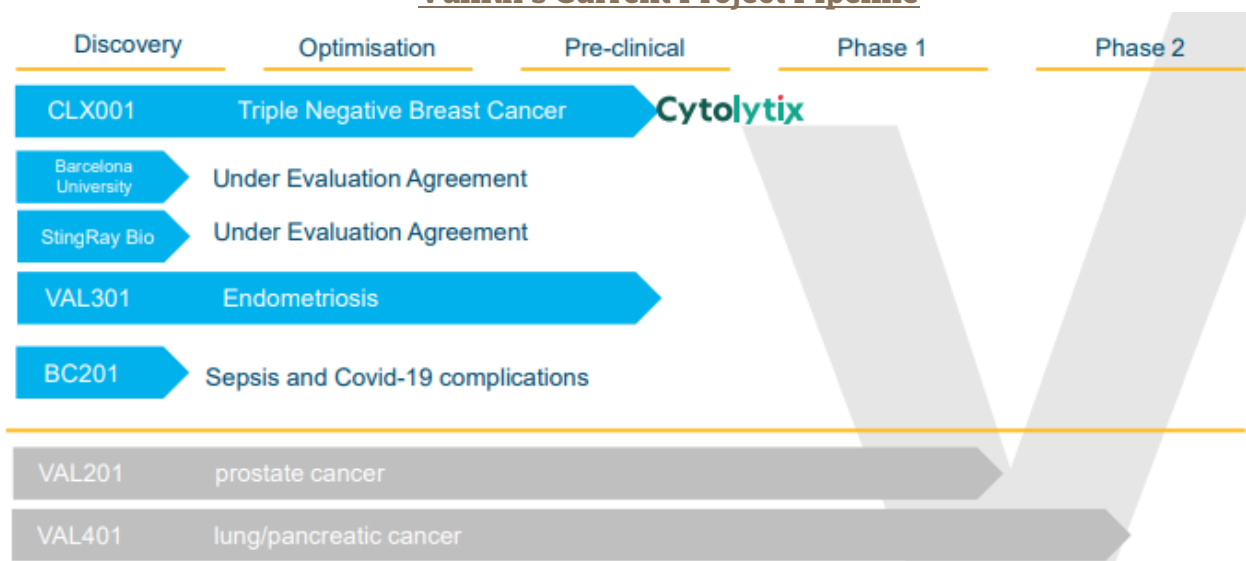


Source: ValiRx, Investor Presentation December 2023

With the necessary scientific and commercial preparation, projects are launched as a ValiRx Special Purpose Vehicle ("SPV"), presenting opportunity for external funding and investment from partners to progress into clinic. When the SPV is fledged and gained independent financing, the Group will continue to provide all support necessary to maximise its opportunity for success. Income received is reinvested into the next generation of preclinical projects. SPVs are considered valuable commercial entities, each being positioned to strategically exit from ValiRx when the time is right, recognising that only through collaboration with external industry and financing partners can such ambitions be achieved.

Management works with a range of external partners to ensure the right expertise is incorporated into the design and studies delivered in a timely fashion, thereby minimising risk and optimising outcomes. In-licensing interests span from lead optimisation to early clinical development.

ValiRx's Current Project Pipeline



Source: ValiRx, Investor Presentation December 2023

Evaluation Pipeline – First successful completion

Prior to in-licensing projects, ValiRx conducts a rigorous scientific/commercial evaluation of each opportunity.

This 6–12-month period provides the Group with the right to assess whether the project is a good fit for its pipeline. The scientific assessment typically consists of a range of cell-based assays to understand and demonstrate the mechanism of action of the lead drug candidate, while assessing the disease area of highest potential. If the Evaluation is positive, a negotiation period is entered before a full license is executed. The project is then transferred to a dedicated subsidiary and promoted to ValiRx's in-house pipeline.

The projects currently under evaluation are detailed overleaf:

ValiRx – IP License Agreements and Evaluation Projects

Project	Originator	Disease	Molecule	Started Date	IP Licensing Agreement/ Evaluation Project Status
2022.1	University of Barcelona (Spain)	Uterine and Pancreatic Cancers	Peptidomimetic KRAS binder	10 February 2022	This peptidomimetic drug candidate targets a novel binding pocket of KRAS, a protein that is well recognised to be important in cancer cell processes. A programme of work is underway to confirm the lead optimisation data and mechanism of action through a series of <i>in silico in vitro</i> and <i>in vivo</i> techniques; to synthesise and standardise the drug candidate molecule; to confirm the anti-cancer activity and safety profile; and to assess whether there is scope to expand the range of diseases to be targeted for treatment by the candidate.
2023.1	University of Barcelona (Spain)	Cancer (various)	KRAS (2)	6 June 2023	Under the 2022.1 Project, the <i>in vivo</i> study that followed 2022's successful <i>in vitro</i> testing did not achieve the desired level of anti-cancer activity. In demonstrating no adverse toxicity, however, this led to the conclusion that further research around the molecular series would be beneficial. As a result, a grant to further study the effects of the same lead series was made available to the research group. The Expanded Evaluation Agreement is scheduled to be active for up to four years, with the potential to extend by a further four years, with each project being subject to a standard set of legal conditions, and each lead series undergoing a separate evaluation process. Each evaluation process is expected to last up to 12 months, with success potentially leading to the set-up of a ValiRx subsidiary to further progress the project.
2023.2	StingRay Bio Limited (UK)	Cancer	Small Molecule	9 November 2023	ValiRx has entered into an agreement with StingRay Bio Limited ('StingRay') to investigate a lead series of drug candidates for use in oncology. Under the agreement, the Group will carry out a defined series of preclinical tests on the molecules over a twelvemonth period to validate the technology and determine suitability for commercialisation. Research conducted at Inaphaea Biolabs and collaborative partners will progress lead optimisation of the lead series molecules and ascertain activity, utilising patient derived cells from the recently acquired Imagen BioBank; as well as assessing safety profiles of lead candidates nominated from within the series.

Source: ValiRx, [RNS of 31 August 2022](#), [RNS of 24 October 2022](#), [RNS of 7 June 2023](#), TPI

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