Stock Data	
Share Price:	15.97p
Market Cap:	£14.65m
Shares in issue:	90.17m
52-week high/low:	65.00p/10.00p

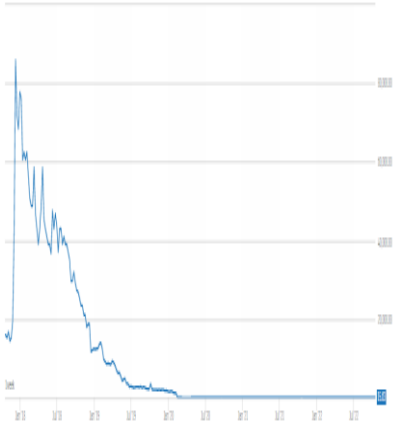
Company Profile	
Sector:	Health Care
Ticker:	VAL
Exchange:	AIM

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

Past performance is not an indication of future performance.

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ValiRx plc

ValiRx has announced its formation of a new partially-owned subsidiary company, Cytolytix Limited ('Cytolytix'), and that Cytolytix has signed an IP License Agreement with King's College London ('KCL'). Established to progress the Group's triple negative breast cancer project, CLX001, through preclinical development to a stage of readiness for clinical trials, ValiRx holds 60% of the subsidiary's shares with the balance being split between KCL (20%) and the molecule's two academic inventors, with representatives from each party on its Board. Resulting from the strategy launched in 2020 to bring new academic projects into the Group's pipeline, this is an important first step towards the commercialisation of innovative and protectable science being carried out in university departments. While also continuing to evaluate the suitability of both its Barcelona and Hokkaido projects for similar full in-licencing, management continues to seek further such opportunities. This, together with potential for significant value creation as its preclinical pipeline progresses in tandem with opportunities to secure out-licensing agreements, suggests an eventful coming 2023.

Strong balance sheet provides runway into 2024

The £2.5m (gross) ValiRx successfully raised through an equity placing plus Broker Option on 5 July 2022, leaves the Group well-resourced for the coming 18 or so months. Operating as a virtual biotech with an ungeared balance sheet, the Group has an enviably low level of cash burn; in H1 2022, for example, this amounted to less than £100k/month. It would, however, be realistic to expect this to rise somewhat during the second half and into 2023E, as the Group progresses its existing Project Pipeline, potentially acquires its own laboratory infrastructure and funds Cytolytix's preclinical developments while continuing to search for further such opportunities as well as licensing/funding partners, this presently appears sufficient to cushion it into 2024E.

This could of course change should management be presented with a specific product development success(es) or pipeline opportunities that the Board consider warrant additional spending/commitment(s). This could result from specific progress in its collaborative development pipeline or while exploring options to build-out the management's translational contract research organisation ('tCRO') initiative with a view to adding new revenue streams to the business. Recognising that success of this strategy in tandem with further conversion of assets from evaluation pipeline into full licencing will demand additional resource and experience at all levels, the Group recently strengthened its Board and operational team through the recent appointments of Ms Stella Panu as Non-executive Director ('NED') and Dr Catherine ("Cathy") Tralau-Stewart as interim Chief Scientific Officer (a non-board position).

Creating a more efficient & effective drug development service

Currently operating as a fully virtual biotech company, ValiRx out-sources all testing of current evaluation and preclinical projects through a wide range of external CROs. As has previously been detailed, the Board's view remains that this fragmented approach to early-stage drug development is non-optimal and, accordingly, it has been assessing options to acquire capabilities to enable a more efficient and reactive development process. With publication of its half year results, the Board has confirmed its working strategy has progressed towards identifying a target lab infrastructure acquisition capable of establishing future revenue flows into the Group.

Through acquiring and integrating new CRO operations in-house, the first major milestone of becoming an acquisitive tCRO, the Board considers it will be able to diversify its pipeline, create efficiencies and expand its capabilities, not only advancing its existing projects but also enabling a wider range of preclinical testing services to be offered to third parties. The revenue generated from providing such services should enable continued investment in advanced testing and analysis and support the progression of the Group's in-house pipeline projects. Sources of innovation include academic and research institutions and early-stage companies that would benefit from the Group's approach to 'connected innovation', science, finance and commerce.

Project Pipeline focussed on cancer and women's health

ValiRx's priority areas of therapeutic focus are cancer and women's health. The Group selects only the most promising preclinical projects for progression through the drug development process, to become ready for clinical trials. Its development process for each molecule is specifically structured to minimise risk and maximise the chances of successful clinical development and approval for clinical use.

ValiRx - Product Development Pipeline

Source: ValiRx

With the necessary scientific and commercial preparation, projects are launched as a ValiRx Special Purpose Vehicle ('SPV'), presenting an opportunity for external funding and investment from partners, to continue progression into clinical development. When the SPV is fledged and has independent financing, the Group will continue to provide all support necessary to deliver success. The income received from this 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 delivery of studies at the right time, minimising risk and optimising outcomes. In-licensing interests span from lead optimisation to early clinical development.

Evaluation Pipeline – First successful completion

Prior to in-licensing projects, ValiRx conducts a rigorous scientific and commercial evaluation on the project. This 6–12-month period provides the Group with the right to assess whether the project is a good fit for its pipeline. If the Evaluation is a success, a full license will be executed to license the project into a dedicated subsidiary. 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; and to assess the disease area of highest potential. Once the Evaluation is complete a negotiation period is entered to set up the subsidiary and executed the license, after which the project is promoted to ValiRx's in-house pipeline.

The remaining projects currently under evaluation are detailed below:

ValiRx – Evaluation Pipeline

Project	Originator	Disease	Molecule	Started Date	IP Licensing Agreement/ Evaluation Project Status
2021.2	Hokkaido University (Japan)	Endometrial, Pancreatic, Bile duct Cancers	Peptide	16 December 2021	This peptide-based programme targets a novel mechanism of action, binding a target that is identified as being over-expressed in endometrial, pancreatic and bile duct cancers. A programme of work is underway to ensure that the peptide can be synthesised to industry standards using industry standard techniques; formulated to access the protein target; that the biological activity is as expected, with sufficient anti-cancer activity within the safe dosing limits; and whether the range of cancer (or other disease) types can be expanded.
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 in silico and in vitro 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.

Source: ValiRx, TPI

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