ValiRx plc

ValiRx has published its half yearly report for the period ended 30 June 2022 along with an update on significant post-period events. While reflecting on the geopolitical and macroeconomic complications faced, the Chairman's statement confirmed not only that the strategic changes the Group initiated in 2021 continued during the period, but also the significance of its successful equity placing plus Broker Option that completed on 5 July 2022 with a total raise of £2.5m (gross). This provided a comfortable cash position going into the second half that should enable it to progress its collaborative development pipeline while also offering opportunity to explore a range of 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 the success of its tCRO strategy in tandem with conversion of assets from evaluation pipeline into full licencing will require additional resource and experience at all levels, the Group is seeking to strengthen the Board along with its executive and operational teams in the near future. This together with potential for significant value creation as its pre-clinical pipeline progresses along with opportunities to secure out-licensing agreements, suggests an eventful coming 18 or so months.

Financial Highlights for the six months to end-June 2022

- Research and developments costs £200,531 (2021: £166,500)
- Administrative expenses £611,370 (2021: £618,228)
- Share-based payment charge £261,052 (2021: £nil)
- Total comprehensive loss for the period of £992,481 (2021: £743,178)
- Loss before income taxation of £1,074,784 (2021: £785,434)
- Loss per share from continuing operations of 1.53p (2021: Loss 1.14p)
- Cash and cash equivalents at 30 June 2022 of £97,699* (2021: £1,239,035)

**Equity Placing plus Broker Option raising a total of £2.5m (gross) completed on 7 July 2022*

Post-period event – First Evaluation Project moved to full in-licencing

Shortly after announcing its 5 July 2022 Placing and Broker Option, on 13 July 2022 ValiRx confirmed its successful completion of the Evaluation stage of the triple negative breast cancer project from Kings College London and its decision to move forward with full in-licencing. As the first such progression within the Group's new strategy, this marks an important milestone, increasing the breadth of its overall pipeline. Management continues to seek further opportunities to bring under its Evaluation process, as well as continuing to assess the Barcelona and Hokkaido projects for suitability for full in-licencing.

Creating a more efficient & effective drug development service

Whilst the principal use of proceeds from ValiRx's £2.5m (gross) fundraising is to provide ongoing working capital for its existing business, the Directors believe that the strengthened balance sheet will also facilitate its ability to acquire its first revenue generating CRO business, the first major milestone of becoming an acquisitive tCRO.

Currently operating as a fully virtual biotech company, the Group out-sources all testing of current evaluation and pre-clinical projects to 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

Stock Data

Share Price:	11.10p
Market Cap:	£10.01m
Shares in issue:	90.17m
52-week high/low:	65.00p/10.00p

Company Profile

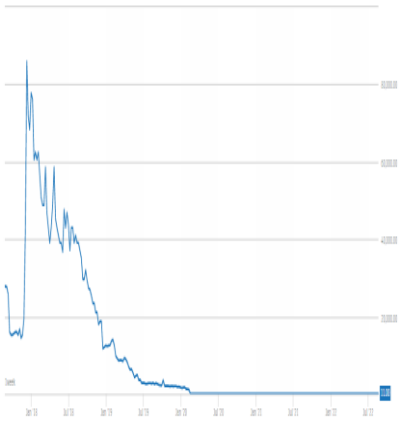
Sector:	Health Care
Ticker:	VAL
Exchange:	AIM

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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TPI acts as joint broker to ValiRx plc

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, ValiRx considers it will be able to create efficiencies and expand its capabilities, not only advancing its existing projects but also enabling a wider range of pre-clinical 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.

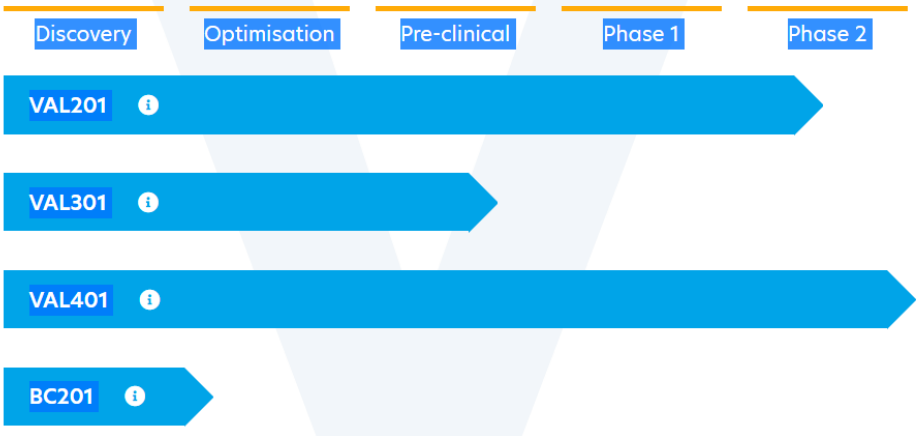
Presently financed through to 2024

While operating as a virtual biotech with an ungeared balance sheet, ValiRx has an enviably low level of cash burn, which in the first half amounted to less than £100k/month. Although it would 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, assumes full in-licensing of its first Evaluation Pipeline success and continues its search for further such opportunities as well as licensing/funding partners, the cushion provided July's funding round presently appears sufficient to cushion it into 2024. This of course could change should management be presented with a specific product development success(es) or pipeline opportunities that the Board consider warrant additional spending/commitment(s).

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 pre-clinical 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's Current Project 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 re-invested 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.

Interims confirm progression of all pipeline projects

VAL201 in prostate cancer – VAL201's Phase 1/2 clinical trial treating men with prostate cancer with varying doses of VAL201 concluded in January 2020, with the clinical study report submitted in January 2021.

The molecule's short peptide structure (i.e., composed of a relatively small number of amino acids) is inspired by the naturally occurring androgen receptor and is designed to intercept and prevent the binding of the androgen receptor to SRC kinase (an enzyme implicated in cancerous cell growth pathways). By preventing the androgen-mediated activation of SRC kinase, VAL201 can prevent cancerous cell proliferation (or growth) without interfering with other functions of the androgen receptor or SRC kinase. Importantly, this precision method, mimicking a natural process, proposes a high specificity of cancer treatment, with a lower side effect profile.

Sub-licensing VAL201 to the US biotech company TheoremRx Inc. hindered by macro-economic conditions- Although TheoremRx has faced challenges relating to the current macro-economic conditions, they have demonstrated good progress towards completion of the financing process, and ValiRx's Board remains confident that they have the commercial, scientific and financial experience to honour their commitment to the project. A Letter of Intent ('LOI') to sub-license VAL201 to TheoremRx has been in place since November 2021. On completion of its financing, a sub-license will be executed between ValiRx and TheoremRx enabling international oncology development of VAL201 globally in exchange for upfront, milestone and royalty payments.

VAL301 in endometriosis – ValiRx announced on 1 May 2020 that a Material Transfer Agreement ('MTA') had been signed with an undisclosed Japanese pharmaceutical company, which enables it to carry out its own laboratory-based evaluations. If successful, this new preclinical data may trigger the positioning of VAL301 into a new ValiRx subsidiary facilitate further commercial development and partnering of this programme.

VAL301, the same peptide ingredient as VAL201, is being investigated for the treatment of women with endometriosis and is in the preclinical stage of development. The molecule presents an opportunity to suppress hormone-driven cellular growth in the absence of outright hormone suppression; by interrupting only the hormone driven cell growth while sparing the other hormone activities, infertility and related side effects are potentially avoided. Independently of the work being carried out in Japan, ValiRx has commissioned further preclinical testing of the peptide to support the mechanism of action in the treatment of endometriosis. This will potentially provide greater insight into the interactions of the peptide with multiple cellular proteins under differing stimulation conditions as well as considering formulation aspects of the project.

VAL401 in adenocarcinoma - ValiRx continues to seek partners to advance VAL401 into the next stages of development and has engaged an external business development agency to assist in identifying and approaching potential partners.

VAL401 was originally developed for treating lung cancer and completed an exploratory Phase II trial in late-stage cancer patients in 2017. The data indicated that some patients treated with VAL401 benefited from an improvement in quality of life, particularly in measures of pain, nausea, anxiety and insomnia; and a statistically significant improvement in overall survival from time of diagnosis when compared to case matched control patients from the same clinic. Following discussions with clinical key opinion leaders, it was suggested that patients with pancreatic cancer could derive great benefit from a product like VAL401 due to improvements to severe abdominal pain, lack of appetite and nausea related to the disease.

BC201 in Covid-19 - On 2 June 2020, ValiRx announced that it had entered into a collaboration agreement with Oncolytika Limited and Black Cat Bio Limited to consider the potential for VAL201 to develop BC201. The Group provided samples of VAL201 to enable the testing programme and access to the clinical data, although as yet has received no commitment to support the project financially. Subject to a successful outcome, ValiRx would receive 40% of any licensing income generated by the project. BC201 uses the peptide ingredient of VAL201 to diminish the excessive immune response and consequently reduce severe symptoms of Covid-19. The theoretical action of the peptide is two-fold, (i) by blocking the Androgen Receptor mediated activity of SRC Kinase, the peptide down-regulates the expression of TMPRSS2 a transmembrane protein believed to be required for Coronavirus cell entry and; (ii) by directly dampening the immune response. This latter mechanism has potential for use against sepsis and autoimmune conditions in addition to the current Covid-19 programme of work.

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 projects currently under evaluation are detailed below.

ValiRx Evaluation Projects

Project	Originator	Disease	Molecule	Started Date	Project Status
2021.1	King's College London (UK)	Triple Negative Breast and Ovarian Cancers	Peptide	16 September 2021	Successfully undertaken the Evaluation Stage. Terms are now being finalised to enable the in-license to be completed. This peptide drug candidate will now be licensed into a subsidiary company of ValiRx in order to progress through preclinical development.
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, RNS of 31 August 2022, TPI

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