ValiRx plc

ValiRx has released its half year report to end-June 2023, along with an update covering significant post period events. Highlights from a busy year to date included not only the launch of the Group's wholly owned subsidiary, Inaphaea BioLabs, which recorded its first external sales just two months later, along with the acquisition of Imagen Therapeutics' scientific assets plus the signing of collaboration agreements with Physiomics, OncoBone and Agility Life Sciences, whose complementary capabilities build-out its tCRO® concept. The inclusion of such one-off operational and investment activities kept first half cash burn at a relatively high level, taking the period-end cash position to c.£0.89m, since when the Board has been managing its resources in the most efficient manner with a view to reducing monthly outgoings while maintaining momentum over the remainder of 2023 with additional balance received post period in the form of R&D tax credits. Multiple opportunities continue to be presented through ValiRx's portfolio of clinical and preclinical stage assets which, along with continuing progress with existing and prospective evaluation projects, raise Inaphaea's marketing banner ever higher. Given that it has already identified an extended list of other potential customers, ValiRx is confident Inaphaea will secure further service contracts capable of generating high margin revenues in the coming months.

Financial highlights from the half year report to 30 June 2023

- Total comprehensive loss for the period of £1,035,424 (2022: £992,481)
- Loss before income taxation of £1,152,325 (2022: £1,074,784)
- Loss per share from continuing operations of 1.03p (2022: Loss 1.53p)
- Expenditure in H1 includes one-off costs associated with the set-up of Inaphaea and acquisition of Imagen asset
- Cash and cash equivalents at 30 June 2023 of £891,246 (2022: £97,699)
- Post period receipt of R&D tax credits of £192,671 (2022: £133,413)

Inaphaea Laboratory Facility – Strategic Rationale for tCRO®

ValiRx seeks to occupy a distinctive position amongst its international contract research peer group. The ambition of its tCRO® facility is to offer experimental systems more closely related to human biology and to demonstrate high reproducibility, thereby increasing confidence in translation into clinical studies. Inaphaea's 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%

Stock Data

Share Price:	6.75p
Market Cap:	£6.91m
Shares in issue:	102.32m
52-week high/low:	21.40p/6.03p

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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operating margin in the medium to longer term) to support its in-house development projects in the future. 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.

Flexible lease terms were originally negotiated to enable expansion into adjacent floorspace in order to ensure no capacity constraints. Despite this, total outgoings are still likely to be significantly less than the cost of acquiring a similar existing, albeit less bespoke, facility. Going forward, additional overheads are expected to comprise increased headcount, including scientists (which will contribute to ValiRx's central strategy as well as laboratory operations), adding a total of c.£0.30 million to the Group's total annual fixed costs. Along with the additional capabilities and flexibility this will provide for ValiRx's own projects, the internalisation of research has been estimated to generate typical saving of c.£40,000 on each evaluation and c.£100,000 for each preclinical programme. Accordingly, the higher fixed costs are expected to be partially offset by c.£0.25m in annualised near-term savings associated with bringing its own projects in-house.

Inaphaea Facility Support Early-stage Acquisitions plus Further Expansion

Source: ValiRx, Investor Presentation March 2023

By adding an extended range of professional services/capabilities that offer expert knowledge while guiding future development decisions, which are supported through an overlay of data collation, curation and analysis to generate a deeper biological understanding, ValiRx believes its services will be capable of significantly de-risking future clinical trials.

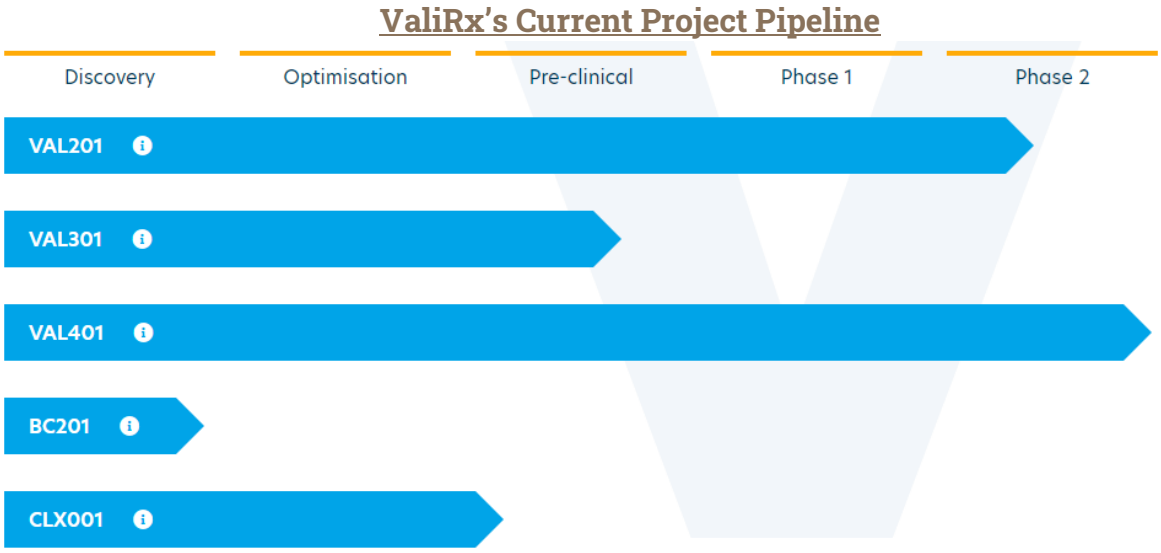
ValiRx's internal project pipeline initially focussed on cancer and women's health

ValiRx's initial therapeutic focus is on cancer and women's health. The Group selects only the most promising pre-clinical projects for progression through the drug development process, in anticipation of commencing clinical trials. Process for each molecule is then specifically structured to minimise risk and maximise the chances of successful development and approval for clinical use.

ValiRx- Recent Progress with Clinical Assets Out-Licensing and Cytolytix Studies

VAL201	TheoremRx LOI remains in place, with exclusivity carve-out from China
VAL201	Active marketing in China
VAL401	External agency progressing commercial outreach
CLX001	Initial safety screen – no major concerns Formulation optimisation – Lead and back up formulations generated and under study

Source: ValiRx, Investor Presentation June 2023

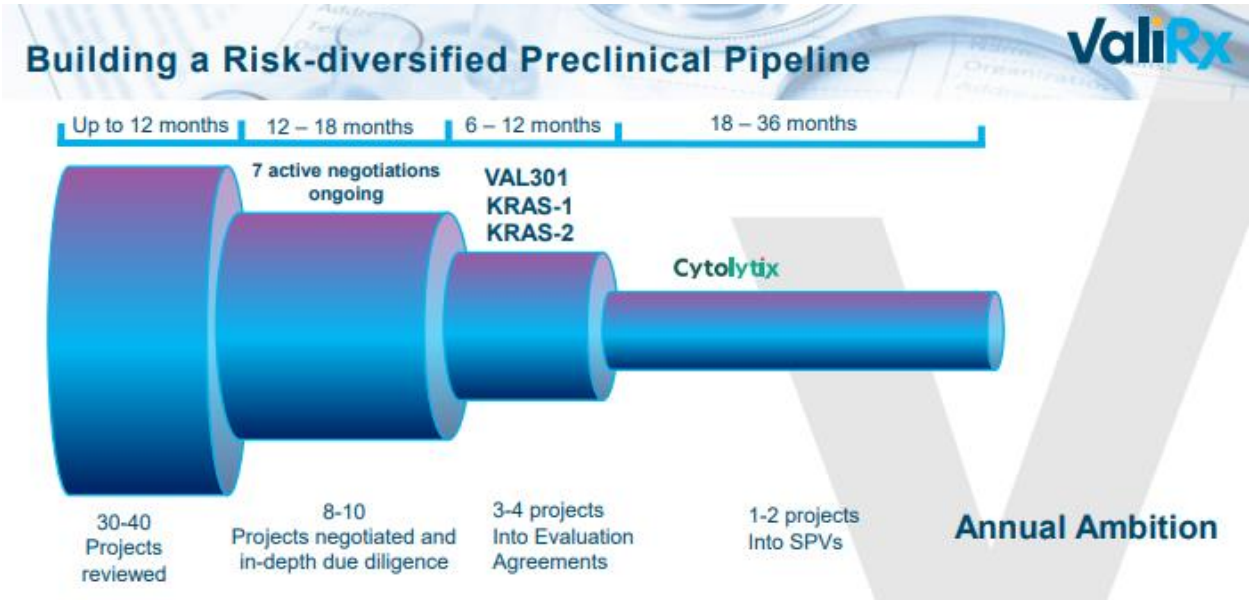


**Note: On 8 June 2023, ValiRx announced that a change to the terms to the Letter of Intent ("LOI") signed with TheoremRx Inc. (TheoremRx') covering a proposed sub-license of VAL201 had been restricted geographically and no longer covered the Greater China region* *Source: ValiRx, RNS of 8 June 2023*

The launch of majority owned Cytolytix to house the CLX001 project for the treatment of triple negative breast cancer was possibly ValiRx's highlight for 2022. Following a 9-month evaluation period consisting of manufacturing assessment, *in vitro* and *in vivo* testing, the nano-formulated peptide licensed from Kings College, London, proved to be commercially and scientifically appropriate for further development. As the first project to successfully graduate the Group's evaluation process, this is a flagship example of how it works with academics to bring innovative science into industry. As a case study, it is helping to set the standard for further international evaluations, collaborations and relationships.

ValiRx – Building a risk-diversified preclinical pipeline

As detailed below, ValiRx's ambition is to annually review 30 to 40 projects, which should then either be gradually eliminated or progressed through negotiation plus in-depth due diligence, before moving into Evaluation Agreements. Ultimately, this is followed by being transferred into SPVs in anticipation of then attracting interest from independent, external parties who would earn-in to the opportunity by assuming responsibility for the funding of clinical trials.



Source: ValiRx, Investor Presentation June 2023

ValiRx – IP License Agreements and Evaluation Projects*

Project	Originator	Disease	Molecule	Started Date	IP Licensing Agreement/ Evaluation Project Status
2021.1	King's College London (UK)	Triple Negative Breast and Ovarian Cancers	Peptide	16 September 2021	Following successfully progressing through the Evaluation Stage and completing a formal IP in-licensing agreement, this project was incorporated into a 60%-owned subsidiary company, Cytolytix, in October 2022. The remaining 40% is split between King's College London (20%), and the two academic inventors of CLX001), with ValiRx responsible for overseeing progress through preclinical development, including preparation and submission of grant applications, co-ordinating and updating all interested groups, etc.)
2022.1 2023.1	University of Barcelona (Spain)	Uterine and Pancreatic Cancers, Cancer (various)	Peptidomimetic KRAS binder KRAS (2)	10 February 2022 6 June 2023	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. On 6 June 2023, ValiRx announced that the original evaluation agreement had been expanded to a broader collaboration including additional molecules targeting KRAS (2) (Kirsten Rat Sarcoma) as possible drugs for treating cancer.

**ValiRx announced the conclusion of its evaluation agreement with Hokkaido University (Japan) on 16 June 2023 with no further commitment to the project by either party at this time*

ValiRx, RNS of 31 August 2022, RNS of 24 October 2022, RNS of 7 June 2023, RNS of 16 June 2023, TPI

ValiRx potential news flow – Outlook for the coming 12 months

Significant news flow is anticipated from ValiRx over the coming twelve months. TPI expects this to include:

- Further external laboratory services customers anticipated during FY2023
- Signing 2 to 4 more Evaluation Agreements
- Cytolytix progress updates
- Acquisition of additional capabilities to build-out the tCRO
- Technological integration to expand Inaphaea's tCRO® service offering
- Progress commercial discussions for pipeline licensing plus deepening customer relationships

Source: TPI

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