ValiRx plc

Acquisition of Imagen Therapeutics assets boosts tCRO® launch

Inaphaea BioLabs Limited ('Inaphaea'), ValiRx's recently incorporated and wholly-owned subsidiary, has completed the fitting-out and staffing of a new laboratory in MediCity (Nottingham) to conduct cell-based experiments. Leveraging its team's extensive drug development expertise in support of both in-house developments and external client projects, this facility is destined to become a centre of excellence through which the Group intends to optimise translation of early drug discovery projects towards the clinic. Focusing initially on women's health and oncology, ValiRx's concept of a Translational Contract Research Organisation ('tCRO®'), which employs the power of advanced data generation, bio-analytics and interpretation, thereby integrating a range of currently fragmented niche service offerings/specialisations, is now in an advanced stage of creation. Having already established a strategic collaboration with Physiomics plc (AIM: PYC), a sector-leading consultancy, ValiRx has successfully completed its first small, yet important acquisition of assets from Imagen Therapeutics Limited ('Imagen') and, more recently, sealed an agreement with OncoBone Limited ('OncoBone'), which introduces virtual CRO services, the Board is demonstrating its ability to complement and broaden the facility's offering while also enhancing data generation capabilities in a highly capital efficient manner. This should enable the Group to substantially build-out its risk-diversified preclinical pipeline in the coming year. Together with experimental validation assays which were successfully completed over the past two quarters and an extended list of potential customers (including 60%-owned Cytolytix) already identified, the Board expects Inaphaea to complete its first service contracts capable of generating high margin revenues in the coming months.

Inaphaea Laboratory Facility – Strategic Rationale

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. Having fully equipped and staffed Inaphaea's Medicity (Nottingham) laboratory to undertake cell-based experiments, process validation will be completed this quarter. Moreover, management has already 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.

A target list of potential customers (including Cytolytix, for which a limited subsidiary was created in October 2022 to hold an IP license signed with Kings College London) has already been identified while awareness continues to be 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 in-house development projects in the

Stock Data

Share Price:	8.25p
Market Cap:	£8.44m
Shares in issue:	102.32m
52-week high/low:	21.40p/7.67p

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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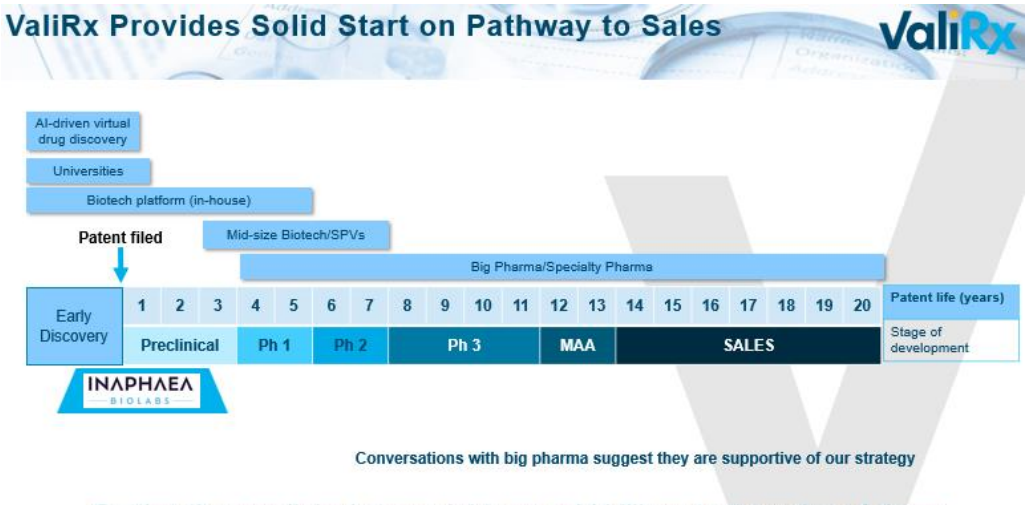
future, with first external contracts expected to be delivered during CY2023. Inaphaea's set-up and running costs of c.£0.5 million comprised investment in the new lease, staffing, operational capability and equipment for in-house use, support for the launch of the tCRO® service plus an initial runway 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 were still considered 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 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.

ValiRx's Proposed New 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.

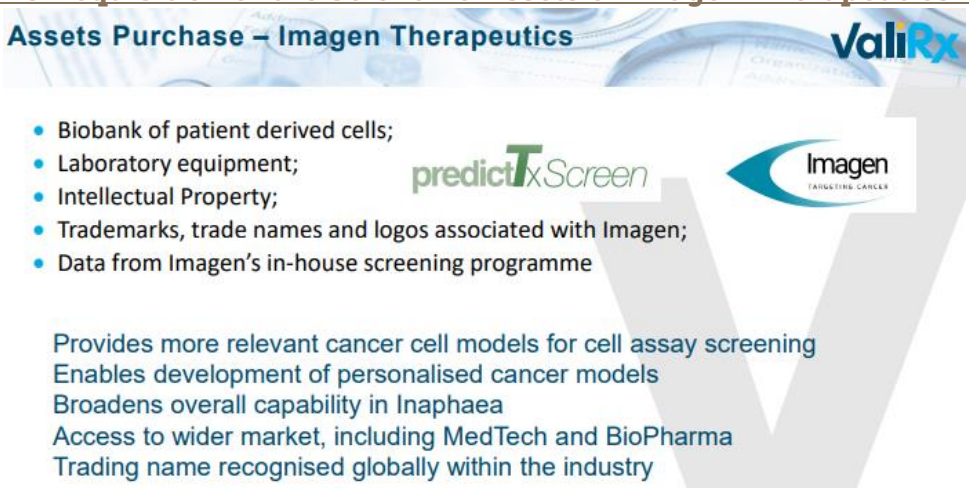


Source: ValiRx, Investor Presentation March 2023

Imagen Therapeutics offers screening potential for a wide range of oncology drug candidates

ValiRx completed the acquisition of the scientific assets of Imagen (previously an established pharma services company offering a patient-derived screening platform suitable for large global clients) from its appointed liquidators earlier this month for a total cash consideration of £170,000. Prior to its insolvency, Imagen offered a sophisticated, end-to-end platform based on its patient-derived cell ('PDC') models that supported patients, oncologists and drug developers with faster and more accurate prediction of anticancer efficacy.

ValiRx's Acquisition of the Scientific Assets of Imagen Therapeutics Limited



Source: ValiRx, Investor Presentation June 2023

In particular, Imagen's biobank of patient derived cell lines could become a valuable resource to enable Inaphaea to offer screening of a wide range of oncology drug candidates. This could represent an important step towards ValiRx's ambition to make its assays more closely aligned to a complex human system, rather than rely on commercially available immortalised cell lines. As such, it is not only able to avoid using the relatively aged offering available from ATCC's ('American Type Culture Collection') global biological resource centre, but also the high costs implied for commercial screening. The Imagen transaction also included important laboratory equipment that had already been budgeted by Inaphaea at a substantial discount to normal purchase cost for such items along with other related IP.

The drug development industry recognises that advanced patient-derived *in vitro* models which better reflect patient tumours *in vivo* are urgently needed for fast and accurate prediction of patient response to treatment. Sourcing patient tumour biopsies for laboratory screening is a highly regulated activity and requires specific technology and expertise for tissue handling and maintenance. Imagen's proprietary technologies enabled development and expansion in a laboratory's PDC models directly from fresh patient tumour biopsies. PDC model establishment had been demonstrated to be fast and efficient, with success rate nearing 90%.

Imagen's large collection of such models, comprising hundreds of well-characterised, low passage versions across more than 30 different tumour types, provides access to a leading and unique resource. It had been utilised to create various service offerings, including predict*Db* (providing access to the online, curated database), predict*Rx* (to enable rapid identification of the optimal treatment of combination strategy) and predict *Tx* (an *in vitro* pharmacology service.) The latter, predict *TX*, is considered to be a service that could be quite quickly replicated to form part of Inaphaea's broader tCRO® offering through its ability to access a multitude of additional endpoints in addition to cell count and cell death to monitor cellular processes.

Agreement with OncoBone provides clients with virtual CRO services and partner selection

OncoBone has an extended history of working in CRO business and a large global network of high-quality CRO partners, which now also encompasses Inaphaea's tCRO® capabilities. It offers expertise to clients as a virtual CRO, supporting candidates in the process of identifying and evaluating suitable partners for their proposed study,

assisting with planning and obtaining quotes for the required expertise. This agreement represents another important step towards ValiRx continuing the building-out of its tCRO® concept through Inaphaea. By integrating the power of advanced data generation, bio-analytics and interpretation, Inaphaea's customers can opt for a 'one-stop-shop' preclinical service, rather than being forced to look around highly fragmented niche offerings and specialisations. While advising their customers with selection of the most suitable CRO (in anticipation of then supporting their study planning, protocol detailing, process monitoring and reporting etc.), OncoBone's familiarity with Inaphaea should assist in gaining future recommendations.

Further acquisition potential - Discussions continue with revenue generating targets

Whilst the priority remains to build and grow the tCRO® capabilities in a capital efficient and predominantly organic manner, ValiRx also remains in discussions with other revenue generating acquisition targets (ranging from c.£0.5m to c.£.2m in projected sales) as part of its growth strategy. Target acquisitions may be financed through a mixture of cash and shares. All are considered to be complementary and accretive to the Group's new facility (covering laboratory infrastructure, niche technologies and bioinformatics). By participating in consolidation amongst existing sector players, the Board recognises multiple opportunities to acquire new capabilities/skills that can be built-out from its own operations.

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

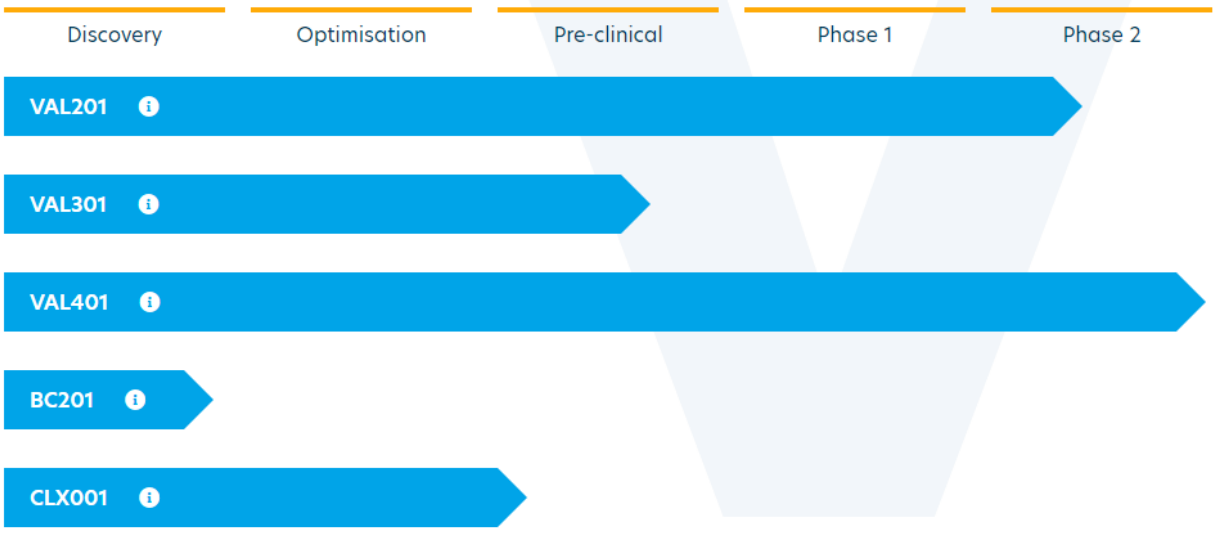
ValiRx's initial therapeutic focus is on cancer and women's health. The Group selects only the most promising pre-clinical projects for progression through the drug development process, in anticipation of commencing clinical trials. Process for each molecule is then specifically structured to minimise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

ValiRx's Current Project Pipeline



**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.

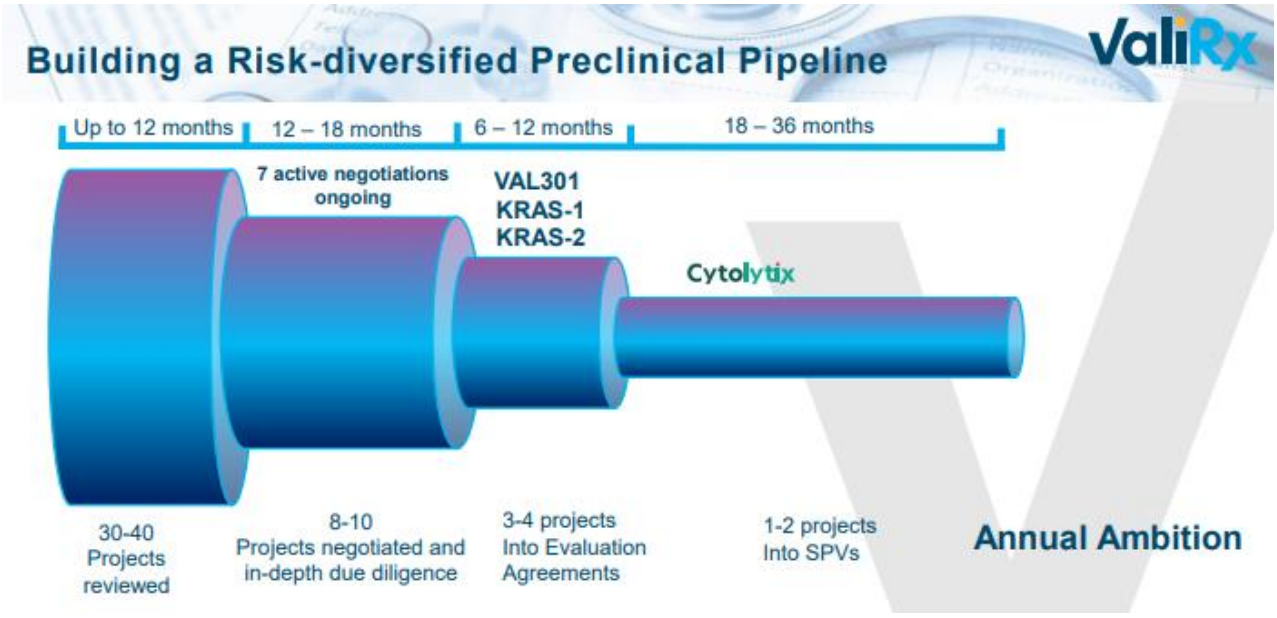
Evaluation Pipeline – First successful completion

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

Having seen its evaluation project with Hokkaido University run to completion in 2022, the subsequent assessment period concluded on 16 June 2023, beyond which there has been no further commitment from either party. The cessation of this project illustrated ValiRx's intent to use the evaluation period to fully explore the suitability of a technology for full in-licencing. Projects not meeting the rigorous hurdles are ended promptly to avoid unnecessary costs. Projects currently under evaluation or having been moved to the Group's in-house pipeline are detailed overleaf:

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 transfered 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 – Funding situation

ValiRx released its full year 2022 results on 5 June 2023. The Group's cash balance at period end was £1.14m (2021: £0.59m), added to which an equity placing plus Broker Offer undertaken on 17 January 2023 contributed a further £1.3m (gross). Operational cash burn during 2022 averaged c.£143k/month which, following March's incorporation, staffing and facilitation of Inaphaea is expected to have risen somewhat, although its extent is being limited through opportunities to internalise certain ongoing development work and processes. The balance sheet will also have suffered a further £170k drag from the cost of acquiring certain of Imagen's assets, although this was offset by receipt of certain high-quality laboratory assets that otherwise had been budgeted for purchase by Inaphaea during this financial period.

Having received a high level of potential external customer enquiries with respect to Inaphaea's tCRO® capabilities and with the laboratory now available to accept workload, ValiRx's Board is confident of securing its first, reasonably high margin, external service contacts before entering FY2024. Assuming some contribution from these presently unbudgeted opportunities, while also anticipating only a limited cash element with any successfully concluded acquisition(s), the balance sheet should retain sufficient funding to ensure its ability to continue building out its operations into next year.

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:

• First customers for external laboratory services anticipated during FY2023
• Signing 2 to 4 more Evaluation Agreements
• Cytolytix progress updates
• Announcement of at least one revenue generating acquisition
• Technological integration to expand Inaphaea's tCRO® service offering
• Progress commercial discussions for pipeline licensing plus deepening customer relationships

ValiRx 3-year share price chart

It is almost exactly 3-years since the current management, headed by CEO, Suzanne Dilly (appointed 8 June 2020), and Non-executive Chairman, Kevin Cox (appointed 26 June 2020), assumed their roles. The chart below highlights the Group's share price performance since that time:

Source: LSE

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