



## CEO introduction

Thanks to everyone who participated in our Live Q&A session on the 25 November. The recording of the session is now available on our website in the Videos and Audiocasts section of the News page <https://www.valirx.com/news>, along with a PDF copy of the presentation given, which can be viewed alongside this "Answers" document.

We received a number of questions that were not directly covered in the Live session, so we have noted the answers to these in the sections below, as well as providing summaries of the questions that we did answer.

As part of our shareholder communication policy, we are always happy to receive further questions and interactions from all shareholders, and will aim to hold our next Live Q&A event towards the end of Q1 2022, unless events dictate one is needed earlier.

Finally, I'd like to take this opportunity to wish a safe and pleasant holiday season to all of our shareholders, and we look forward to continuing our work in the new year.

Best wishes,

Suzy

Dr Suzanne Dilly  
Chief Executive Officer  
ValiRx PLC

**As a shareholder, it is frustrating that the Japanese Pharma Company have had VAL301 for 1.5 years. Can you tell us exactly what they have done with it, and when we will hear if they are interested in buying/in-licensing it, or just your wasting time, i.e. sitting on it?**

This question refers to the Material Transfer Agreement in place between ValiRx and an undisclosed Japanese Pharma Company. Announced on 1 May 2020, this agreement described the transfer of material to Japan for evaluation in the Japanese Pharma Company's laboratories.

This evaluation is ongoing. The Japanese Pharma Company and ValiRx have shared and discussed our respective preclinical experimental results regularly. As the agreement with the Japanese Pharma Company is non-exclusive, we have also been discussing this project with other potential collaborators

Importantly, however, we view VAL301 as an active project in our Women's Health development pipeline, and we continue to progress our experimental plan alongside the Japanese group.

The work being carried out will enable a better understanding of the mechanism of action of VAL301 and how this will impact the growth of endometriosis cells, as well as exploring potential dosing schedules in this challenging area of drug development. The analysis being carried out by Physiomics PLC is supporting our activities.

VAL301 has the potential to be a first-in-class, disease modifying treatment for endometriosis patients, so it is important we get every step right and fully understand the data. The nature of this challenge also highlights why we are seeking additional capabilities to provide the necessary data to have confidence of moving into clinical trials.

**When will the TheoremRX deal be signed, and will there be a payment at deal signing? How quickly do you envisage that they will start their first clinical trial?**

We signed the Letter of Intent to enter a sub-license for VAL201 with TheoremRx Inc in early November, with the intention that all final documentation would be completed, and first payments made before year end.

Over the past couple of weeks since our announcement on 2 November 2021, they have carried out significant levels of scientific due diligence on the project, looking at every detail of how our clinical trial was run, and the supporting documentation behind the clinical trial results. We have fully co-operated with them, and continue to find them an engaging and motivated team to work with.

The exact timing of the completion of the final documentation is not under our control – it depends not just on ValiRx and TheoremRx, but also on the approval timelines of CRT (Cancer Research Technology, the commercialisation arm of CRUK). As VAL201 is the subject of a license from CRT to ValiRx, their review and approval of our sub-license to ensure that it meets the obligations of our original license is essential.

When the formal paperwork is fully completed and TheoremRx have completed their fund-raising, we anticipate that they will move to start their next clinical trial promptly. We have been assisting them in preparing for their next trial already, by introducing them to appropriate UK-based CROs.

**VAL have retained the rights to develop this for conditions other than cancer. Can you share your thoughts about these other indications?**

Our flagship Women's Health project in endometriosis remains an important project in our pipeline, and is currently the lead non-oncology use of the VAL201 peptide. As discussed in an earlier answer, the experimental work surrounding this project is currently focusing on understanding the mode of action of

the peptide within the cell, and within different cell types, so may lead to an understanding of other disease areas that could be of interest for further development.

The consortium between ValiRx, Black Cat Bio and OncoLytika considers the use of the VAL201 peptide for use in patients with a hyperimmune response to Covid-19 infection, but may also have implications in sepsis and other disease areas which are exacerbated by particular types of inappropriate immune response. Experimental work on this project is ongoing.

#### **How many indications do TheoremRx intending to explore for VAL201?**

The sub-license for which we have signed a Letter of Intent with TheoremRx details the milestone payments for each oncology indication. This recognises that VAL201 may be developed for more than one cancer type.

TheoremRx have detailed their plans to develop VAL201 in prostate cancer as their first priority, but they are very much aware of the potential for use in other hormone stimulated cancer types. In particular, although prostate cancer is stimulated by androgen (hormone), VAL201 may also inhibit cell proliferation in estrogen driven cancers such as some types of endometrial or breast cancers.

TheoremRx are experts in a range of cancer types, and we look forward to further development of the VAL201 programme as they progress their plans.

#### **Are the CRUK payments up-to-date?**

Absolutely. We are fully compliant with the obligations of the CRT licence and it is fully in force.

#### **Do you have any updates on BC201? Please give a timeline, and how likely is sepsis to take over from a COVID indication, if utility is shown**

BC201 is in development as part of a consortium with OncoLytika and Black Cat Bio. OncoLytika is leading the programme and we will share any results with shareholders as and when available, subject to protection of commercial and academic interests. Covid is still a highly relevant disease, as evidenced by the recent surge in cases, and remains the priority target at this time. Sepsis is an unmet need but developing drugs in this area is very challenging. The data generated in the current experiments will help us understand more about the potential for treating sepsis.

#### **When will the Directors join the Shareholders, in buying some shares on the open market?**

Directors purchased Valirx shares in July and August 2020. The directors and senior management also purchased shares on the open market in January 2021.

#### **The Investor Brochure by Cenkos was really good. Do you have any indications if it is going to attract new Institutional Investors.**

Institutional Investors typically invest after they have had the opportunity to thoroughly research and follow a company over a period of time. This initiation note prepared by Cenkos was a really useful step in being able to provide Institutional Investors with detailed background information on the company and our markets, and will help us to build longer term relationships. Following this detailed introduction, we plan to discuss our longer term strategy with Institutional Investors to ensure they are clear on the ambition and plans of ValiRx.

Supported by Cenkos, we are preparing additional documentation to support more intensive Institutional Investor discussions in the near future, including presenting to them during a “non-deal roadshow” early in 2022.

We are currently working with Cenkos to build a following of interested Institutional Investors. We do not currently intend to place new shares in an equity placing for the purposes of raising working capital, or for the purposes of letting Institutional Investors onto the shareholder register.

**If Institutional Investors buy in via dilution, it has been alluded that this will only be for the potential acquisition of new capabilities, or facilities, which VAL can then use; both to develop their own compounds, and also as a potential offering to others. Can you give some examples of where there may be a market need for this?**

Our intention is that capital raising will be considered for value-adding acquisitions that have the potential to improve delivery of the company strategy.

We believe the world of preclinical development would benefit from more sophisticated and relevant data generation, advanced data analytics and expert interpretation. We are actively seeking to build a CRO with such capabilities, potentially starting with an under-pinning platform. An example could be a lab facility, which may a lab centred around a new technique for data generation, or a lab that can provide a broad range of basic skills.

Virtual biotech business models, such as ValiRx, routinely use these types of facilities on a service basis, as do academics and larger biotechs, supplementing their in-house capabilities.

CRO services will generate revenues from the broader industry, and add value to our in-house programmes by consolidating assays and techniques that will ensure our drug candidates progress through preclinical testing more efficiently and effectively.

Our intention is to acquire companies/technologies that bring near term income streams to help finance internal development, and help make our research self-sustaining.

**Regarding the new compounds. Will Physiomics be helping in the initial assessments/feasibility, or do you have another Company in mind?**

Physiomics PLC have excellent capabilities for understanding and interpreting data across many areas of cell biology. The collaboration on VAL201 and associated projects relating to the same peptide has already proved to be of significant value. We are confident there will be opportunities to collaborate on future projects.

**Can you talk us through the process of dealing with Universities (or other) groups. Do they approach you? How do you and the SAB decide what to trial? After the preliminary assessment, if the compound is placed into a SPV, how early do you start to market it. What do Big Pharma or other development companies want to see in terms of preclinical efficacy work?**

We have spent a good proportion of time over the past year building relationships with universities and charities to spread the word about the work that we do and our plans for developing a pipeline of novel drug candidates. In particular, Mark Treharne, Corporate Development Manager, has attended numerous partnering events, such as BioEurope, which provides excellent opportunities to identify and review projects from all over the world that fall into our areas of interest.

Our typical process is that Mark collects initial summaries of information, which we review internally against pre-determined checklists for how well each project meets our objectives. If a project is deemed

a good fit, then more detailed project data is requested under a confidentiality agreement. If the project is still of interest after review of this data we refer it to our Scientific Advisory Board (SAB).

Our SAB comprises industrial and academic scientists who are all experts in their particular fields of science. We task them to review our short list of projects during quarterly meetings. Projects that are selected for advancement at this stage are assigned an advisor to work closely with the ValiRx team and the originating team.

An Evaluation plan is then proposed to allow ValiRx to assess the project under a limited license to determine if the science is suitable for incorporation into our pipeline.

We have ambitions to achieve 4 incoming evaluation agreements per year once the system is fully operational.

**How will ValiRx make money at the highly risky early development stage if so many projects fail at early stages of development?**

We intend to de-risk the projects that we support by making sure that the science we carry out rapidly provides relevant information to assess whether the project has the potential to become a marketed product. Focusing resources on our speciality area of preclinical development will help ensure high quality projects have all the necessary data to progress towards clinical trials. This approach will also provide early knowledge of potential problems which will reduce abortive later-stage studies.

Maintaining a high through-put of projects through our systems will help to improve our ability to make objective judgements about which projects will succeed.

**Is there more funding available in the US? Is this why you have gone with TheoremRx for VAL201?**

We have contacts and relationships globally, and want to ensure that the right funding is found for the right projects, wherever that funding comes from. In many areas, and particularly in the US, it is becoming increasing common that industry experts are grouping together to raising funding specifically around a focused pipeline of projects – just as TheoremRx have for VAL201. These groups generally have the necessary drive and focus to succeed, as well as the financial and scientific capabilities to do so.