



## CEO introduction

As always, many thanks to everyone who has sent in questions this month.

We are delighted to launch our new logo and website this week. The corporate re-branding reflects the evolution of the Company's strategy, the new management team and product pipeline.

As promised earlier in the Summer, we are looking into ways to further increase shareholder interactions. Although we had hoped to be in a position to hold an event in Q4 2020 and meet you in person, it's clear that this is still not advisable in the current climate. We are currently considering holding a live webinar in the near future and hope to provide more information soon.

With this in mind, please send your questions in as usual, and also consider whether there are any more general topics that you would like us to cover in a webinar.

Best wishes,

Suzy

Dr Suzanne Dilly  
Chief Executive Officer  
ValiRx PLC

## Science Questions

**How far did VAL get with the 301 “reformulation” – e.g. were you successful in progressing to an implantation device, or an oral delivery formulation?**

The formulation work for the VAL201 peptide for all of the possible uses (cancer, endometriosis and as a component of the BC201 combination) is not yet completed. We are confident the simple injectable solution used in the VAL201 clinical trial is effective in delivering the drug but will investigate further optimisation before a final commercial form is confirmed.

On 4 July 2019 the Company announced that Aptus Clinical had been commissioned to prepare the clinical development plan for VAL301, which included consideration of appropriate formulations.

At present, VAL301 is the subject of the agreement with the undisclosed Japanese Pharma company to evaluate the use of the product in endometriosis. As detailed in the RNS on 1 May 2020, this evaluation includes considering their proprietary delivery methods. The results of this evaluation may assist to inform the dose delivery options for all related projects.

**If oral delivery is a feasible option, was a patent placed for the use of VAL201(301) in Benign Prostatic Hyperplasia (BPH)?**

VAL201 was licensed from Cancer Research Technology (CRT – now a part of CRUK) for the development of anti-cancer therapies as announced on 9 July 2008. The license does not include the use of the same peptide for non-cancerous diseases.

The patents that cover the use of VAL201 as an anti-cancer agent do not specifically cover BPH. However, the closeness of disease manifestation of prostate cancer and BPH would make a standalone patent untenable. Consequently, we have not applied for such a patent.

**Just wondering if we can expect an update on the BC201 virus project any time soon please?**

As detailed in the announcement on 2 June 2020, the consortium investigating the use of BC201 for the treatment of patients with Coronavirus infection is currently carrying out a programme of preclinical assessment. When this has been completed, we will request the consortium to release an up to date summary.

**The benefit of a stage 1/2 trial is that we actually get to test on the patients we intend to treat which gives us an advantage moving into full stage 2, do you think you have enough data from the 1/2 trial to effectively convince another company to come on board?**

The data collected in the VAL201 clinical trial are still in the process of being fully analysed, so it is impossible yet to assess the full impact. However, the headline results in patients suggest there is a marked disease impact and a strong safety and tolerability profile. This gives us confidence that the full analysis of the data will provide sufficient evidence to support substantive discussions with potential partners and for the project to progress into further clinical trials with such partners.

**In your opinion is there any possibility this could potentially be fast tracked if the data from a full stage 2 trial began to show similar or better results given that the safety and tolerability is very good.**

The processes for fast-tracking medicines to market approval and patient access are driven predominantly by the level of medical need of those patients. For example, patients suffering a disease for which there are few marketed treatments available may be able to access treatments that are still in development.

ValiRx intends that the next stage of clinical trials of VAL201 be carried out by a partner, and as such this partner will be able to consider the results to assess whether seeking early access is appropriate. Given the constantly evolving regulatory environment, it is too early to say what would be required for early access at that time.

**What could happen with VAL301? Will it be effective for treating endometriosis?**

At present, VAL301 is the subject of an agreement with an undisclosed Japanese Pharma company to evaluate the use of the product in endometriosis.

Should the Japanese Company wish to develop VAL301 further we will discuss all options, such as global or regional licensing with a mixture of upfront, milestone and royalty payments. In the case of a regional license, ValiRx will retain rights to other regions and co-develop the product, or license to additional partners.

As is the nature of scientific research, until clinical studies have been carried out, it is not possible to say whether or not VAL301 will be effective in treating the condition.

### **Corporate and Strategic Matters**

**I would like to ask if discussions with other pharmaceutical companies can take place upon release of headline results, or is it a case of waiting for the full results been published until a joint venture can be thrashed out?**

All ValiRx projects in our portfolio have already been the subject of preliminary conversations with potential partners. As a result of this, these potential partners have now been updated with the headline results, and those that have expressed interest in seeing further details will receive the full results when they are available. The timetable for completion of any potential transaction will be determined by the levels of interest and normal commercial processes.

**Is Black Cat responsible for raising the cash & investigating VAL products?**

Black Cat Bio Limited is an independent private company that is a member of the BC201 virus consortium with ValiRx and Oncolytika (announced 2 June 2020), and separately has an agreement with ValiSeek to seek funding for the VAL401 project (announced 14 January 2020). Black Cat Bio has no mandate to raise cash or carry out investigations on ValiRx's other products.

**To date has anyone shown an interest in providing Black Cat Bio with funding to take 401 forward.**

As detailed in the question above, Black Cat Bio has an agreement with ValiSeek to seek funding for the VAL401 project (announced 14 January 2020). When Black Cat provides ValiRx with a substantive update, this will be released via RNS in a timely manner.

**Question regarding the 301 deal with the unnamed Japanese Pharma co:  
If they find that our compound is useful to them but can't come to a beneficial financial agreement  
what protocols are in place to stop them using the information already provided to them?**

This question refers to the investigation of VAL301 for the treatment of endometriosis, which is subject to a material transfer agreement with an undisclosed Japanese company as announced on 1 May 2020. Although the precise terms of this agreement remain confidential beyond those detailed in the announcement, this type of agreement typically contains standard restrictions ensuring that the product and information provided about the product is only used for the evaluation purposes as detailed in the agreement.

Further, VAL301 is the subject of a number of patents worldwide (granted and pending), which belong to ValiRx. The content of all medicinal products is well defined for marketing authorisation. The use of VAL301 in a commercial product would be publicly available information and would constitute a breach of contract.

**Is there a share placing scheduled now the headline results are released?**

No. As stated in the announcement on 23 September 2020 Valirx currently has approximately £2m in cash and a significantly reduced cash burn rate. The Company has sufficient funding to progress its new strategy for the foreseeable future. The Company's strategy also includes the intention to secure funding through partnering the current assets and to receive fees for further product development.

In the event that the Company undertook a further placing it would be conditional on shareholder consent at a General Meeting.

**Is it possible that good news about a product could be known by other people before ValiRx know?**

ValiRx is a virtual biotechnology company, meaning that we out-source a lot of functions, including laboratory-based research to third party organisations. Researchers carrying out this work will know the results of experiments before we do. However, we have strict confidentiality clauses in all contracts with such organisations. If a third-party contractor was found to be acting on information that was not in the public domain, for example by buying or selling shares, they would be in breach of contract. It would also be a violation of the EU Market Abuse Regulation, which is overseen by the UK Financial Conduct Authority.

Likewise, if we were in the process of a negotiation to in-license or out-license a product, a decision taken by an outside company may be known by individuals within that company before ValiRx is aware that a decision has been made.

**With Covid restrictions increasing, will this affect product progress?**

As announced on 19 May 2020, the Company identified that there was a possibility of a delay in processing the data from the VAL201 clinical trial due to restricted access to the clinical unit at University College Hospital (UCLH) in London during lockdown. As the database is now locked, this is no longer a factor in our timelines.

With variable pandemic restrictions across the UK, ValiRx is very fortunate to have a flexible team that can work remotely, and productivity is predominantly unaffected by local restrictions. We will assess the Covid risk for all projects and take mitigating actions should they be required.