CEO introduction

I'd like to start this time by thanking everyone who attended and participated in our Live Q&A event last month. We were pleased with the level of attendance and the quality of questions asked. It's always good to put a face to a name, and while nothing can really replace real-life interactions, the accessibility provided by online events has been a really positive step forwards for shareholder communications.

We will look to hold more events of this type in the future, so any feedback on our level of interaction would be gratefully received as we remain committed to communicating transparently with shareholders to ensure a clear understanding of the business.

Below are our answers to the questions submitted in advance of the Live Q&A event last month, as well as questions submitted specifically for the monthly Q&A.

Best wishes

Suzy

Dr Suzanne Dilly
Chief Executive Officer
ValiRx PLC

Science Questions

Where do you feel VAL201 would best sit in prostate cancer therapy? (which line 1st, 2nd or later and after which other therapy?)
Earlier this year ValiRx commissioned interviews with prostate cancer specialists (US, EU, UK) in order to understand their interpretation of the data collected and of the need for a new drug candidate of this nature. The answers provided were personal opinions, but the overarching feeling was that VAL201 should be developed initially as a second line therapy for metastatic prostate cancer with a view to moving into other patient groups (first line and end-stage) after the first market authorisation is complete. One reviewer proposed testing combination treatments with both enzalutamide and abiraterone. As ValiRx intends to out-licence VAL201 for the later stages of drug development, the exact positioning of the drug, and any alterations to the current assumptions will be for the partner to decide. We are presenting the programme to potential partners using the assumptions described above, while also highlighting the possibilities for additional market opportunities, for example by expansion into other cancer types, by reformulation into an alternative dose format or by treatment of patients at different stages in the treatment pathway.
Do you think we will hear about val301 potential for use in endometriosis this year? **When are we likely to hear about the Japanese collaboration?** **Do you have a max. time frame you are willing to wait before you decide to move on from the Japanese pharmaceutical company? If so, do you have other companies who are interested in VAL301?** **Do you have any contact with the Japanese Pharm in regards to VAL301? Can you provide any information as to where we are with the progress of VAL301? Do we know if they are currently conducting any trials for VAL301?**
We've encompassed all of the above questions into a summary of the current position with VAL301. VAL301 is the use of the same peptide as VAL201 but for the treatment of the women's health condition of endometriosis. Although endometriosis is not a cancerous condition, it is characterised by an inappropriate hormone-driven growth of cells that causes significant pain and life-disruption in up to 10% of women. VAL301 offers the potential to reduce that cell growth in a comparable manner to how VAL201 reduces cancerous cell growth in men with prostate cancer. This would provide a disease modifying treatment that could make a significant positive impact on women's lives. In May 2020, the Company announced the Material Transfer Agreement of samples of VAL301 to an undisclosed Japanese Pharma Company. This allows the Japanese Pharma Company to undertake preclinical testing to evaluate whether they feel VAL301 would be a good fit, both scientifically and commercially, for their pipeline of women's health projects. We have had detailed scientific conversations with the Japanese team on several occasions in the intervening period, where they share results and we provide advice and interpretation on these. The timing for the completion of their evaluation is entirely under their control, and we do not believe it to be beneficial for us to pressure them into making an earlier decision before they have obtained the data that they wish to generate.

The experimental programme being carried out by the Japanese Pharma Company is entirely preclinical. No clinical studies can be carried out under the agreement that is currently in place.

In the meantime, we continue to market VAL301 to any other companies that may have an interest in developing the project for endometriosis, and the arrangement with the Japanese Pharma Company does not hinder these discussions in any way.

In addition to this, we have commissioned additional preclinical assays that consider the mechanism of action of the VAL301 peptide. These experiments have been designed to assist in demonstrating and adding evidence to the mechanism of action of the peptide in both the endometriosis and oncology uses. The data generated during this period of work will be provided to Physiomics plc (AIM: PYC), in order to assist in building their models, and to better understand the fundamental activity of the peptide within a cell.

Regarding the collaboration with Physiomics, have they completed all the necessary work for VAL201?

Can you share with us the order in which Physiomics will conduct modelling on our drugs? We have given them three drugs, VAL201, VAL301 and BC201, Which is first, second and third?

Have you explored with PYC the potential for use in sepsis using VALl201?

The Company announced the extension of the agreement with Physiomics plc (AIM: PYC) in January 2021. This detailed that Physiomics will be carrying out a programme of work spread over a 9-month period to consider all three programmes that use the VAL201 peptide as an active ingredient – VAL201 in prostate cancer, VAL301 in endometriosis and BC201, the collaborative project with Black Cat Bio and OncoLytika considering the peptide in the treatment of patients with severe symptoms of Covid-19.

The programme of works provides an analysis of the clinical data collected for VAL201, and the comparison of this to the preclinical data generated for all three programmes, aiming to provide additional scientific evidence of the mechanisms of action and proposing hypotheses to be tested in further clinical or preclinical testing on all of these projects.

As the behaviour of the peptide in the cell will have similar characteristics regardless of the disease studied, the work is not split strictly into the project areas – i.e. it is not the case that they will work on the projects sequentially. The behaviour of the peptide will be modelled based on the data generated, and conclusions relating to each project can then be drawn from those models.

At the current time, Physiomics have carried out analysis on the clinical data, and when the new preclinical data being generated for the endometriosis project (detailed above) and for BC201 (detailed below) are available, they will continue to amalgamate these new data points into their models.

The conclusions surrounding BC201 will be applied to the understanding of whether the peptide could also be used as a treatment of sepsis. The increased overall understanding of the activity of the peptide, by Physiomics and by our Scientific Advisory Board will enable better understanding of all potential applications of the peptide.

Are you able to share the results once you receive them from Physiomics with the shareholders?

Depending on the nature of the results generated within the Physiomics collaboration we intend that the results will be written into publications for release in the peer-reviewed literature. This means of releasing data ensures that the data is searchable and accessible to future researchers and is broadly agreed to be the most appropriate manner for release of clinical trial results.

By ensuring accurate and scientifically useful dissemination of the data on which future research can be built, we ensure that we maximise the impact of the contribution by the individual participants in our clinical trial.

What are the trial timelines on val401?

We are actively seeking funding or to out-licence VAL401 to progress to the next stage of clinical trials. The next clinical trial is expected to be of approximately three years in duration from the time at which funding is confirmed.

Is there any experimental evidence for BC201?

Preclinical experiments for BC201 are being performed under the collaboration agreement between ValiRx, OncoLytika and Black Cat Bio.

These experiments include the analysis of protein expression in cells as a result of treatment by BC201, in particular the expression of the TMPRSS2 protein that is essential for the viral particle entry into cells in Covid-19; and the levels of Neutrophil Extracellular Traps in blood samples after ex-vivo treatment, which represent the treatment of the hyperimmune response.

When the experimental data for these tests is finalised, we will notify the market and update our website to include the new information.

Corporate and Strategic Matters

You have stated many times you are in talks with other pharmaceutical companies, how confident are you on doing a deal in the next three months?

Do you have a timeline for finding a partner/investor for VAL201?

In regards to a deal for VAL201, are you able to give us any information as to how many interested parties have shown interest? i.e more than 3? Are you in advance decision with any of them?

The exact timing of many corporate events is challenging to pinpoint. Likewise, the level of confidence in finding an appropriate partner or purchaser for VAL201 is challenging to articulate without being able to provide specific points of reference.

We are seeking a partner that has the right capabilities, financially, scientifically and commercially, to take on the further development of VAL201 and is committed to making the project a success.

A typical biotech licensing deal incorporates upfront and near-term milestone payments, clinical and commercial milestones and royalties on sales. Our level of confidence that the partner is committed to progressing VAL201 to commercialisation and achieving the later milestones is key to selecting the right partner for long term development.

For reasons of commercial sensitivity, we are unable to reveal the numbers of parties we are or have been in discussions with, or the stage of those discussions. We acknowledge the public interest at this point, and commit to ensuring that as soon as definitive news is available to announce, it will be done in a timely and as transparent manner as possible, however we are also cautious of making announcements at too early a stage before details such as timelines or financials can be definitively stated.

Do you think our M/Cap is too low from where the company is at today.
The recent SP Angel research report that coincided with our annual report release detailed a peer reviewed comparison of market cap levels. Clearly there is a wide range of market caps within the UK biotech sector and ValiRx has room to potentially move up within that range based on the implementation of our new strategy.
The share price has completely flatlined in the last 6 months. What action are you considering that will add value to the company in the short term/medium term? To increase our shareholder base. Have you considered give a presentation to institutional investors?
Since the placing at 7.5p in July 2020, the share price has improved significantly and stabilised. Although briefly rising, it has settled to a level that is more or less consistent over the past six months. We believe this stability in the share price reflects the stronger financial position of the Company and we are working hard to implement our new corporate strategy in order to build future value into the company. Strategic changes take time to take effect, and also to be fully reflected in both the market cap and the share price. We believe the work being carried out by the team now will build long term value and stability into the company.
I've heard that there are payments to be made to CRT and that you are in breach of your license for developing VAL201, can you confirm whether ValiRx has any rights to the VAL201 patents?
ValiRx currently holds a license from CRT (Cancer Research Technology) for VAL201. The terms of this license include payments to CRT on hitting development milestones and reporting obligations for all aspects of development on the project. We are in regular contact with the team at CRT as they assist in our conversations with potential licensees, and we can confirm that there are no outstanding liabilities from ValiRx to CRT and the license is fully in force.