CEO introduction

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

We appreciate that shareholders value speed as well as accuracy and transparency in answers to important questions, and the Q&A system can seem cumbersome in this regard with responses taking a few weeks to communicate. We believe this balance of timeliness with fair distribution of information is appropriate and reminds shareholders that this is a voluntary addition to improve communications that is beyond the regulatory requirements.

Although it seems a little early, I would like to wish you all a Happy Easter!

Best wishes

Suzy

Dr Suzanne Dilly
Chief Executive Officer
ValiRx PLC

Science Questions

Has VAL201 ever shown any anti-inflammatory response (Covid-19), or does it target DNA or RNA which are the targets of Covid-19? It targets a specific human protein.

BC201 incorporates the VAL201 peptide as a component of a possible treatment for patients suffering severe symptoms of Covid-19. The mechanism of action for VAL201 in this application should be considered from several angles.

- Firstly, the link between the levels of expression of the Androgen Receptor on cells and susceptibility to severe symptoms of Covid-19 are clear and well published. Treatment with VAL201 has the potential to moderate activity of the Androgen Receptors and expression of the protease TMPRSS2, which is required alongside the ACE2 receptor for the virus to enter the cell, thus reducing infectivity.
- Secondly, the role of VAL201 in blocking the hormone mediated activity of SRC kinase is proposed to have a direct impact of the production of Neutrophil Extracellular Traps (NETs). These NETs are part of the immune response and are initially helpful for removing virus (or bacteria) after an infection. In severe cases of Covid-19, just as in sepsis, these NETs can cause bystander collateral damage, causing multi-organ failure, which triggers further production of NETs and perpetuates the cycle. By breaking this NET cycle, severe symptoms caused by the over-reaction of the immune system is moderated. It is not as straightforward as an "anti-inflammatory effect".
- Finally, as the virus uses the infected cell's internal machinery to replicate, the inhibition of a key pathway by the VAL201 peptide, may also slow the replication rate of the virus, giving additional time for the immune system to respond appropriately.

This multi-faceted approach is considered a key advantage of the BC201 programme, and the consortium developing BC201 is investigating each benefit individually, as well as in synergy.

How much longer will phase 2 take for Val 201 & 401? And will there be more trials thereafter and what will be the expected timeline please?

ValiRx's strategy is now to identify programmes at the preclinical stage of development and move these towards clinic-ready status. As a result of focusing on preclinical development, we intend to out-license or partner our clinical projects.

Therefore, ValiRx is not planning to be directly involved in the next stages of clinical testing for either VAL201 or VAL401.

In general, Phase 2 and Phase 2 cancer trials can each take around 3 years. However, clinical trials can vary significantly in length according to how many and what type of patients are required, the schedule of testing involved, where the trials are run and the available budget. With these factors in mind, the trial duration for either programme is not possible to accurately predict.

Corporate and Strategic Matters

I have been a shareholder for around 11 months and am excited by the prospects around VAL201. I am looking to increase my holding for the long term so am not looking for a quick return but my only concern is around funding. Are you confident that ValiRx will get to a point this year where It will be generating its own income so it's not reliant on placings in the future?
A priority for ValiRx is to secure near-term funding by out-licencing or partnering the existing clinical programmes (VAL201 and VAL401). We are in active discussions with a number of companies to achieve this. In the longer-term, the strategy we introduced last year sees revenues entering the Company from two sources. Firstly, our strategy for creating subsidiary companies and assisting in their operation is intended to bring fees into ValiRx, which we expect to cover day-to-day working capital requirements as the business builds. This will be via service contracts between each subsidiary and ValiRx, whereby ValiRx will continue to provide the corporate framework in which the subsidiary can operate, including, for example, project management resource, IT and accountancy functions. Secondly, we expect to retain an equity interest in each subsidiary, so that ValiRx will benefit from an exit event, e.g., out-licence or sale. The exact timing of the first revenues to enter the Company is difficult to predict, but we are confident that the strategy is the right one for the Company, and will result in the most efficient route to revenues.
Within the limitations of what can be said which is not market sensitive, are you able to give any update on the progress of VAL 401?
VAL401 is currently the subject of the arrangement with Black Cat Bio Limited, announced by the Company on 14 January 2020, whereby Black Cat Bio has been given the remit to seek funding for the next VAL401 clinical trial. This agreement is ongoing. Black Cat Bio provides regular progress updates and ValiRx routinely provides scientific input into their financing conversations. We also continue to promote VAL401 alongside the pipeline of projects held within ValiRx at conferences and partnering events to help identify additional interested parties. More information is available on the Company website https://www.valirx.com.

Can you inform me of your pay package inc share options please and do you get paid by Valiseek as well. Can I have the salary info now please. Should not need to wait 3 weeks for it.

Full details of directors' salaries in 2020, along with details of the warrants that were outstanding as at 31 December 2020 and share options held will be published in the fully audited accounts in Q2 2021.

The role of CEO at ValiRx PLC is my only salaried position. Although I remain a director of ValiSeek Limited and Tangent Reprofiling Limited, neither of these positions are salaried or accrue other benefits to me.

Does the collaboration with PYC indicate that you value VAL201 in excess of £100 million as you mention a 6% funding deal that is capped at £6 million.

Do you think this is a realistic valuation and would you think it's achievable within the next 12 months or so or is this £100 million + something that you would expect over a longer period I.e. a number of years?

The agreement with Physiomics plc provides for ValiRx to pay up to 6% of net revenues for any income related to the further development of the VAL201 peptide by a third party. The total payable is capped at £6 million.

The intention of the cap is to limit the ongoing liability and is a reflection of the potential "value-add" of the Physiomics technology.

For sound commercial reasons, we cannot speculate on the value of VAL201, nor when it might be realised.

A typical biotech deal consists of an upfront payment, milestone payments and a royalty/revenue share. Depending on the nature and type of company involved, the quantum, frequency and bias between these three factors will vary significantly.

I'm presuming there is no truth to the AZ rumours circulating on lse this morning? Seems like nonsense but would be nice to nip it in the bud for all concerned

This question refers to a series of social media posts which display emails purporting to be circulated within AstraZeneca. These emails were not addressed to any member of ValiRx and as such we cannot comment on the veracity of emails circulated internally in third party companies.

We consider it highly likely that these emails are fake.

We remind shareholders that such speculation is potentially damaging to the Company, discouraging genuine approaches from the wider biotech and pharmaceutical industry. Confidentiality is essential during commercial negotiations.

There are some rumblings regarding an offer on 201 being turned down by Valirx, I presume from the Japanese company. I understand these agreements have confidentiality clauses but surely some information on this should be available to the shareholders via rns.

On 1 May 2020, ValiRx announced the Material Transfer Agreement that enabled the undisclosed Japanese Company to commence their evaluation of VAL301 in the treatment of endometriosis. To the best of our knowledge the Japanese Company has no interest in VAL201 in the treatment of prostate cancer.

We regularly consult with our Nominated Adviser (NOMAD) on all events that are likely to be subject to the regulatory requirements of AIM. The Board is confident we fully comply with the AIM Rules.

Sharing information about speculative offers, ongoing discussions and negotiations before a transaction has been agreed would violate confidentiality and be counter to good corporate governance and may indeed be a breach of the AIM Rules and the Market Abuse Regulations ("MAR").

Would it have been better for all individuals to start a new venture for early stage technology incubation?

I'm a bit concerned about what the cancer patients who participated in the trial are now thinking. They gave their time and dedication during difficult times and now with the "new strategy" to transform the company to early stage technology incubator.

The corporate structure, experience and market visibility of ValiRx were considered to provide an ideal platform from which to evolve the Company's proposition and engage effectively with a wide range of innovators and investors to build a pipeline of exciting new projects. The Board believes this approach will create long term value for investors and ameliorate the typical fluctuations of clinical development.

As part of this evolution, the clinical projects within ValiRx will be licensed or partnered with companies that have the strategic intent to continue further development and have the requisite clinical and operational experience. This will ensure that out-licenced programmes continue in the most appropriate manner and best serve the needs of patients in the longer term.

We highly value the commitment of the trial participants and seek to ensure that all data generated through their generous participation is fully utilised in further development and possible future clinical application of VAL201 and VAL401 in areas of unmet medical need.