CEO's welcome

As this is the first "Answers Session" released under our new communications strategy, I want to preface this with a few explanations. Firstly, this is a six-month trial period of the strategy, in which we intend to publish updates on our website approximately once a month, with additional releases if required around any particular issues or frequently asked questions.

Secondly, by updating via the website, the updates are available and accessible to all, but please remember, this is not a regulatory information service, so the answers cannot contain any price sensitive information that has not already been released in the public domain. We will also be monitoring the incoming questions to look for information that we should be making clear in our broader communication strategy. The updates published on our website contain the highest possible level of accuracy.

Finally, I'm delighted to see that the system has been well received so far, in particular that some people have reached out and asked questions who have not previously contacted us. This justifies to me that the system was needed, and I hope the trial proves a success. Thank-you to everyone who participated, I hope you find the answers you're looking for here.

I've split the questions into broad categories, so if you've asked more than one question, you may find your answers have been split into multiple locations. I have also combined similar questions for a single answer.

Best wishes,

Suzy

Dr Suzanne Dilly
Chief Executive Officer
ValiRx PLC

Science Questions

How much longer before the reviews of the compounds and an official RNS update? Especially VAL201 is it likely to be updated in September as hoped or are we looking to early next year?
We have been waiting for news for a long time, if the news or progress is delayed could you inform us, and if possible the reason for the delay?
Can you update on how the review of data for the compound 201 by Dr Dilly is coming along?
Please see our RNS and associated factsheet from 19th May 2020, this provided an update and review at that time of all compounds. This RNS and factsheet also confirmed the expected timelines for progression of all projects. As new information emerges, or timelines evolve, we will endeavour to provide further updates in a timely manner, please also note our answer to the question below regarding the close-out period for the trial, giving further indication of the timing of results.
When did the close-out period begin for the VAL201 Phase I/II clinical trial and how long will it take to be completed?
As stated in our RNS and factsheet update on 19th May 2020, the VAL201 clinical trial officially ended on 27th January 2020. As this date is reported as the closure of the treatment period, it can also be considered as the beginning of the close-out period. During this close-out period, activities include "source data verification" (checking of all data entered into the study database against medical records to ensure accuracy); data analysis and site close-out visits. Among other activities, these examples provide an indication of the level of work needed during the close-out period. The COVID-19 national lockdown presents some challenges to some of these activities, and our team are working closely with the clinical site to ensure smooth progress. As noted in our RNS on 19th May 2020, delays due to the lockdown are possible due to restricted access to the clinical site, but we are working to minimise these, and will update shareholders if the timelines referred to in the RNS are not going to be met. The regulatory guidelines dictated that the Clinical Study Report must be submitted to the regulators within 12 months of the end of trial.

I am very intrigued by the Japanese connection and would ask what are the financial implications if the Japanese company TAKE ON 301 and possibly 201?
The Japanese Company with whom we have a Material Transfer Agreement (as announced on 1st May 2020) has a particular interest in developing a women's health product, so, while VAL301 fits their strategy well, there is no indication of any interest in VAL201. If the Japanese Company wishes to develop VAL301 beyond their current evaluation, they will be able to consider a selection of standard options such as global or regional licensing with a mixture of upfront, milestone and royalty payments. In the case of a regional license, ValiRx would retain rights to other regions and be able to co-develop the project, or to license to additional partners.

I note from the RNS on the sale of Trac and Biofit to DDT Ltd there is no mention of retaining any rights to the use of Trac as there was when Trac was sold previously a few years ago. Dr Morris said then that Trac was needed to further the use of Genice. I would be grateful if you could clear up this apparent contradiction.

As announced in our RNS of 16th June 2020, we have decided to discontinue development of the GeneICE program, and therefore had no further need to access the TRAC technology in relation to this program.

What are the plans for therapeutic development?

Initially we are focussing on the continued development of VAL201, in ensuring the clinical trial close-out is completed on schedule; and on VAL301 ensuring that the work being carried out under the Material Transfer Agreement with the Japanese Pharma Company, announced on 1st May 2020, proceeds smoothly.

Further projects may be brought in to complement these programs in areas where we feel our team can add value. If such programs are sourced, a regulatory announcement would be made.

When will the first drug be brought to market?

ValiRx aims to partner projects during the development process, such that drugs within the ValiRx pipeline are unlikely to be brought onto the market directly by ValiRx. As specialists in discovery, preclinical and early clinical phase development, ValiRx adds value at the early stage of drug development. The projects ready for late stage clinical development will be passed to specialists in this stage, and then likely onto commercialisation specialists who will bring the drugs to market.

VAL201 has completed a Phase 1/2 clinical trial, so is required to complete Phase 2 and 3 before market authorisation can be considered – the timeline for this will be dependent on the design of those trials. VAL301 is at preclinical stage, so requires all three clinical phases of development. VAL401 has a shorter route to market due to the nature of it as a reformulated generic drug, and requires at least one further clinical trial (depending on size and results) before market authorisation could be considered.

Therefore, of these three pipeline products, VAL401 can be considered furthest along the development pipeline. However, the timing of market authorisation is difficult to predict, especially as it is controlled by a third party.

Who is going to fund the programs and have you any prospect partners. If so, who are they?

Our preferred business model is to partner projects at the earliest feasible stage in order to reduce risk, reduce direct cost, and to increase the range of skills and expertise being input to the project. Each project has different needs in a partner and will be assessed accordingly.

VAL301 has an agreement already announced with a Japanese Pharma Company, whereby the third party is covering the costs of the current developments and sharing the information generated.

Partner identities can be released only when those agreements have been finalised in order to avoid prejudicing ongoing negotiations. Even when agreement is reached, there can be continued restrictions on announcing the identity of the partner according to their own corporate policies. However, all partners will be selected for their suitability to continue the science, with resources and expertise as a prerequisite.

Will Black Cat Bio Limited be used to take specific drug lines further than the current ValiRx business model and if so when and how is funding envisaged?

Will ValiRx sell individual drug lines to Back Cat Bio Limited, to provide cash necessary to fund further ValiRx research?

Black Cat Bio Limited ("Black Cat") is a private company, operating independently from ValiRx.

A Letter of Intent was signed between Black Cat, ValiSeek and Tangent Reprofiling Limited, as announced on 14th January 2020, stating that when Black Cat has raised a minimum fund level, ValiSeek will be restructured to allow the VAL401 project to be licensed to Black Cat, and the shareholders of ValiSeek to become shareholders of Black Cat (including ValiRx plc as one of those shareholders).

Furthermore, on 2nd June 2020 Black Cat, Oncolytika Limited and ValiRx formed a collaboration to allow Black Cat and Oncolytika to investigate the use of VAL201 for the treatment of patients suffering severe effects of Coronavirus SAR-CoV2 infection. In this arrangement, ValiRx has committed to provide surplus material from the VAL201 clinical trial and expertise from the Company, to support the collaborative investigation.

Black Cat has expressed no interest in developing any other assets from ValiRx. ValiRx will always seek the most appropriate partner for each project to minimise risk and increase the likelihood of success.

Will partners be involved in both Black cat and ValiRx...or only within the former...ala most recent Covid related initiative?

Black Cat Bio Limited's corporate strategy is decided by Black Cat. If a potential partner wishes to partner with Black Cat, then they will do so directly.

If a potential partner wishes to partner with ValiRx, they can do so directly – or if appropriate, the ValiRx project can be placed into a ValiRx subsidiary in order to ringfence funding and facilitate joint venture arrangements.

Corporate Matters

Do you have a firm date for the next AGM yet?
Our RNS on 8th June 2020 included the information that we have been granted a three month extension to the usual deadline for submitting audited accounts – being now nine months after year end rather than six months. This is due to the recognition that the Coronavirus lockdown has made the audit process slower due to home-working. The AGM date will be announced when the audited accounts are released so that the accounts can be formally adopted at the AGM as per the usual procedure.
Will existing shareholders be given opportunities to participate in future fund raising….mindful adequate time needed, as each investor raises cash…(whereas Institutions have cash on hand)….eg…selling shares in ISA and take out…..etc
In the placing carried out in May 2020 (announced as a conditional placing on 4th May 2020), existing shareholders were provided with a facility to participate on the same terms as new placees by subscribing for "Broker Options". The Board, following discussion with its broker, would consider offering a similar facility in future fundraisings.
When will Val relocate from central London offices to more cost effective offices?
As noted in our RNS on 16th June 2020, we are constantly reviewing all costs associated with the Company. In the event that the Board decides to move from its current premises, shareholders will be informed in the normal manner.

Team Members

When will remunerations be confirmed for those retained and those recently joined? So we can see what their skill set is costing Val?
Please see our RNS released on 16th June 2020. Our management team now consists of a total of seven individuals, costing an estimated £300,000 per year (from 1st June 2020). Biographies of all team members are available on our website. Details of remuneration for individual directors will be detailed in the Annual Report in due course.
Why do we still need to retain Martin Lampshire as a NED, when last two placings went ok?
Martin Lampshire is a valuable member of the board as a non-executive director. He brings significant financial and corporate experience to the Board. His role includes investor relations, and he is instrumental in ensuring that Peterhouse, as the Company's broker, fully understand the ValiRx model, and present the opportunity to the right profile of investor. We feel the Board is now appropriately balanced with Executive and Non-Executive directors.
What kind of relationship do you have with the outgoing board members.
The outgoing board members had been in place for a long period of time, and had contributed significantly to both the scientific and corporate development of ValiRx. As such, all current board members recognise their contributions, and continue to wish them well in their future endeavours.