SP Angel Healthcare

ValiRx

Initiation of Coverage

5th November 2020

Source: ValiRx

Contents

SP ANGEL

Non-Independent Research
MiFID II Exempt

5th November 2020

***CORP**

Stock Data

Ticker	VAL.L
Share Price:	23p
Market Cap:	£14.9m

Source: Bloomberg (prior day's close)

** SP Angel provides Research Services to ValiRx and therefore this information should be viewed as a Marketing Communication.*

Company Description

Clinical-stage life sciences company focused on the development of treatments in oncology and women's health

Share Price Chart (p)

Source: Bloomberg

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Initiation of Coverage

ValiRx plc*

A Refreshed Strategy

Key points

- **New incubator strategy to drive incremental value:** ValiRx has outlined a new strategy to identify promising early-stage assets and provide scientific, financial and commercial support to progress the assets to a clinical and investor-ready stage. The Group is in discussions with potential partners to select its first candidates.
- **Partnering discussions underway for VAL201:** ValiRx recently posted headline results from a Phase 1/2 clinical trial testing VAL201, the Group's small molecule therapy in patients with advanced prostate cancer. Headline results indicated an adequate safety and tolerability profile whilst a clinical report due in Q420 should provide further data of interest to potential partners who would look to finance the next stage of trials.
- **Evaluation of VAL301 by a potential partner nearing conclusion:** An undisclosed Japanese company is currently evaluating VAL301, the Group's preclinical stage treatment candidate for endometriosis, a common gynaecological condition. Should the evaluation be successful, there is potential for an agreement to be struck regarding VAL301. This may take the form of a full development license agreement, with upfront payments and royalties, or a co-development agreement through a JV.
- **COVID-19 treatment candidate:** ValiRx is part of a collaboration which aims to develop BC201, a combination treatment for patients suffering from a hyperimmune response to SARS-CoV2 infection. ValiRx is not responsible for financial support but, in return for the use of VAL201 in BC201, the Group retains a 40% stake in the programme. As a result, ValiRx is eligible to share in any income generated by the project, such as an out-licencing agreement.

Outlook: With a new management team in place, ValiRx has outlined a refreshed strategy which has the potential to add both additional assets and value to the Group's current offering. This strategy could provide ongoing, near-term income via a service fee, as well as longer term value via an equity holding, should the asset be out-licensed or acquired. We believe this new strategy will complement the Group's existing programmes. The completion of the VAL201 Phase 1/2 trial is a significant milestone and the headline data, combined with the Clinical Report (expected in Q420), should support ongoing discussions with potential partners.

Year-end Dec	2016A	2017A	2018A	2019A	H120A
Income (£)	-	88,773	-	146,517	10,453
Pre-tax Profit (loss) (£)	(5,751,375)	(3,553,982)	(4,829,138)	(2,719,494)	(884,523)
EPS (p)	(8.22)	(2.00)	(0.94)	(0.26)	(4.43)
Net Cash/(Debt) (£)	(733,536)	311,290	372,872	(5,634)	64,972*

*Source: ValiRx; *Placing of £1.35m completed in July 2020 (post-period end)*

Investment Thesis

With a new management team in place, ValiRx has refocused its strategy to identify, develop and generate data for undervalued yet promising preclinical therapies. This should increase the value of the assets and help attract further investment, as well as interest from industry. The Group is also focused on continuing discussions regarding its existing portfolio with a view to strike potential agreements. Discussions are continuing for VAL201 after the completion of the Phase 1/2 trial, whilst VAL301 is being evaluated by an unnamed Japanese pharma company. Should either of these discussions result in a deal, this would represent a significant milestone for the Group.

VAL201 trial results should support partnering discussions

At the end of September 2020, ValiRx announced headline results from its Phase 1/2 clinical trial of VAL201, the Group's treatment candidate for advanced prostate cancer. Headline data from the trial demonstrated the drug's safety and tolerability as well as an early efficacy signal. ValiRx is currently in discussions with industry regarding its options for further clinical development. Once the full trial results are released (expected in Q420), the Group intends to share this data with potential industry partners. Prostate cancer represents a major health burden and is an area of intense focus. There were 1.3m new prostate cancer cases globally in 2018, making it the fourth most commonly occurring cancer overall and the second most commonly occurring cancer in men.

Preclinical incubator to provide incremental value

In July 2020, ValiRx outlined a new strategy to identify and develop promising early-stage therapies. The Group aims to identify projects in which development has stalled for reasons such as lack of funding, change in priority or lack of expertise. ValiRx aims to use its own expertise, including scientific, corporate and project management, to progress the assets to the next stage of development and attract further investment. If this strategy is successful, the Company aims to cover its working capital costs through service fee income, whilst retaining an interest in the long-term value of the asset via an equity holding.

New management team in place

In 2020, the Group underwent a management change with Dr Suzanne Dilly, previously CEO of ValiSeek, taking up the role of CEO of ValiRx. Dr Kevin Cox also joined the Board as Non-Executive Chairman. Both have considerable experience in the sector, holding senior level positions at multiple biotechnology companies. The financial and academic experience of the new management will be instrumental in the Group's new strategy of selecting and incubating undervalued assets and bringing them to an investor-ready stage. Furthermore, their experience in managing transactions should help progress development and partnering activities of the Group's existing assets.

VAL301 being evaluated by a potential partner

The Group is developing VAL301, a promising preclinical stage treatment for endometriosis. Endometriosis is an incurable, inflammatory disease which affects one in ten women of reproductive age. Preclinical studies demonstrated that VAL301 targeted abnormal endometrial growth without disrupting other hormone-induced processes. This may offer an improvement on current standard of care treatment, which come with a range of damaging side effects and impact fertility. In May 2020, ValiRx struck a material transfer agreement with an unnamed global Japanese pharmaceutical company. The Japanese pharma is evaluating VAL301 with a view to potentially licence the asset. Should the pharma company decide to licence VAL301 this could result in an agreement with an upfront payment, conditional milestones and royalties on future net sales.

VAL401 offers potential benefit in pancreatic cancer

VAL401 was originally developed for the purposes of treating lung cancer and in 2017, VAL401 completed a small phase 2 trial in late stage cancer patients. The data indicated that some patients treated with VAL401 showed an improvement in quality of life, particularly in measures of pain, nausea, anxiety and insomnia. Discussions with clinical key opinion leaders recommended the use of VAL401 in pancreatic cancer. This is because it could target severe abdominal pain, lack of appetite and nausea which is related to the disease. ValiRx expects they will have to complete at least one further trial for VAL401 in pancreatic cancer patients before considering an application for market authorisation. We expect drug regulators would look favourably on the expedited development of VAL401. This is because VAL401 is a reformulation of a generic drug, with a well-documented safety profile and targets an underserved disease indication with low survival rates.

Collaboration aims to use VAL201 in COVID-19 treatment

ValiRx responded to the current pandemic by entering into a collaboration agreement to explore the use of VAL201 as part of a combination treatment for patients suffering a hyperimmune response due to SARS-CoV2 infection. Project funding is to be provided by Black Cat Bio, a collaborator, whilst ValiRx is providing samples of VAL201 for preclinical experiments, as well as access to clinical data. Subject to a successful outcome, such as an out-licencing agreement, ValiRx is to receive 40% of any income generated by the project. This collaboration, in a high-profile area, gives ValiRx the option to generate additional value from VAL201, without the requirement for additional funding.

Peer Group review

ValiRx operates in oncology, an area of intense focus for industry. Therefore, we compiled a peer group of several AIM or LSE standard-listed drug developers with oncology assets at a clinical or preclinical stage. ValiRx's current market capitalisation is over fourfold less than that of the peer-group median (£70.8m). Given that ValiRx has two clinical stage assets as well as a promising preclinical programme which includes VAL301, we believe that this price discrepancy is unjustified and that ValiRx's shares consequently have considerable upside potential.

Given the current partnership discussions for the Group's existing assets and the new incubator strategy, it is difficult currently to value the combined business. We look to provide forecasts for the business in due course.

Peer-group comparison of AIM or LSE Standard-listed drug developers with oncology assets at a clinical or preclinical stage

Name	Ticker	Mkt Cap
Median	-	**70.8**
Valirx Plc	**VAL LN**	**14.9**
Hemogenyx Pharmaceuticals*	HEMO LN	39.7
Sareum Holdings	SAR LN	68.4
Tiziana Life Sciences	TILS LN	221.9
Redx Pharma	REDX LN	131.8
Scancell Holdings	SCLP LN	73.3
Evgen Pharma	EVG LN	13.9
Faron Pharmaceuticals	FARN LN	134.6
Midatech Pharma	MTPH LN	17.0

Source: Bloomberg; SP Angel act as Broker to Hemogenyx

Company overview

Company Summary

ValiRx is a clinical-stage biopharmaceutical company based in Eliot Park Innovation Centre, Nuneaton. The Group aims to develop a range of early-stage therapies to an appropriate stage to seek licencing agreements. The Company is focused on the development of small molecule therapies for oncology and Women's Health. ValiRx operates a semi-virtual business model, outsourcing product development to Contract Research Organisations (CROs) and medical research institutions.

History

ValiRx listed on AIM in 2006 with a focus on progressing assets into clinical trials. In 2020, the Group underwent a significant management change and outlined a new strategy to identify promising early-stage assets and provide support for their preclinical development in return for equity and a service fee.

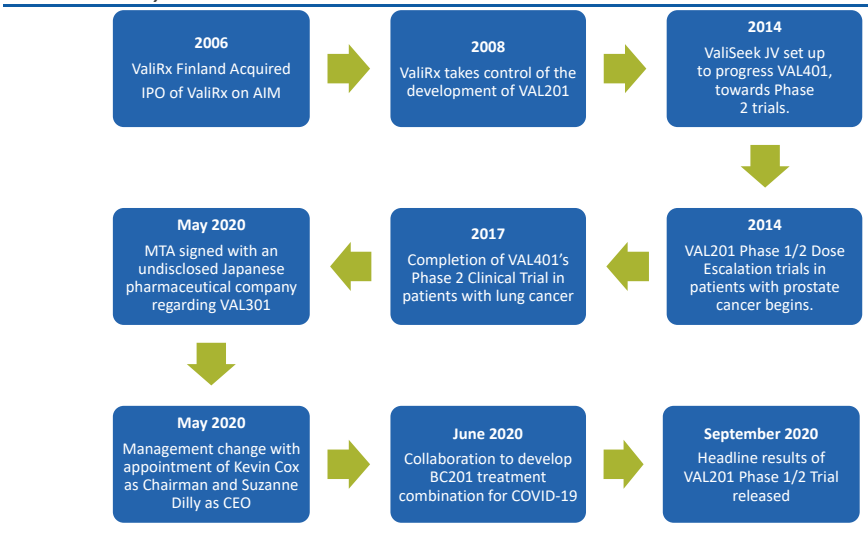
Company Structure

The Company currently operates through two divisions, ValiPharma and ValiSeek, however we expect this to expand as the Group looks to integrate new assets into Special Purpose Vehicles (SPVs) as part of the Group's incubator strategy.

1. **ValiPharma** is focused on the development of VAL201 for the treatment of androgen independent prostate cancer as well as treatments derived from VAL201, such as VAL301, a treatment candidate for endometriosis.

2. **ValiSeek** is a 55.5% subsidiary joint venture of ValiRx. ValiSeek was incorporated in 2013 and formed a JV with Tangent Reprofiling Limited (a SEEK group company) in 2014. As part of the JV, ValiSeek acquired a worldwide exclusive licence for VAL401, a small molecule treatment for lung and prostate cancer. In 2017, ValiSeek completed a pilot Phase 2 clinical trial with VAL401 and is seeking external partners to continue its clinical development.

ValiRx history



Source: Company website

Diverse pipeline across oncology and Women's health

ValiRx has developed a pipeline of preclinical and clinical stage assets which target a diverse range of indications across oncology and women's health. These include:

- **VAL201**: A small molecule therapy for the treatment of advanced prostate cancer. VAL201 recently completed a Phase 1/2 clinical trial in 12 patients with advanced or metastatic prostate cancer (ClinicalTrials.gov ID: NCT02280317). Headline results indicated an adequate safety and tolerability profile. A clinical report is due in Q420 which should provide further safety and disease impact data.

- **VAL301**: is a reformulation of VAL201 and has demonstrated encouraging preclinical data as a treatment candidate for endometriosis. Endometriosis is an incurable, chronic condition whereby the lining of the womb grows elsewhere in the body. ValiRx has an ongoing collaboration with an undisclosed Japanese company who are evaluating VAL301 with a view to potentially partner with ValiRx to further develop the molecule.

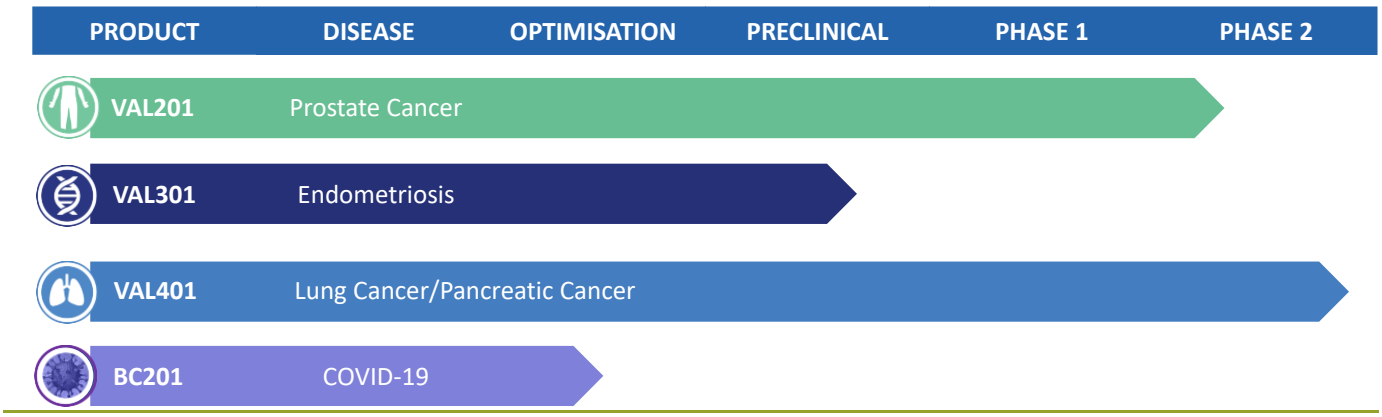
- **VAL401:** Is a reformulation of risperidone, an existing antipsychotic therapy. ValiRx identified potential anti-cancer properties in VAL401 and subsequently completed a Phase 2 trial in end stage cancer patients with non-small cell lung cancer (ClinicalTrials.gov ID: NCT02875340). With input from clinicians, the Group aims to progress VAL401 as a treatment for Pancreatic Ductal Adenocarcinoma, a cancer indication underserved by current treatments.

- **BC201**: ValiRx is collaborating with Black Cat Bio and Oncolytika Ltd to develop BC201, a potential treatment for patients suffering a hyperimmune response to SARS-CoV2 infection. BC201 is a preclinical-stage, combination treatment consisting of VAL201, Vitamin B3 and DNase, an enzyme which degrades DNA.

Scope for new assets as part of an incubator strategy

Alongside the current assets, ValiRx is looking to build out its pipeline of promising preclinical stage assets via its incubator programme. The Group is currently evaluating a number of opportunities and we expect further news flow in the short-term as the Company selects its first candidates for the programme.

ValiRx pipeline



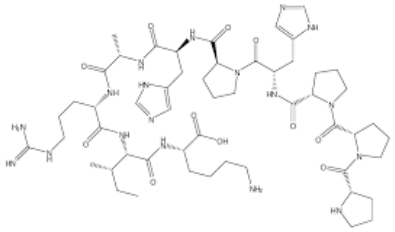
Source: Company website

VAL201: Prostate Cancer

The Company's lead asset, VAL201, is a treatment candidate for prostate cancer. The molecule was originally developed by Cancer Research UK. In 2008, ValiRx acquired the commercial rights to VAL201 in return for conditional milestone payments and royalties. VAL201 has been shown pre-clinically to treat hormone-dependant and refractory prostate cancer. A Phase 1/2 trial testing VAL201 in prostate cancer patients was recently completed, with the data indicating that further investigation is warranted.

Structure of molecule and mechanism of action

VAL201 structure



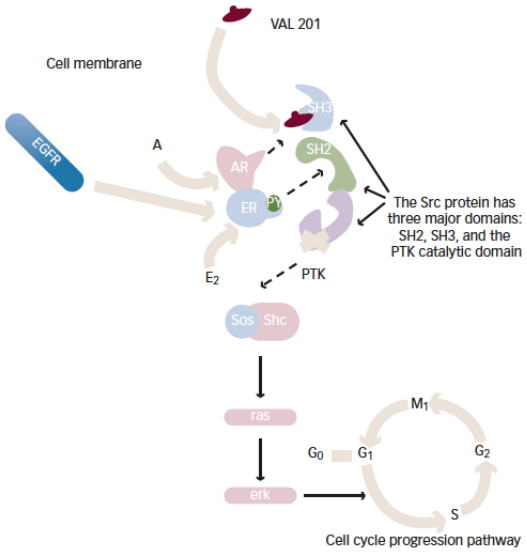
Source: PubChem

VAL201 is a small molecule treatment consisting of a short decapeptide (i.e. of ten amino acids). The treatment is designed to modulate the androgen (testosterone) hormone signalling pathway to reduce the DNA synthesis which can promote cancer cell proliferation. When androgen binds to the androgen receptor, it triggers a Src-mediated signalling cascade, which eventually controls cell cycle progression, i.e. cell division. Mutations which disrupt this pathway, and its corresponding control of cell division, can lead to the development of cancers, such as androgen-dependent prostate cancer.

VAL201 is designed to selectively bind to a region of Src kinase, a protein which is central to the androgen hormone signalling pathway. This binding inhibits the ability of Src to interact with the androgen receptor and subsequently reduces the downstream DNA synthesis which can lead to tumour cell growth.

As mentioned, certain tumour cells are dependent on androgen hormone signalling for growth therefore, by targeting this pathway, VAL201 is thought to selectively prevent tumour growth by specifically inhibiting the proliferation of tumour cells rather than that of normal cells. Preclinical experiments have indicated that VAL201 operates via a more targeted approach compared to chemo- and radiotherapy. This should reduce the risk of damaging side-effects as observed in these conventional treatments.

VAL201 proposed mode of action



A = Androgen; AR = Androgen Receptor; EGFR = Epidermal Growth Factor Receptor; ER = Estradiol Receptor; Source: Auricchio & Migliaccio, European Oncology & Haematology, 2012.

Conventional therapies are sub-optimal

Current treatments for prostate cancer include radiotherapy, radical surgery and hormone therapy. Radiotherapy can be used for localised prostate cancer but can cause fatigue, sexual dysfunction, bowel and urinary problems. Surgery is another treatment option, but it is a costly, invasive technique with risk of post-surgical complications, such as infections, urinary incontinence and sexual dysfunction.

VAL201 offers a targeted treatment with fewer potential side-effects than hormone treatments

Hormone therapies are another common treatment used to treat the progression of disease. They act either by blocking the release of the androgen hormone or by competing with androgen to bind to the androgen receptor. An issue with hormone therapies is that they aim to block all androgen or androgen receptor functions, including those unrelated to Src and cancer progression. As a result, hormone therapies have multiple undesirable side-effects including impotence, hot flushes, increased body fat, decreased muscle mass, osteoporosis, depression and fatigue. VAL201 is thought to selectively inhibit androgen-induced activity of SRC kinase, which can lead to cancer proliferation, without impacting other activity of the androgen receptor. This is expected to lead to reduced side-effects.

Recent Phase 2 trial results indicate further studies warranted

In 2014, ValiRx initiated a Phase 1/2 study evaluating the use of VAL201 for the treatment of advanced prostate cancer (ClinicalTrials.gov ID: NCT02280317). The trial was a dose escalation study aimed at confirming the treatment's safety and tolerability. Certain efficacy measures were also monitored.

The trial took significantly longer than expected to complete, however, in September 2020, ValiRx announced top-line results from the trial. The results showed that 54% of relevant patients demonstrated a positive response to the treatment. Although this was an early stage study, the data indicate that further clinical investigation of the drug is warranted.

VAL201 Phase 1/2 trial timeline

Action	Date
Clinical Trial Started	Dec-14
End of Trial	Jan-20
Database lock	Jun-20
Topline results	Sep-20
Clinical Study Report (predicted)	Q4-20

Source: Company announcements

Trial design

The trial was conducted at the NIHR University College London Hospital (UCLH) Clinical Research Facility, a specialist facility in London. The trial enrolled 12 patients with locally advanced or metastatic prostate cancer. Patients received an injection of VAL201 once a week, in a three-week cycle, for a maximum of six cycles. The endpoints of the trial were as follows.

- **Primary endpoint:** To estimate the Maximum Tolerated Dose (MTD) or Maximum Administered Dose (MAD) of VAL201.
- **Secondary endpoints:** To evaluate the pharmacokinetics and anti-tumour activity of VAL201.

Early efficacy signal

In the trial, disease impact was measured using the Prostate Cancer Working Group 2 (PCWG2) guidelines. The PCWG2 guidelines allow for the measurement and comparison of multiple disease progression markers over time, including primary and secondary tumour size, as well as other biomarkers such as Prostate Specific Antigen (PSA) levels, which can indicate changes in a patient's prostate cancer. These markers allow for calibrated measurement of disease progression.

The trial results are summarised below:

- 12 patients were dosed with VAL201
- 11 patients had sufficient PCWG2-relevant data collected
- 6 of these 11 (54%) were deemed to have responded to treatment with VAL201

Patients were categorised as responding to treatment when they showed no disease progression by PCWG2 criteria during the course of the trial.

Safety and tolerability

The headline results flagged a patient having severe hypertension (high blood pressure) while in the trial. We understand that this patient already had a history of hypertension and that following treatment for the raised blood pressure, the patient completed the remainder of the trial. Moreover, the patient completed the trial at the maximum drug dose (8mg of VAL201/kg) administered in the dose-escalation study.

Given that a Maximum Tolerated Dose has not yet been determined for VAL201, all doses remain available for further testing. As such, further studies are expected to establish optimal dosing strategies for the drug to maximise its potential positive effects while mitigating against any unwanted side effects.

Next steps

Full clinical report expected by the end of 2020

ValiRx expects to receive the full Clinical Study Report in Q4-2020. This report should provide far more data on the trial and allow the Company to evaluate next steps for this programme, including potential plans for further clinical development with possible partners. This large report is expected to contain further information on the pharmacokinetics of VAL201 and the ability of the treatment to reduce prostate-specific antigen (PSA) or reduce the rate of increase of PSA on a per patient basis. PSA is a key biomarker for the diagnosis and screening of prostate cancer and this data would be of interest to potential partners who are evaluating VAL201.

Discussions underway to find a partner to progress the programme

Although the trial was an early stage study, designed primarily to asses safety and tolerability, the data warrant further investigation of VAL201's possible effect. Further clinical studies would require larger patient numbers and a control group. ValiRx is currently in discussions with potential partners with a view to progress VAL201 to the next development stage. Potential outcomes include a licencing deal, an outright purchase of the asset or a co-development agreement.

Potential future trial design

With the successful completion of the Phase 1/2a study, we expect the next stage to be a Phase 2b trial. The next trial will be designed with input from the partner; however, we expect the trial to be a randomised placebo-controlled study in a relatively large patient population (c.50-200 patients) which aims to evaluate the safety, tolerability and efficacy of VAL201. This trial will also be an opportunity to finalise the dose for VAL201 for subsequent clinical trials.

Target Market summary

Prostate cancer represents a major health burden. There were 1.3m new prostate cancer cases globally in 2018, making it the fourth most commonly occurring cancer overall and the second most commonly occurring cancer in men. Prostate cancer is the second leading cause of cancer death in the US. In 2020, 192k men are expected to be diagnosed with a form of prostate cancer with 33k deaths expected to occur. Despite this, the death rate from prostate cancer has halved in the past thirty-years due to improved treatments such as radiotherapy and hormone therapies. However, there remain limited options to patients whose cancers no longer respond to these treatments. Consequently, potential novel treatments, such as VAL201, are much needed for patients with prostate cancer which has returned after initial therapy.

Positioning of VAL201 as a prostate cancer treatment

Due to its unique mechanism of action and potential low side-effect profile, we believe that VAL201 could be used at all stages of prostate cancer progression, with the most effective stage of treatment likely to be at the hormone sensitive stage.

VAL201 may be used in different stages of prostate cancer

Disease Stage	Comments	Utility of VAL201
Watchful waiting	Disease progression is only monitored and not yet treated with invasive therapy.	VAL201 is thought to prevent the onset of tumour formation, with few side-effects, it could be used at this stage, to slow disease onset
Active surveillance	Next step from watchful waiting, regular tests/biopsies to check for signs of progression, so treatment can begin. The aim of active surveillance is to avoid invasive treatment for as long as possible.	As VAL201 is thought to prevent tumour formation, while having few side-effects, it could potentially be prescribed at this stage.
Hormone sensitive	Diagnostic tests/biopsies have determined that the prostate cancer could respond to hormone therapy	VAL201 has been demonstrated to reduce hormone-sensitive tumour proliferation, we expect this to be the most likely stage to be prescribed
Hormone insensitive	Biopsies indicate that the cancer has stopped responding to hormone therapies	Preclinical studies indicate that VAL201 has an effect against hormone-insensitive cancers, therefore may be a viable therapy at this stage.
Metastatic	The cancer has spread from the prostate to other areas of the body, such as lymph nodes. Five-year survival at this stage is c.30%.	VAL201 has also been shown to reduce metastases by 50% in animal models. As such it has the potential to be used in the later stages of disease.

Source: Cancer Research UK; ValiRx; SP Angel

Follow on indication for VAL201

Whilst ValiRx remains focused on finding a partner to progress the application of VAL201 in prostate cancer, there is scope to test the molecule in other cancer indications. Likely follow-on indications would be in hormone associated solid tumour conditions such as breast and ovarian cancer. Breast cancer is the most common cancer in the UK, whilst ovarian cancer five-year survival rates are below 50%.

Strategy development: Preclinical incubator

In July 2020, ValiRx outlined a new strategy to identify promising early-stage assets and provide corporate and project management support for their preclinical development. If this strategy is successful, ValiRx aims to cover its working capital costs through service fee income. The Group looks to retain an interest in the asset via an equity stake in the holding vehicle. This enables ValiRx to participate in any long-term value gain of the asset, such as the striking of an out-licensing agreement or an acquisition.

Focus on overlooked preclinical assets

The Group aims to identify projects from industry in which development has stalled for reasons such as lack of funding, change in priority of the company, or lack of expertise to progress the project. These criteria do not imply that there is a fundamental issue with the underlying asset, such as lack of addressable market or a safety issue. This should contribute to a reduced cost to purchase the asset.

Selection of promising early stage projects from universities

Another area of focus is the selection of early stage academic projects. Universities represent a large pool of promising assets. These projects have usually generated initial data through the support of academic grants. However, further support is usually required to develop these assets to a stage where institutional investors are likely to invest. These investors often want to see advanced preclinical data before evaluating a project, but it is difficult to support funding for these experiments through academic grants. ValiRx aims to use its expertise and network to select promising programmes from universities and support these assets across the 'valley of death', the funding gap between grant financing and third-party investors.

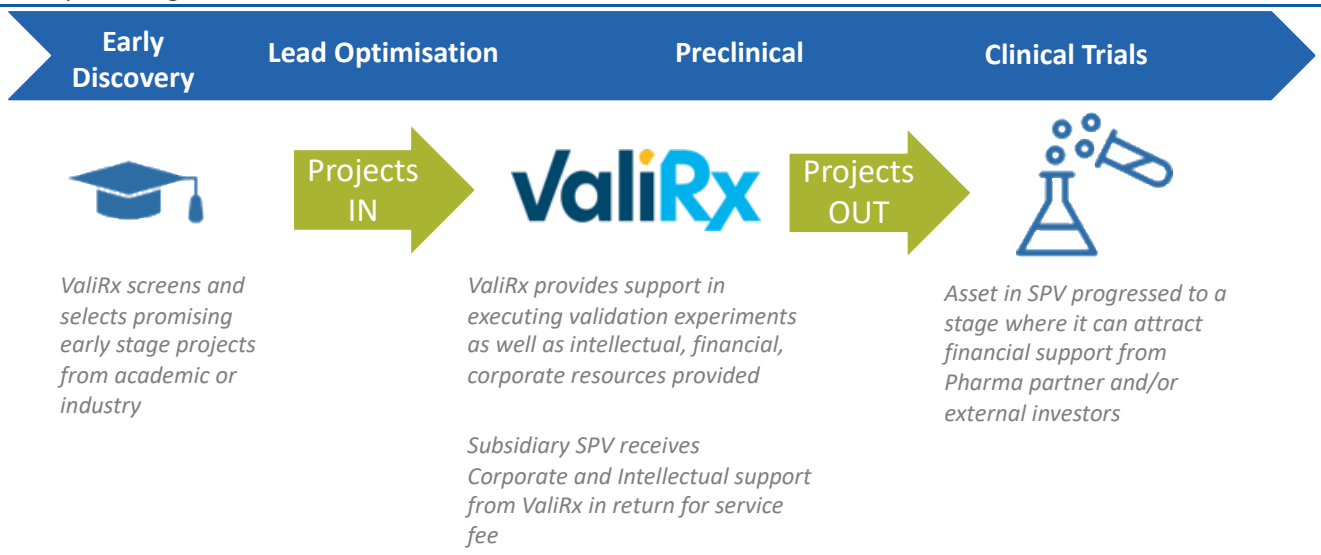
ValiRx's support enables potential for value creation

ValiRx aims to use its own expertise in drug-development to progress the selected programmes. This includes the provision of seed funding for preclinical studies to be carried out, allowing for data generation. The support of ValiRx should enable the asset to attract further, third party investment to take the programme to the next milestone, such as first-in-man trials. Due to the progression of the asset, we expect follow-on funding rounds to be completed at a higher valuation than ValiRx's initial investment, adding incremental value to the Group.

Use of SPVs to facilitate third-party investment

The Group aims to progress each programme within a separate SPV, such as a new subsidiary. ValiRx would hold an equity shareholding in the SPV, alongside any investors and the original founders of the technology. Once the SPV has achieved appropriate funding, ValiRx looks to charge a service fee from the SPV in return for the provision of accountancy services, project management and scientific, regulatory and commercial advice. The use of an SPV enables third parties to invest into the vehicle. Therefore, the SPV can source external funding for costly clinical trials. This should de-risk the investment proposition for ValiRx. It will not be expected to be solely responsible for funding the project through clinical trials to an appropriate stage for partnering discussions.

ValiRx partnering business model



Source: ValiRx

BC201: A potential treatment for COVID-19 disease

ValiRx has been primarily focused on developing its existing pipeline of treatments for oncology and Women's Health. However, the Group has responded to the current pandemic by outlining a programme to use VAL201 as part of a treatment combination for COVID-19 disease.

The treatment candidate, known as BC201, consists of the following:

- **Src Kinase-Androgen Receptor Inhibitor**: A reformulation of VAL201.
- **Niacin:** Also known as Vitamin B3 and used as a cholesterol lowering drug.
- **Dornase Alfa:** synthetic version of DNase, an enzyme which breaks down DNA.

BC201 has been proposed to target both the infective nature of the virus, as well as the damaging autoimmune response observed in some patients with severe disease

Collaboration with Black Cat Bio and Oncolytika to progress BC201

In June 2020, ValiRx entered a collaboration agreement with Oncolytika Limited and Black Cat Bio Ltd to explore the use of VAL201 as part of a combination treatment for COVID-19 disease. Black Cat Bio is coordinating the project, with ValiRx and Oncolytika managing certain project elements. ValiRx is providing samples of VAL201 for preclinical experiments as well as access to safety and tolerability data collected from the VAL201 prostate cancer trial. The collaboration agreement covers a maximum of two years.

ValiRx not committing cash funding to the agreement

Funding of the project is through Black Cat Bio and ValiRx has stated it has not committed any cash funding to the project. In return for providing VAL201 for the collaboration, ValiRx is to receive 40% of any licensing income generated by the project. This low risk strategy enables ValiRx to participate in any upside generated by this collaboration, such as an out-licencing agreement, without committing capital.

Current progress

A patent covering the use of BC201 in COVID-19 has been submitted by Oncolytika and Black Cat Bio. The partners have commenced initial preclinical studies on BC201 to demonstrate proof of principle for the proposed mechanism of action. Successful completion of these studies would warrant further investigation of the treatment candidate such as *in vivo* preclinical studies.

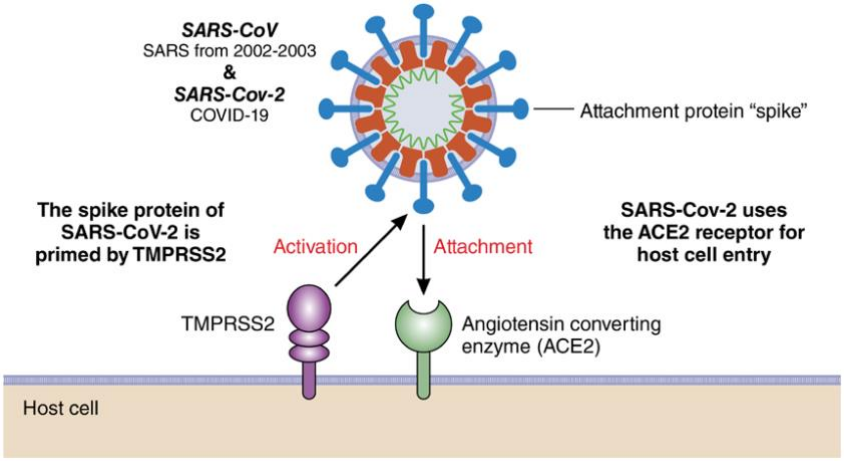
Dual action potential of BC201

1. Inhibit viral entry into host cells

Viruses infect the cell by binding to the host cell via a receptor on the surface of the cell. In the case of SARS-CoV-2, the host receptor is the human angiotensin-converting enzyme 2 (ACE2). Entry into the host cell is a complicated process mediated by a glycoprotein known as the Spike (S) glycoprotein expressed on the surface of SARS-CoV-2. To facilitate binding to ACE2, the S protein is cleaved by TMPRSS2, another protein expressed by the host cell.

As expression of TMPRSS2 is androgen specific, the use of VAL201 as an inhibitor of the interaction between Src kinase and the androgen receptor may result in reduced expression of TMPRSS2. This could inhibit the ability of SARS-CoV-2 to attach to ACE2 and infect the host cell. The collaborators are looking to perform preclinical experiments to further investigate this potential target.

TMPRSS2 mediates viral entry into the host cell via the ACE2 receptor



Source: Clerkin et al; Circulation. 2020;141:1648–1655.

2. Reduce the damaging hyperimmune response to infection

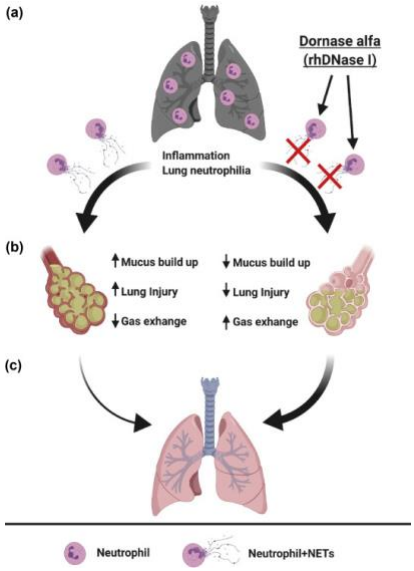
Alongside the potential antiviral effect, the collaborators believe that BC201 could reduce the damaging immune response observed in certain COVID-19 patients. SARS-CoV-2 infection may provoke an aggressive immune reaction in certain patients. This reaction includes cytokine storms, an excessive release of proteins which attract immune cells, causing inflammation. This inflammatory response causes severe damage to organs, such as the lungs, which can lead to acute respiratory distress syndrome (ARDS), a major cause of COVID-19 related death.

BC201 focuses on Neutrophil extracellular traps (NETs). NETs are web-like structures released by certain white blood cells in response to infection. The formation of NETs is implicated with certain acute and chronic inflammatory diseases, such as Multiple Sclerosis and Sepsis. Therefore, the collaborators believe that modulation of NETs is a potential target to reduce the inflammatory response to COVID-19 infection. NETs are thought to be produced via a process of regulated cell death known as NETosis. Activation of NETosis is thought to be associated with Src kinases. Therefore, the application of VAL201, a Src Kinase-Androgen Receptor Inhibitor, could reduce NETosis and subsequently reduce the subsequent hyperinflammatory immune response.

Addition of Niacin and DNAse to further support reduction of NETs

Whilst the application of VAL201 is the key active of BC201, the addition of Niacin and Dornase alfa is thought to further support the reduction of NETs and NET formation. The generation of reactive oxygen species (ROS) is thought to be involved in NETosis. Niacin (vitamin B3), can inhibit ROS generation therefore should further reduce NETosis. NETs consist primarily of DNA. Therefore, the application of Dornase alpha (DNase), an enzyme which cleaves DNA should further reduce the presence of NETs in circulation.

Proposed mechanism of BC201 to reduce hyperinflammatory response to SARS CoV-2

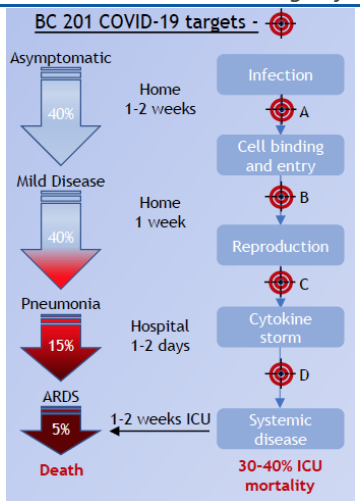


Source: A. P. Earhart & G. Schrum et al, New Microbes and New Infections, May 2020, 100689

BC201 could be used in multiple stages of COVID-19 disease

The application of anti-inflammatory treatments at an early stage of infection may reduce the effectiveness of the immune system to combat the virus, thus aggravating infection. As BC201 has a proposed dual mechanism of action – targeting both viral infection as well as a hyperinflammation, it could be used at an earlier stage of infection. This may reduce the odds of a damaging immune response developing.

BC201 has potential for intervention at a broad range of COVID-19 disease stages



Source: ValiRx

Target Market summary

Whilst the development of an effective vaccine programme against SARS-CoV-2 is seen as the endgame for the pandemic, the development of effective treatments for COVID-19 patients is needed to reduce mortality and ease pressure on healthcare infrastructure. There are a number of potential therapies for COVID-19 in the pipeline however, as of writing, there remains only one treatment, Veklury (remdesivir), which has received FDA approval for the treatment of COVID-19. In its latest Q3 results, Gilead, the developer posted $873m in revenues for Veklury highlighting the demand for COVID-19 therapies. Veklury is an antiviral treatment and there remains an unmet need for the treatments which modulate the damaging immune response observed in many COVID-19 patients.

Repositioning of prostate cancer treatments against COVID-19

The repurposing of existing therapies from other conditions may offer a faster route to a COVID-19 therapy rather than developing a novel treatment (Veklury was originally developed for the treatment of Ebola). It has been suggested that hormone therapies labelled for prostate cancer could be used to treat COVID-19 disease. As well as facilitating SARS-CoV-2 entry, TMPRSS2 has been shown to be highly expressed in both localised and metastatic prostate cancers. TMPRSS2 is regulated by androgen-mediated signalling and hormone therapies used to treat prostate cancer patients have been shown to reduce expression of TMPRSS2. A recent retrospective study analysed data on 9,280 COVID-19 patients (*Alimonti et al., 2020, Annals of Oncology)*. Although cancer patients were 1.8 times more likely to develop severe COVID-19 disease, patients with prostate cancer who are on androgen-deprivation therapies had a five-fold reduced risk of developing COVID-19 infections. The authors suggest that hormone treatments could be used transiently in high-risk populations to reduce infection and COVID-19 disease severity. These findings strengthen the rationale for repositioning prostate cancer treatments which modulate the androgen-signalling pathway, such as VAL201, as potential therapies for COVID-19.

Sepsis is an appropriate follow on indication for BC201

Whilst the collaboration is focused on developing BC201 for the treatment of COVID-19 patients with a hyperimmune response, Data from the COVID-19 programme could help inform the application of VAL201 in other inflammatory conditions. The formation of NETs is implicated with certain acute and chronic inflammatory diseases, such as sepsis. Sepsis is an acute, life threatening disease whereby the patient's immune system attacks host tissue in response to an infection. This can lead to long-term tissue damage, multiple organ failure and death. In the UK alone, c.250k people are affected by sepsis with c.52k deaths occurring (UK Sepsis Trust).

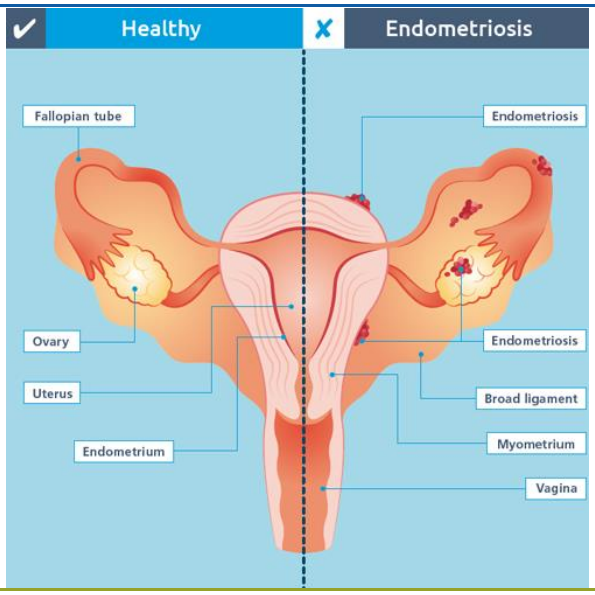
VAL301

Alongside prostate cancer and the COVID-19 programme, ValiRx is developing VAL301, a treatment candidate for endometriosis. VAL301 is a reformulation of VAL201 therefore, it has the same active ingredient but targets a different disease indication. Preclinical studies of VAL301 have demonstrated that the molecule can target abnormal endometrial growth without disrupting other hormone-induced processes required for a healthy lifestyle. This strategy may offer an improved treatment to current standard of care, which come with a range of damaging side effects.

Endometriosis

Endometriosis is an incurable, chronic condition whereby the tissue lining of the womb (uterus) grows elsewhere in the body such as the fallopian tubes and ovaries. The growth of lesions can lead to inflammation and scarring. Symptoms include moderate to severe pain, heavy bleeding, fatigue, and infertility. There is also an increased risk of developing ovarian cancer.

Endometriosis leads to growth of uterine tissue lesions outside uterus



Source: TrainingMatters.com

VAL301 mechanism of action

The growth of endometrial lesions is thought to be facilitated by the production of oestrogen, a hormone. VAL301 targets the interaction between tyrosine kinase Src and the oestrogen receptor. This could reduce the downstream DNA synthesis which can lead to cellular proliferation within the endometrial lesion. As VAL301 only inhibits non-genomic regulation of oestrogen signalling, genomic regulation of the pathway can continue. This could preserve other functions required for healthy tissue. As a result, VAL301 is thought to relieve symptoms of endometriosis without the contraceptive effect of other hormone therapies.

Encouraging preclinical data generated

The Group has generated encouraging preclinical data from tests of VAL301 in models for endometriosis. *In vivo* data demonstrated that VAL301 reduced endometrial lesion size. Reduction of lesion size was dose-dependent, indicating that the effect was related to treatment with VAL301. Furthermore, two generations of offspring were produced by treated animals. This is a significant finding as it suggests that fertility remains unaffected. Infertility is a major side effect of many treatments for endometriosis. Most treatments require the individual to come off the drug if they are looking to conceive, which can lead to a relapse of symptoms. The preservation of fertility while remaining under treatment would be of significant interest to prescribing clinicians. Finally, the application of VAL301 is not thought to affect bone density, a key side effect observed in other standard treatments.

MTA signed with Japanese company

In May 2020, ValiRx struck a material transfer agreement (MTA) with an unnamed global Japanese pharmaceutical company. The Japanese pharma is evaluating VAL301 with a view to potentially licence the asset. The MTA covers a series of preclinical studies related to the efficacy and delivery of VAL301 as a treatment for endometriosis. As part of the MTA, ValiRx is supplying quantities of VAL301 to the Japanese pharma. The Japanese pharma is conducting the programme of work at its own expense.

Potential for licencing agreement

Preclinical evaluation as part of the MTA is ongoing by the Japanese pharma. Should the evaluation be successful, there is potential for an agreement for VAL301. This may be a full development license agreement or a partnership agreement with the Japanese pharma contributing to joint development of VAL301. Outside of the MTA, ValiRx is currently reviewing a clinical development plan for VAL301. Should the Japanese pharma partner decide not to progress with VAL301, ValiRx would look to take the molecule into the clinic with financial support from another partner.

Current treatments for endometriosis are inadequate

Endometriosis is a fairly common condition. It is thought that 10% of women of reproductive age suffer from endometriosis. In the US alone, c.6m women are thought to suffer from the condition. Despite the prevalence of the condition, there is no cure and current treatments remain suboptimal. We have outlined the most common treatments for endometriosis below:

- **Contraceptives:** As the formation of endometrial lesions is driven by the production of oestrogen, hormonal contraceptives, such as the pill, are commonly prescribed as an initial line of therapy. These treatments have a strong history of safety and tolerability however, common side effects include nausea, irregular bleeding and depression. Furthermore, individuals have to come off treatments should they wish to conceive.

- **Painkillers:** Over-the-counter painkillers, such as ibuprofen, are commonly prescribed to ease discomfort. However, they may cause nausea and diarrhoea, whilst long term use may lead to kidney damage and increased cardiovascular risk. More severe pain can be treated with opioid-based medication however, these are highly addictive substances and may lead to opioid-dependence.

- **GnRH treatments:** Gonadotropin-releasing hormone agonist (GnRH agonist) are also prescribed. GnRH agonists lower oestrogen production however, long term use can lead to reduced bone density which can increase fracture risk and osteoporosis.

- **Surgery:** In severe cases, surgery, such as laparoscopy and hysterectomy, are options. However, they are costly procedures which can lead to infection and permanent infertility. Furthermore, some lesions may not be removed leading to recurrence of symptoms.

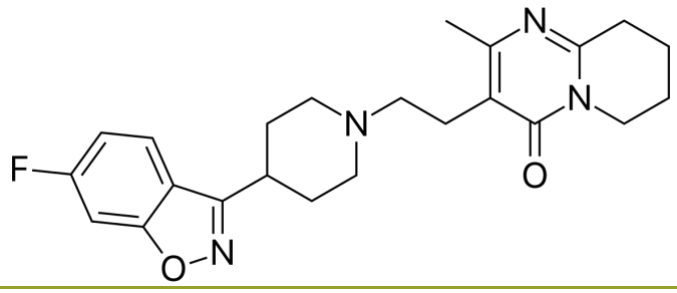
VAL401: Lung Cancer

Alongside treatment candidates based on VAL201, ValiRx is developing VAL401, an anticancer treatment candidate based on an existing therapy.

Structure of molecule and mechanism of action

VAL401 is a lipid formulation of a generic drug, risperidone, which has over two decades of clinical use in the treatment of mental disorders. Risperidone has a history of use as an off-label treatment for late stage cancer patients in palliative care. The treatment is used to reduce opioid-induced nausea and chemotherapy-induced delirium. ValiRx designed the lipid reformulation to facilitate cellular uptake of the molecule, an activity not achieved by the original formulation.

Structure of risperidone

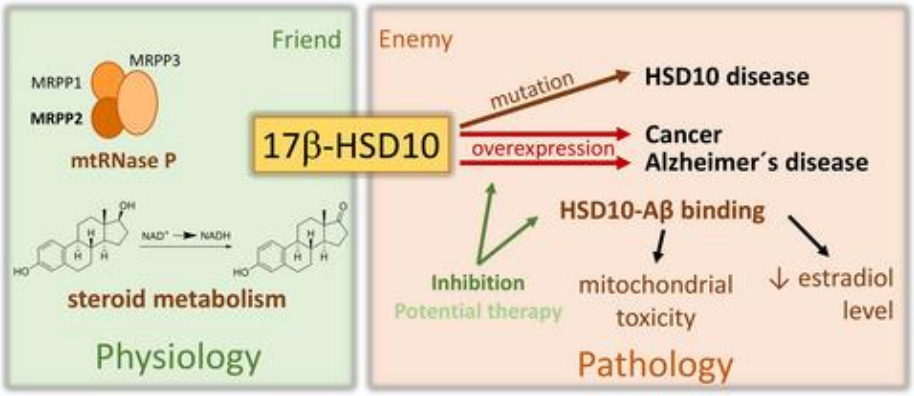


Source: PubChem.com

VAL401 targets a metabolic pathway implicated in cancer

The anticancer effect of VAL401 is thought to function via the inhibition of hydroxysteroid dehydrogenase type 10 (HSD10). HSD10 is an enzyme found in the mitochondria of cells. It is responsible for the metabolism of a number of steroids including hormones, such as androgen and oestrogen. HSD10 activity has been implicated in some forms of hormone-dependent cancer (Ayan, Maltais, & Poirier, 2012; He & Yang, 2006)

HSD10 is implicated in the development of cancer and neurodegenerative disease



Source: Vinklarova et al.; Journal of Neurochemistry; 2020

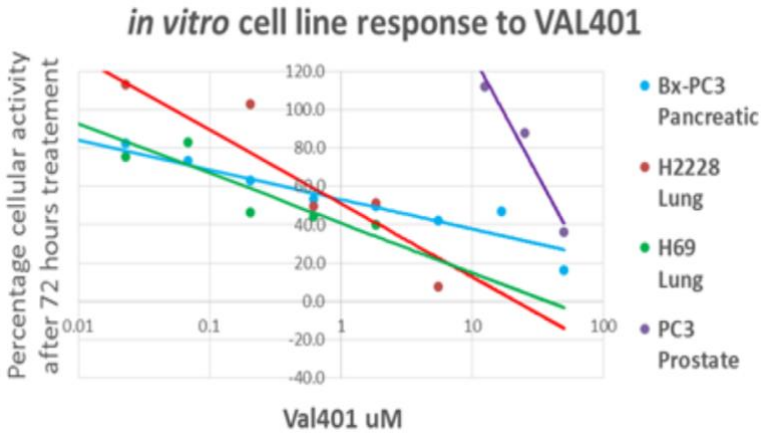
Phase 2 trial completed in lung cancer patients

VAL401 was originally reformulated for the purposes of treating lung cancer after encouraging pre-clinical data supported further investigation in this indication. In 2017, VAL401 completed an open label, exploratory phase 2 trial in late stage non-small cell lung cancer patients (ClinicalTrials.gov ID: NCT02875340). Eight NSCLC patients received an oral formulation of VAL401. The data indicated that some patients treated with VAL401 showed an improvement in quality of life, particularly in measures of pain, nausea, anxiety and insomnia.

Pivot to Pancreatic cancer as lead indication

Whilst VAL401 previously completed a small trial in lung cancer patients, ValiRx is now looking to progress further development in pancreatic cancer. This decision comes after discussions of the Phase 2 trial results with clinical key opinion leaders. The clinicians recommended further testing in pancreatic cancer as VAL401 could target the severe abdominal pain, lack of appetite and nausea which is related to the pancreatic disease. Furthermore, prior *in vitro* and *in vivo* studies of VAL401 demonstrated pre-clinical efficacy against cancer types outside of lung cancer, including prostate and pancreatic cancer. Due to the poor prognosis of pancreatic cancer patients (only one in four patients survive more than a year after diagnosis) we view that VAL401 would be well positioned as a first-line treatment for this disease.

Preclinical studies of VAL401 inidicates effect against lung, pancreatic and prostate cancer cells



Source: ValiRx

Repurposed drug therapies may have shorter timelines to approval

The repurposing of existing therapies from other conditions may offer a faster route to approval rather than developing a novel treatment. The safety profile has been approved by regulators and manufacturing has already been scaled-up for commercial purposes, a potential bottleneck for new therapies. VAL401 has been widely used, albeit in a different indication, therefore there is a large volume of safety and tolerability data. Due to the availability of safety data, regulators may require fewer or smaller trials to be completed for reformulated drugs compared to new chemical entities.

ValiRx expects they will have to complete at least one further trial for VAL401 before considering an application for market authorisation. Due to the low survivability and lack of adequate treatment options for pancreatic cancer, drug regulators may look favourably on the development of new treatments, such as VAL401, which could improve quality of life and reduce disease progression.

Potential future trial design

In order to demonstrate the utility of VAL401 in pancreatic cancer, additional clinical trials are required. In discussion with management, a potential trial design could be a c.120 patient, blinded, placebo-controlled trial which compares VAL401 on top of standard of care treatment against standard of care only. ValiRx has stated that it is looking for external partners to fund further development of VAL401. ValiSeek has signed LOIs with a European and a US partner, regarding the further advancement of VAL401 into the next proposed clinical trial, on a co-financing basis.

Black Cat Bio looking to fund future clinical development of VAL401

In January 2020, ValiSeek signed a letter of intent with Black Cat Bio for the funding and future clinical development of VAL401. As part of the LOI, Black Cat will source the funding with support from Zenith Partners, a financial services company. If Black Cat raises a certain amount (undisclosed), the VAL401 IP license will be transferred from ValiSeek to Black Cat Bio. In return, all shareholders of ValiSeek will become shareholders of Black Cat Bio. ValiRx, and its shareholders would hold a proportional shareholding directly in Black Cat therefore would stand to benefit from any future upside. Black Cat are currently fundraising, and confirmation of funding is yet to be announced. If this arrangement is unsuccessful the Group will seek alternative methods of progressing VAL401.

Current treatments for pancreatic cancer remain suboptimal

Pancreatic cancer remains a lethal condition with poor patient outcomes. The disease is the 5th most common cause of cancer death in the UK, with only one in four patients surviving more than a year after diagnosis. Despite significant improvements in survival rates for many indications, the pancreatic survival rate has not changed significantly in the past 40 years (Cancer Research UK). Surgery remains the only curative treatment, however most patients usually present with late stage disease which is difficult to operate on. Most treatments for patients with advanced pancreatic cancer focus on controlling cancer growth, improving the quality of life or providing relief of symptoms (palliative care). Common treatment options include chemo- and radiotherapy.

Lung cancer remains a high profile follow up indication for VAL401

Whilst the current focus is on progressing VAL401 as a treatment for pancreatic cancer, its application in lung cancer remains a viable follow-up indication. Similarly to pancreatic cancer, lung cancer has one of the lowest survival outcomes of any cancer. This is because over two-thirds of patients are diagnosed at a late stage when curative treatment is not possible (Cancer Research UK). As such, the disease remains a major unmet medical need.

Key Management

Dr Suzanne Dilly - Chief Executive Officer

Dr Suzanne Dilly is an experienced entrepreneurial scientist. After commercialising her Chemical Biology post-doctoral research in the University of Warwick spin-out, a2sp Limited, Suzanne was awarded a prestigious Royal Society of Edinburgh Enterprise Fellowship, during which formal commercial and entrepreneurial training completed her transition from lab to boardroom. Completing commercial transactions to progress projects through multiple companies, Suzanne has been working in small company virtual biotech's since 2006.

Dr Kevin Cox Non - Executive Chairman

Kevin has over 25 years' experience in the life science industry. Serving as CEO of high growth biotechnology businesses, he has extensive experience in strategy, corporate development, M&A, financing and joint ventures. With a passion for improving translational science, Kevin has strong links to government, funding bodies and academia, and has contributed to a number of public sector advisory committees. Kevin currently has non-executive roles with Biorelate Limited and the British Neuroscience Association and is executive chairman of Biotaspheric Limited.

Mr Gerry Desler - Chief Financial Officer

Gerry is a chartered accountant, who qualified in 1968 with a City firm, before becoming a partner (1970) and Senior Partner (1985). During his time in the City, he has specialised in consultancy work, much of it involving funding and venture capital. Gerry was previously the Finance Director of Premier Management Holdings plc, an AIM listed company and is on the board of a number of private companies. Gerry also holds positions as Company Secretary at Prospex Oil and Gas Plc both AIM listed companies.

Mr Kevin Alexander - Non-Executive Director

Kevin is a qualified solicitor in England and an attorney in New York and he was a partner at major law firms in both London and the United States for over 25 years. Since leaving the law he has been involved in forming and managing various businesses, both private and public. Kevin is a director of ValiRx Plc and joined the board in September 2006. He has an MA in law from Cambridge University.

Mr Martin Lampshire - Non-Executive Director

Martin started his career in Lloyds Bank's Commercial Services division in 1989 after completing the ACIB qualification. He has over thirty years' experience in Corporate Broking, assisting in a variety of equity raises including IPOs, secondary fundraisings, vendor and private placings across a variety of sectors. He has also worked in a number of overseas financial centres including Hong Kong, Singapore, Kuala Lumpur and Dubai. Martin is currently an Executive Director of Global Resources Investment Trust Plc and a Non-Executive Director of Bould Opportunities Plc.

Mr Kumar Nawani - Head of Operations

Kumar has been working over 20 years in international trade, client & vendor management, business development, brand development, e-commerce, procurement, IT management & compliance roles with established public and private companies here in the UK and previously in Hong Kong. Kumar has been with the ValiRx Group since January 2008 and as an active member of the ValiRx management team.

Mr Mark Treharne - Corporate Development Manager

Mark began his career in the City in 2011 and has worked in Corporate Broking and Equity sales working for numerous different firms including Daniel Stewart, Northland Capital Partners and Pello Capital. His role includes enhancing the reputation of the company within the City and working closely with City firms to identify new therapeutic assets to incorporate into the ValiRx portfolio.

Key Risks

ValiRx is an early stage healthcare company and is exposed to risks inherent to the sector. Of the risks outlined below, R&D and regulatory risk are the most relevant to the Company.

R&D risk

The Group is at a relatively early stage of development and may not be successful in its efforts to use and to build a pipeline of product candidates and develop approved or marketable products. Successful commercialisation of the Group's products is likely to depend on successful progress through clinical studies, licensing and or partnering and registration. Development of product candidates involves a lengthy and complex process and products may not meet the necessary requirements in terms of toxicity, efficacy or safety, or the relevant regulators may not agree with the conclusions of the Group's research and may require further testing or withhold approval altogether. The Group manages its clinical and regulatory risk by working closely with its external expert scientific, regulatory and clinical advisors and regulatory authorities on the design of key development plans for its pre-clinical and clinical programmes.

Commercial risk

ValiRx has products in clinical trials and is dependent on successfully advancing these lead candidates. These include VAL201, to treat hormone induced cancers and abnormal growth and VAL401, a repurposed compound to treat non-small cell lung cancer. The business model is to ensure future partnering of these compounds with larger co-development partners. Successful commercialisation of ValiRx's products is likely to depend on its successful progress through clinical studies, licensing and/or partnering and registration.

Competition risk

The Group's competitors include major multinational pharmaceutical companies, biotechnology companies and research institutions. Many of its competitors have substantially greater financial, technical and other resources, such as larger numbers of research and development staff. Competition that may lead to third parties discovering or developing products earlier or more successfully than ValiRx, may also impair the Company's ability to secure funding, to advance its clinical trials and have a successful relationship with a co- development partner.

Key personnel risk

The loss of personnel such as Dr Suzanne Dilly, CEO, may have a negative impact on the Company's strategy and ability to achieve future milestones.

Clinical trial risk

Successful commercialisation of the Group's products is dependent on the successful progress through clinical studies and registration. Development of product candidates involves an expensive, lengthy and complex process and products may not meet the necessary requirements in terms of toxicity, efficacy or safety, or the relevant regulators may not agree with the conclusions of the Group's research and may require further testing or withhold approval altogether. Clinical trials could be delayed or prevented from completion by a number of factors. Any failure to complete, or a significant delay in completing, clinical trials for the Group's product candidates could harm the commercial prospects for its product candidates, and therefore, its financial results. With the Group's new incubator strategy, ValiRx is now focused on generating data for new assets via preclinical studies rather than clinical trials. Preclinical studies are usually lower cost and shorter in time than clinical trials, which should lessen this risk going forwards.

Financial Risk

To fund its ongoing operations, we expect the Company to require additional capital over the coming years.

Financials

Income Statement

Year-end December (GBP)	2016A	2017A	2018A	2019A	H120A
Other income	-	88,773	-	146,517	10,453
Research and developments	(2,375,354)	(1,746,808)	(1,698,791)	(984,457)	(99,879)
Administrative expenses	(1,794,284)	(1,467,268)	(2,166,798)	(1,860,379)	(791,866)
Operating loss	**(4,169,638)**	**(3,125,303)**	**(3,865,589)**	**(2,698,319)**	**(881,292)**
Fair value loss on derivative financial assets	(1,619,187)	(23,446)	(442,229)	-	-
Finance income	17	489	-	-	-
Fair value gain on derivative liability	375,621	44,146	-	-	-
Finance costs	(338,188)	(449,868)	(14,565)	(21,175)	(3,231)
Provision for bad debt	-	-	(506,755)	-	-
Loss before income tax	**(5,751,375)**	**(3,553,982)**	**(4,829,138)**	**(2,719,494)**	**(884,523)**
Income tax credit	620,104	416,336	461,296	293,738	60,000
Loss after income tax	**(5,131,271)**	**(3,137,646)**	**(4,367,842)**	**(2,425,756)**	**(824,523)**
Profit from the year from discontinued operations	*182,750*	-	-	-	-
Non-controlling interest	200,518	117,962	69,020	37,049	19,441
Total comprehensive loss for the year	**(4,748,003)**	**(3,019,684)**	**(4,298,822)**	**(2,388,707)**	**(805,082)**
Loss per share – basic and diluted from continuing operations (p)	(8.22)	(2.00)	(0.94)	(0.26)	(4.43)
Weighted average number of shares	**57,743,223**	**151,071,019**	**458,715,753**	**902,637,711**	**18,191,261**

Source: ValiRx

Balance Sheet

Year-end December (GBP)	2016A	2017A	2018A	2019A	H120A
Goodwill	1,528,923	1,602,522	1,602,522	1,602,522	1,602,522
Intangible assets	1,295,690	1,325,283	1,623,950	1,620,207	1,489,598
Property, plant and equipment	10,553	-	-	-	-
Non-current assets	**2,835,166**	**2,927,805**	**3,226,472**	**3,222,729**	**3,092,120**
Trade and other receivables	780,942	766,475	174,089	90,083	100,805
Tax receivable	644,497	424,094	461,193	291,787	351,787
Derivative financial assets	140,675	117,229	-	-	-
Cash and cash equivalents	560,763	701,410	372,872	-	258,753
Current assets	**2,126,877**	**2,009,208**	**1,008,154**	**381,870**	**711,345**
Total assets	**4,962,043**	**4,937,013**	**4,234,626**	**3,604,599**	**3,803,465**
Called up share capital	8,165,650	8,432,708	8,680,694	9,417,225	9,641,009
Share premium	12,998,102	16,419,494	19,779,905	20,596,143	21,598,766
Merger reserve	637,500	637,500	637,500	637,500	637,500
Reverse acquisition reserve	602,413	602,413	602,413	602,413	602,413
Share option reserve	331,453	464,000	885,963	830,449	992,252
Retained earnings	(20,385,278)	(23,378,744)	(27,461,771)	(29,729,817)	(30,534,899)
Non-controlling interest	19,619	(24,744)	(93,764)	(130,813)	(150,254)
Total equity	**2,369,459**	**3,152,627**	**3,030,940**	**2,223,100**	**2,786,787**
Trade and other payables	1,254,139	1,394,266	889,987	1,182,084	772,897
Borrowings	1,294,299	390,120	-	5,634	193,781
Derivative liabilities	44,146	-	313,699	193,781	-
Current liabilities	**2,592,584**	**1,784,386**	**1,203,686**	**1,381,499**	**966,678**
Total liabilities	**2,592,584**	**1,784,386**	**1,203,686**	**1,381,499**	**966,678**
Total equity and liabilities	**4,962,043**	**4,937,013**	**4,234,626**	**3,604,599**	**3,753,465**

Source: ValiRx

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Cash Flow

Year-end December (GBP)	2016A	2017A	2018A	2019A	H120A
Cash flows from operating activities					
Cash outflow from operations	(4,233,412)	(2,952,275)	(3,776,840)	(1,801,714)	(1,015,310)
Interest paid	(338,188)	(35,897)	(866)	(3,093)	-
Tax credit received	375,926	636,739	424,197	463,144	(3,231)
Net cash outflow from operating activities	**(4,195,674)**	**(2,351,433)**	**(3,353,509)**	**(1,341,663)**	**(1,018,541)**
Cash flows from investing activities					
Purchase of goodwill	(141,066)	(73,599)	-	-	-
Purchase of intangible fixed assets	(245,559)	(206,727)	(324,028)	(396,776)	(73,114)
Sale of subsidiary undertaking	857,136	-	-	146,517	2,000
Sale of tangible fixed assets	3,470	-	-	-	-
Non-controlling interests	141,068	73,599	-	-	-
Interest received	17	489	-	-	-
Net cash from investing activities	**615,066**	**(206,238)**	**(324,028)**	**(250,259)**	**(71,114)**
Cash flows from financing activities					
New convertible loan notes	2,993,113	263,704	-	-	-
Repayment of convertible loan notes	-	(347,481)	(25,000)	(138,000)	-
Costs of convertible loan notes	(190,846)	-	-	-	50,000
Share issue	1,695,906	3,068,406	3,720,000	1,576,000	1,400,000
Costs of shares issued	(589,267)	(286,311)	(346,001)	(224,584)	(95,958)
Net cash from financing activities	**3,908,906**	**2,698,318**	**3,348,999**	**1,213,416**	**1,354,042**
Increase in cash and cash equivalents	328,298	140,647	(328,538)	(378,506)	264,387
Cash and cash equivalents at beginning of year	232,465	560,763	701,410	372,872	(5,634)
Cash and cash equivalents at end of year	**560,763**	**701,410**	**372,872**	**(5,634)**	**258,753**

Source: ValiRx

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Recommendations are based on a 12-month time horizon as follows:

Buy - Expected return >15%

Hold - Expected return range -15% to +15%

Sell - Expected return < 15%