



## **Valo Therapeutics Oy Shareholder Update**

Paul G. Higham, Chief Executive Officer  
27 July 2022, Helsinki, Finland.

### **Phase 1 Clinical Study Update:**

#### **Clinical Trial Application Submission**

On June 7th the German Regulatory Authority (PEI) granted clinical trial approval for our Phase 1 study to be conducted with PetiCRAAd-1 at two sites in Germany. All regulatory and ethics related conditions have been met.

During standard stability testing of one of the peptides in our formulation at the fill, and finish and quality contractor in the UK, an increase in the measured impurity level was detected, resulting in the product becoming 'Out of Specification' (OOS). Accordingly, this component could not be released to the clinical study sites in Germany. There are no release delays with either the other peptide or with the oncolytic virus used in the final product.

Previous investigation of this peptide indicates that the increase in impurity level is due to the harmless build-up of sucrose/peptide complexes which should not be classified as impurities. To prove this, and to allow the peptide to be released for the clinical study, a more detailed investigation and characterisation of the impurities is currently being conducted. Valo has identified and engaged a site in the US that can conduct this work and it is expected to begin this week with the analysis being ready at the beginning of August.

Once this analysis is completed and necessary regulatory update made, we expect that the peptide can be released to the clinical sites and the study can start. Based on this timetable, the approximate timing for the start of the study is late September to early October, an approximate one quarter delay to the timing last communicated.

To accelerate recruitment in the study and therefore shorten the timing to results, ValoTx is planning to add a third clinical study site in Germany. Appropriate sites are currently being identified.

### **ValoTx Financing and Stock Market Listing Strategy:**

Valo has completed a worldwide roadshow commencing in Finland with corporate and operational workshops. In attendance was the Board along with ValoTx's management team and its advisors, meeting in person for the first time since the COVID pandemic struck. After the workshop, Paul Higham (CEO) Sari Pesonen (CSO) and the Ironside Capital team marketed Valo to 8 major cities with an excellent response.

A major biotech investment bank was engaged in Florida whose team specialises in the life science space, and C\$4.95m was deposited in an independent escrow agent's account from a cornerstone investor out of Geneva Switzerland. Additional commitments were made to the company which will be processed over the next 4 to 8 weeks.

Despite significant progress being made on the operational front, delays to the commencement of the Phase-1 clinical trial have been caused by the late supply of data from 3rd party suppliers and further information and data requests from the regulatory authority that have required additional testing and analysis.

Given the delay to Phase-1 trial commencement and heightened market volatility currently being experienced, it's believed that a stock exchange listing deferral is sensible to allow equity markets to settle. Subject to market conditions, ValoTx expects the listing will occur in Q4 2022.



## **Antigen Business Unit / PeptiCHIP**

Following the successful exclusive licensing of the antigen identification technology PeptiCHIP from the University of Helsinki, a new 'Antigen Business Unit' has been formed headed by Dr Otto Kari. PeptiCHIP technology comprises a high-speed, high-throughput isolation method for the identification of tumour antigens from small biopsy samples. In combination with a software algorithm, it will provide ValoTx with the ability to identify neo-antigens for tumor and patient specific products in the future. Further development and investment are required to achieve this and will be enabled by the financing round.

### **Personnel**

In recent weeks and months, the company has been able to attract highly experienced people into key roles:

*Hemanshu Shah* joined as CBO on June 1<sup>st</sup>. He is based on the US east coast and brings more than 30 years' experience, in both large pharmaceutical companies (Bristol-Myers Squibb, Johnson & Johnson and Astellas) and emerging biotechnology companies (GPC Biotech, Innate Pharma and Transgene) to the ValoTx core team. Hemanshu also has a track record of successful corporate development and business development transactions and holds a PhD in Pharmaceutical Sciences from Rutgers University (NJ, USA) and an MBA from the University at Buffalo (NY, USA). His role will be focussed on deal-making and collaborations to exploit the potential of Valo's technology platforms and products.

*Anthony Giovinazzo* (MBA, C. Dir. & A.C.C) was formally appointed to the Valo Board at the latest AGM on June 1<sup>st</sup>. Anthony has 43 years of total work experience, is an internationally recognized expert in intellectual property, drug development and commercialization, including numerous licensing agreements and M&A. He was most recently the co-inventor, Chief Executive Officer and Director at Cynapsus Therapeutics, a NASDAQ listed specialty pharmaceutical company that developed the first successful sublingual apomorphine thin film strip for Parkinson's disease. He led the negotiations with several pharmaceutical companies that resulted in the C\$841 million all cash acquisition of the company by Sunovion Pharmaceuticals (Dainippon Sumitomo Pharmaceuticals).

He currently holds numerous Chairmanships and Directorships in the pharmaceutical industry and has raised more than US\$825 million in private and public equity.

*Otto Kari* joined the senior team as VP to head up the newly created Antigen Business Unit (ABU) to further the development of recently acquired PeptiCHIP technology. Otto holds a Ph.D. in Pharmacy from the University of Helsinki, Finland. He has over 15 years of experience in pharmaceutical research and development, with advanced qualifications in R&D and technology management. Further recruitment is underway for a new Manufacturing/CMC Project Director, and a new Research Scientist and a Bioinformatics Scientist are being recruited to join the ABU, both of whom will start with ValoTx following the summer holidays.

### **Formation of the Scientific Advisory Board of ValoTx**

*A new SAB Board, chaired by Prof. Vincenzo Cerullo,* has been formed and its members include:

Prof. Paolo A. Ascierto's, Director of the Department of Skin Cancers, Cancer Immunotherapy and Development Therapeutics at the National Tumour Institute "Fondazione G. Pascale", in Naples, Italy. He has spoken at over 450 national and international meetings, presided as Principal Investigator on over 160 clinical trials, and is author of over 550 publications in peer-reviewed journals.

Dr Jeffery Bockman has worked closely with two Nobel Prize recipients: Dr Sidney Altman, on ribozymes, and Dr Stanley Prusiner, on prions. He led the commercial development of



oligonucleotide therapeutics for viral diseases and cancer at Innovir Laboratories and is the Executive Vice President, Commercial BioConsulting and Head of Oncology at Lumanity.

Prof. Malcom K. Brenner is an award-winning physician-scientist who has pioneered the therapeutic use in cancer of T cell immunologic approaches and genetic engineering strategies. He is the Founding Director, Centre for Cell and Gene Therapy, Baylor College of Medicine (BCM), Houston Methodist Hospital and Texas Children's Hospital.

Dr Kevin Harrington's is the Head of the Division of Radiotherapy and Imaging at The Institute of Cancer Research, London, and a Fellow of the Royal College of Physicians and the Royal College of Radiologists. His research focuses on the use of biologically targeted agents, in combination with treatments such as radiotherapy and chemotherapy, to target cancer cells selectively, especially in head and neck cancer and in melanoma.

### **Communications**

A further Shareholder Update will be circulated as following further progress with the start of the Phase 1 study.

Sincerely,

A handwritten signature in black ink, appearing to read "P. Higham", with a stylized flourish at the end.

Paul G Higham

CEO