

Clinical Trial Update

Highlights:

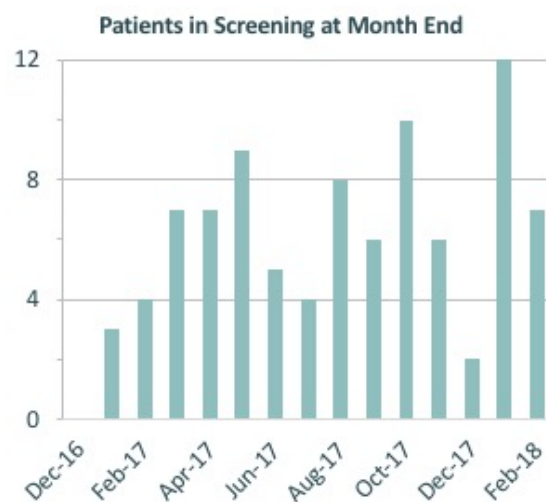
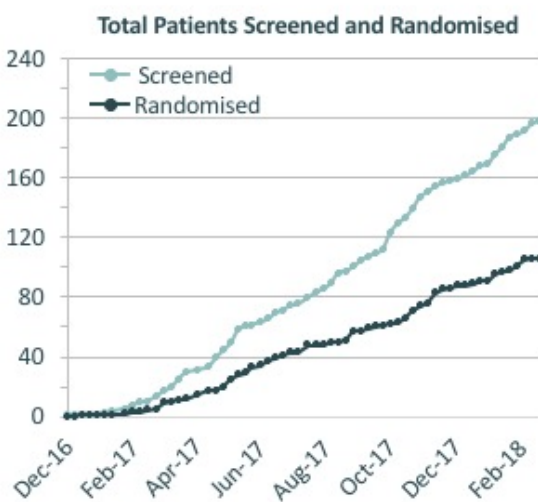
- Continued activity across sites, 107 patients now recruited and a healthy pipeline in screening
- Recruitment remains on track to complete in calendar Q2
- Successful collaboration with PAREXEL to manage the cost impact of extended timeline
- Ocular programme to proceed through the Singapore Eye Research Institute
- Other portfolio development activities progressing on a modest investment basis
- Extensive business development discussions with potential partners ahead of Phase 2b readout

As we approach readout of VF00102, our Phase 2b clinical trial of VF001 in venous leg ulcers (VLU), the Company is pleased to provide a progress update toward this key milestone, as well as our other portfolio activities. Importantly, momentum continues to build and we remain on track to complete recruitment of the study in calendar Q2.

VF001 has the potential to be a first-in-class product that dramatically improves the experience of patients with VLU. More than 90% of patients with these chronic wounds are treated in the community setting and there is a large and unmet need for effective, safe and easy-to-use products. A positive readout from VF00102 will establish VF001 as a genuine contender in this area with little direct competition.

Building Momentum Towards Readout

We are pleased to see momentum building as we continue to actively manage the trial towards readout. In early February, we enrolled our one-hundredth patient and recruitment has continued to grow throughout the month. 107 patients are now randomised and all of our sites have returned to full activity after the year-end holiday season. Eleven new patients were entered into the screening phase of the study during February and, at the end of the month, there is a healthy pipeline of patients in screening – we expect most of these to be randomised in the next week or two.



An encouraging feature of VF00102 is the small number of withdrawals from the study, which remains well below the expected level of 15%; currently the actual figure is close to half this, at 8%. It's pleasing to see that, despite frequent doctor visits and longer assessments while on study, our patients' experience of the trial means they are motivated to continue through treatment and follow-up. Emerging safety data indicate VF001 is well-tolerated, in line with previous experience.

Outcomes from VF00102 will provide meaningful information about the benefit of using VF001 to improve VLU healing. The primary endpoint – change in ulcer size – is the key measure of success from both a commercial and regulatory perspective. VF00102 will be deemed to have met its primary endpoint with a difference between VF001 and placebo of ~10% – for example, if patients receiving placebo (plus standard care) achieve a 60% reduction and patients receiving VF001 achieve 70% reduction. As well as thoroughly assessing healing through secondary endpoints (the proportion of patients with full wound closure and time to healing), the trial also captures important information about pain and quality of life, which are key concerns for patients and payers.

We regularly monitor data quality and the consistency we have observed indicates that the study will provide a sound dataset for evaluating the benefit of VF001. Figures 1 and 2 below show a recent “snapshot” of blinded data from 73 patients who have completed treatment. In interpreting the data, it is important to note that the study remains blinded, and that two-thirds of these 73 patients have been treated with VF001 and one-third with placebo. While the impact of VF001 will be determined when the study is unblinded, the trends and consistency in the data are reassuring.

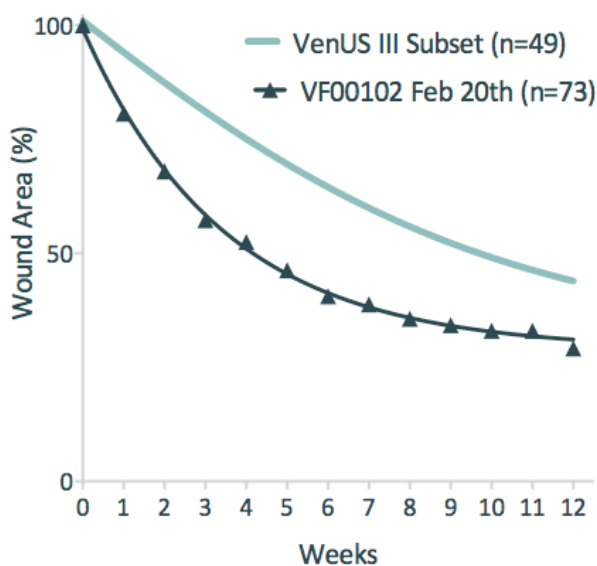


Figure 1. Change in ulcer size.

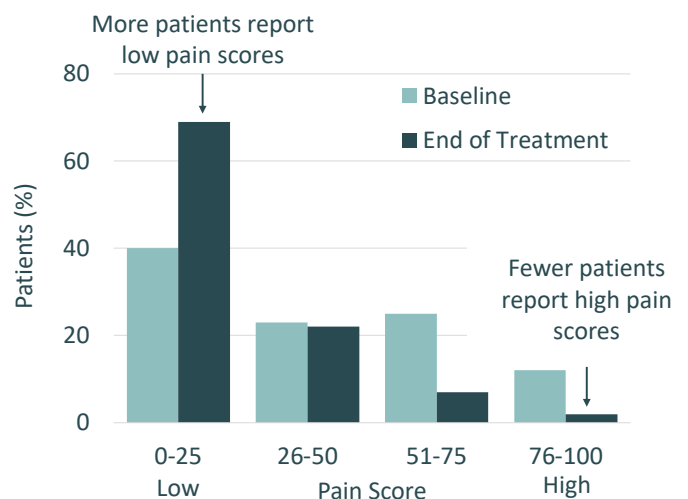
After 12 weeks, average ulcer size reduction in the VF00102 blinded snapshot is ~70% (lower curve) and ~55% (upper curve) in an informal benchmark subset from the VenUS III study*.

*VenUS III is a large UK study in VLU where all patients received standard care. The informal benchmark subset is 49 patients meeting the VF00102 wound criteria (i.e. “Margolis 1”).

Figure 2. Pain levels.

At the end of treatment, more of the 73 VF00102 completers report low pain scores and fewer report high scores compared with the start of treatment.

Note: Figure presents VF00102 blinded snapshot data only. At each visit, patients report pain score on a scale from 0 to 100.



Pipeline Progress

Our ocular programme has reached the point where we need specialised expertise in the target indication, persistent corneal epithelial defect (PCED), in order to conduct the next round of experiments. Our Director of Research and Development, Dr Gary Shooter, has selected the Singapore Eye Research Institute as the site to perform this work. We expect to be able to provide a further update on the ocular programme towards the middle of the year, including submission of an orphan drug designation application for PCED later this year.

We recently reviewed progress on the first year of our harlequin ichthyosis collaboration with Monash University and agreed with their recommendation to refine some aspects of the preclinical development before proceeding further with formulation development. Results from this project's first year work plan will now be available mid-2018.

Beyond VF00102 Readout – Phase 3 Preparation

Our core focus as a company is on research and development of our assets for wound care and other dermatology uses; as well as identifying novel applications of our vitronectin-based platform technology. With a successful VF00102 readout our immediate focus will be:

- EU – returning to the CE Mark process and commercial introduction of VF001
- US – consulting with FDA on the Phase 2b results and the Company's further plans, prior to initiating Phase 3

In addition to completing VF00102, we are already in the process of compiling all of the information that is required for these dossier submissions.

Cost Control – VF00102

We have been exploring the full range of options to manage costs for the Company in consultation with our partner, PAREXEL, who is responsible for the conduct of the study. PAREXEL has continued to be an excellent collaborator and we have agreed a number of key measures to manage the cost impact of the study's overall timelines. The most important of these is a clear deadline for completion of recruitment, beyond which the cost impact of any further delays will be minimised.

Business Development

At the end of last year we began ramping up discussions with global companies who have clear commercialisation capabilities in wound care and this process is accelerating as we approach readout. Our presence at regional wound meetings in Asia, the US and Europe over the next few months are an excellent opportunity for us to not only meet with these companies but also raise awareness among a wider audience and generate further interest ahead of readout. There is significant interest in our progress and a recognition that we have a unique product that is highly targeted to a commercially-important patient population.

About the VF00102 trial

VF00102 is a Phase 2b study evaluating the benefits of adding VF001 to standard care for healing venous leg ulcers. The study design includes rigorous patient selection criteria to enrol a specific group of patients who are most likely to benefit from the addition of VF001. All patients receive standard care – moist dressings and compression bandaging – throughout the trial. Following a two-week screening period, patients receive either placebo or one of two doses of VF001 for up to 12 weeks and are followed for a further 12 weeks post-treatment. The primary endpoint of the trial is reduction in the size of the wound. Other endpoints include the proportion of patients with full wound closure, time to wound closure, improvements in pain and quality of life; and safety.

About VF001

VF001 is a liquid, topical treatment for chronic wounds based on two naturally-occurring substances involved in wound healing, vitronectin and IGF-1 (insulin-like growth factor 1). VF001 comprises a portion of human vitronectin linked to IGF-1. The vitronectin component binds to the base of the wound, creating a biological scaffold to which skin cells attach; IGF-1 provides a signal that stimulates skin cells to multiply (proliferate) and move (migrate) into the wound – cell attachment, proliferation and migration are central processes in wound healing. VF001 is easy to use – a small volume (0.5 ml) is applied to the wound during routine weekly dressing changes.

About Factor Therapeutics

Factor Therapeutics Limited (“Factor”) is a biomedical technology company that is developing treatments for acute and chronic wound healing applications. Factor is a clinical stage company with its lead program (VF-001) in Phase II for the treatment of venous leg ulcers (VLUs). The company is also developing solutions for a variety of interventional wound care and serious orphan dermatology conditions. The company’s platform technology originates from the Institute of Health and Biomedical Innovation at the Queensland University of Technology (QUT), Australia. Factor’s shares are traded on the Australian Securities Exchange (ASX) under the ticker FTT. For more information, please visit www.factor-therapeutics.com.

Important Information

This announcement does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States, or in any other jurisdiction in which such an offer would be illegal. The securities referred to herein have not been and will not be registered under the United States Securities Act of 1933 (the “US Securities Act”), or under the securities laws of any state or other jurisdiction of the United States and may not be offered or sold within the United States, unless the securities have been registered under the US Securities Act or an exemption from the registration requirements of the US Securities Act is available. This document may not be distributed or released in the United States.

Corporate and Investor Relations Contact

Dr. Rosalind Wilson
Chief Executive Officer
Factor Therapeutics Limited
@: rwilson@factor-therapeutics.com