

5th October 2017

Shareholder Communication

Clinical Trial Update and Conference Call

Dear Shareholders,

Shortly after joining Factor Therapeutics Limited (“Factor”) in June this year, I outlined what I – with full support of the Board of Directors – see as the three major priorities for the company. These priorities are (in order of importance):

1. Successfully delivering our Phase 2 trial, VF00102;
2. Ensuring we are prepared for end of Phase 2 activities (including commercial engagement) for the venous leg ulcer (VLU) indication; and
3. Capturing additional future value by initiating selected early stage projects to form the basis for building a pipeline of opportunities for our advanced wound care technology.

Clearly, the number one priority is to guide the VF00102 trial through to completion and ensure we deliver recruitment as rapidly as possible while maintaining study data integrity.

VF00102 (Venous Leg Ulcers) Trial Objectives

The VF00102 trial is designed to rigorously test Factor’s technology. Our mission is to not only define the potential clinical benefit of VF001 for patients with serious chronic wounds, but also generate sufficient data to trigger meaningful commercial and partnering opportunities. Because of the stringent patient recruitment criteria and extent of data collected throughout, VF00102 is a technically demanding trial. Most of our trial sites are more familiar with an “all-comers” approach to recruitment, rather than concise patient selection criteria, so it has taken time for sites to get up to speed. Our goal in designing VF00102 is to avoid approaches that have historically resulted in numerous trial failures in the wound care field.

Activities over the Last Quarter

In our last quarterly update, we outlined several initiatives to boost recruitment. We also articulated several focus areas that we were monitoring closely, including variability in site performance and the potential impact of summer holidays. With all the sites up and running since the beginning of June, the trial has now been fully operational for close to six months and there have been some key lessons learned:

- Wound care and podiatry sites are generally excellent at patient recruitment and our sites are recruiting well above the industry average for this type of trial, demonstrative of the superb level of engagement and enthusiasm for the study. Our sites recognise that this is a scientifically unique trial and they are supporting us very well.
- Vascular surgery clinics have been generally poor at enrolling patients into the study, mainly because they appear to access a slightly different patient population. This is extremely useful information for Phase 3 planning.
- To focus our resources and prioritise our efforts on high-performing sites, we decided to close eight sites in July and August. Trial network optimisation is routine in multi-centre clinical trials once a trial is fully operational.
- August was an extremely busy month as we rapidly added four new sites into the trial that fit the “optimal” recruitment profile: one in California, one in Florida and two in Puerto Rico. The Puerto



Rico clinics are potentially large-volume recruitment sites as healthcare services in the territory are quite concentrated and VLU is highly prevalent in the elderly.¹

- We have been working with individual sites to generate local awareness-raising events and networking functions with primary care physicians and healthcare professionals.
- We appointed a specialist clinical media services provider – TrialWire (www.trial-wire.com) – to execute a targeted campaign to raise awareness about the trial and extend the catchment of patients around six of our most active sites. The pilot phase recently began and in its first three weeks has generated a dramatic increase in website traffic and uptake by more than 50 news health sites across the US. We will know over the next 4-6 weeks what impact this will have on recruitment but the preliminary visibility is very encouraging.

Trial Challenges

The trial has also experienced some unexpected challenges over the quarter:

- Recruitment slowed significantly during the summer holidays, such that only 11 patients were recruited in July/August compared with 28 patients between April and June (and 11 patients in September alone). We have previously indicated awareness of the potential impact of summer but given the aged population we are targeting, we (both Factor and PAREXEL, our partner CRO²) were surprised at such a major slowdown, especially since VLUs are more frequent in warmer weather.
- Hurricane season has had a very serious impact. Eight of the 20 sites in the trial are in Texas, Florida and Puerto Rico and were severely affected by hurricanes Harvey, Irma and Maria. To our dismay this included 3 of the 4 new sites that were added to the trial in August, which were expected to be very strong recruitment sites based on pre-screening surveys (70-80 patients immediately available to the study).
- We have yet to see activity in Miami and Puerto Rico recover and are currently unable to supply VF001 drug product to Puerto Rico while it remains in disaster recovery mode. Our current understanding is that the situation may take as long as two months to recover. We are closely monitoring progress, however contact with the sites in Puerto Rico remains intermittent as telecommunications have still not been fully re-established.

Revised Completion Forecast

The team has been working very closely with our clinical sites and PAREXEL to provide as much support as possible to continue to drive recruitment and recover lost time. As we will indicate in our recruitment update next week, we continue to capture a very high-quality dataset and – remarkably – patient compliance has remained excellent throughout (hurricanes notwithstanding).

Nevertheless, considering the ongoing challenges evident in the last few months we believe that we have lost a quarter (3 months) of recruitment. Factoring in the traditional slow-down in December and January, we are working hard to complete recruitment in calendar Q2, 2018, depending on how quickly affected sites can recover. This inevitably requires us to carefully monitor the Company's financial position to ensure we make the most efficient use of our available financial resources. We have been prudent with capital and, at present, the Company's runway extends to mid-2018 (i.e. approximately 9 months from the date of this communication). We are actively negotiating with

¹ As an unincorporated US territory, Puerto Rico falls under the jurisdiction of the US Food and Drug Administration (FDA) and has a very active biopharmaceutical research and manufacturing industry.

² Clinical Research Organisation.

PAREXEL to identify ways to ensure the best possible use of our current financial resources to complete the trial. We will certainly keep shareholders transparently informed in the coming months.

We will provide a detailed update on the trial in a conference call at 9.30 am (AEDT) on Tuesday, 10th October and dial-in details are provided at the end of this document.

Concluding Remarks

Our clear focus in the coming months will be to continue to carefully manage the trial and support sites in their recruitment efforts, particularly those recovering in hurricane-affected areas. We are incredibly grateful to our clinical sites that are persevering, often under very adverse conditions. It has been extraordinary to witness the devastating impact of Irma and Maria and at the end of this communication we have provided details of several high-quality organisations that are delivering badly needed aid to affected communities.

On a more positive note, since joining Factor a few months ago I have been extremely impressed by the capability and dedication of my colleagues and our collaborators to achieving our goals. The considerable time the team has spent with our investigators and site staff has reinforced our belief that a precision medicine approach to managing hard-to-heal chronic wounds will be life-changing for our patients, and create an offering with a very clear commercial positioning in the market. Our patients and their carers remain highly engaged with Factor's mission.

Thank you for your patience and support.



Dr. Rosalind Wilson
Chief Executive Officer

Organisations supporting recovery efforts
in Puerto Rico:

United for Puerto Rico
<http://unidosporpuertorico.com/en/>

Hispanic Federation
<https://hispanicfederation.org/unidos/>

Direct Relief
<https://www.directrelief.org/>

Americares
<http://www.americares.org/>





Conference Call Registration and Dial In Details

Tuesday 10th October – 9.30am AEDT

Pre-Registration Link: Pre-register and receive a calendar invite, and pin number for fast-track access to the call by clicking on this link -

<https://services.choruscall.com.au/diamondpass/factortherapeutics-604987-invite.html>

If you are unable to pre-register you can access the call at the scheduled time using the **Dial In Details** below:

Conference ID: 604987

Australia Toll Free: 1 800 558 698

Australia Local: 02 9007 3187

New Zealand Toll Free: 0800 453 055

NZ Local (Auckland): 09 929 1687

NZ Local (Wellington): 04 974 7738

NZ Local (Christchurch): 03 974 2632

United Kingdom: 0800 051 8245

United States: (855) 881 1339

For other dial in locations or queries regarding the call please contact Kyahn Williamson at kwilliamson@we-buchan.com