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Ocular Wound Care Program Update

July 2017

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Program Overview

- Factor's core IP is a platform technology
  - Vitronectin (collagen-targeting) peptide + growth factors
  - Multiple potential applications in advanced wound care

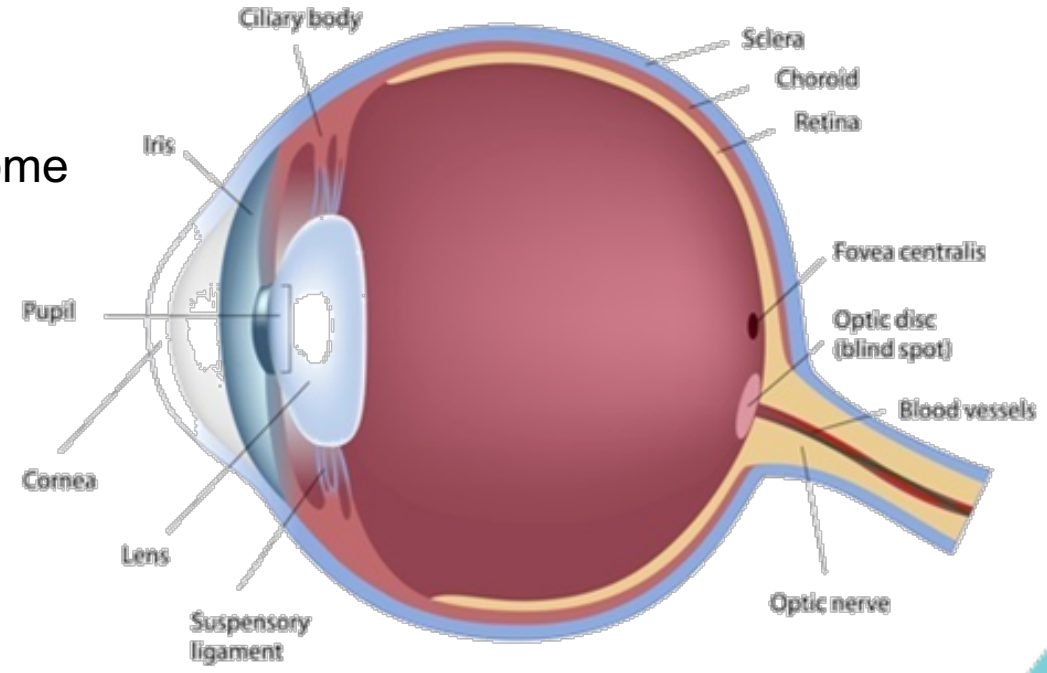
- This program evaluates Factor's technology in ocular (eye) wound care

- With modest R&D expenditure, we have evaluated VF001 and two other candidates (VF003/004) in a standard tissue model, assessing corneal cell proliferation and migration

- Key outcomes :
  - ✓ Built value in our core platform for other indications (including potentially an orphan indication)
  - ✓ Demonstrated proof-of-concept – VF001 and VF004 appear suitable for the indication
  - ✓ New intellectual property filed, potentially providing significant patent life extension
  - ✓ Clear rationale established to move to IND-enabling studies
  - ✓ Additional clinical utility for VF001

What are Persistent Corneal Epithelial Defects?

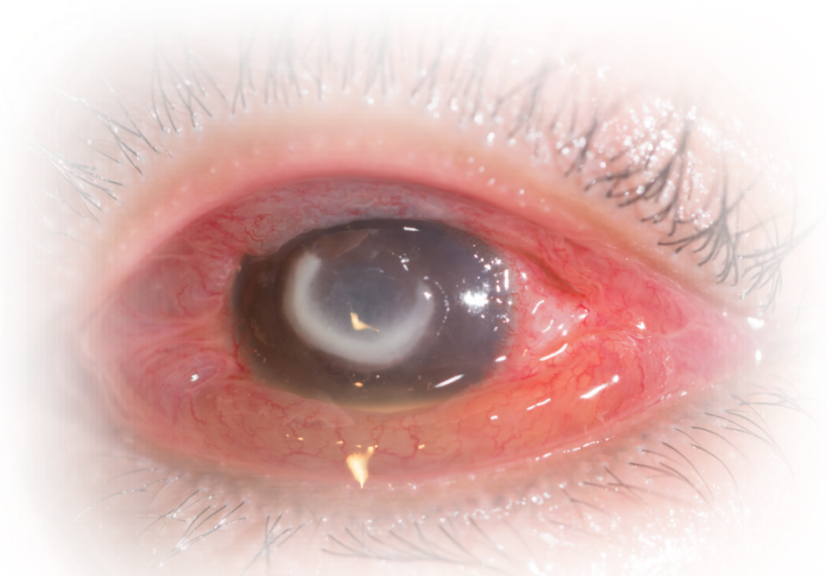
- The epithelial surface of the cornea is a living, protective barrier and its integrity is critical for sight
- Consequences of corneal damage are significant
  - Pain and impaired vision
  - Risk of infection, scarring and neovascularisation[1]
  - May lead to loss of eyesight
- Most corneal injuries heal rapidly, however they can become chronic – persistent corneal epithelial defects (PCED)
- PCED is a type of chronic wound affecting the eye
  - Progression to PCED can delay healing by weeks
  - PCED increases the chance of recurrent defects
- Epidemiology :
  - PCED from neurotrophic keratitis (US) : 150,000 patients[2]
  - Post-cataract/glaucoma surgery: 25 million patients world-wide of which 1-2% are susceptible to PCED[3]



[1]Growth of new blood vessels. [2]Sacchetti et. al. Clin Ophthalmol. 2014; 8: 571–579. [3]Lindstrom, R. Review of Opthalmology March 2015.

PCED is an “Orphan Indication”

- PCED is an orphan indication and can arise from:
  - Surgical and non-surgical trauma
  - Tear-film disorders
  - Neoplasia (cancer)
  - Corneal graft
  - Chemical and thermal burns
  - Neurotrophic, diabetic and herpetic keratopathies
  - Immune disorders



Damage to the corneal surface can result in a chronic wound state that can be hard to heal without additional treatment

- Like other chronic wounds, diabetes is a common co-morbidity (50 percent of PCED cases[1])
- For healthcare practitioners, managing patients with epithelial defects is difficult, time-consuming, and cost- and resource-intensive.
- Patients must make repeated office visits for treatment of often lingering disease. Cost-benefit is similar to other chronic wound care applications

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[1]*Buchholz et. al. Utility assessment to measure the impact of dry eye disease. Ocular Surface 2006;4:155-161.*

PCED May Lead to Bigger Indications

100-150,000 Patients[1]

PCED : High value, relatively small patient population. Orphan indication potentially provides an expedited regulatory pathway for approval

4,000,000 Patients[2]

A post-surgical product to accelerate wound healing (i.e. after cataract/glaucoma surgery) and minimize fibrosis is a major opportunity, but would likely have a lower price-point

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[1]US population, [2]25 million patients world-wide

Typical Treatments

Somewhat like other chronic wounds:

- Aggressive lubrication
  - High frequency artificial tears or ophthalmic ointments
- Discontinuation of problematic medications
- Punctal occlusion (for dry eye)
  - Plugging the tear drainage area of the eye to keep the tears in the eyes longer
- Debridement
  - Remove thickening -> restoration of a healthy leading edge

These treatments are time-consuming, and cost- and resource-intensive
New therapeutic approaches are required

Product Development Landscape

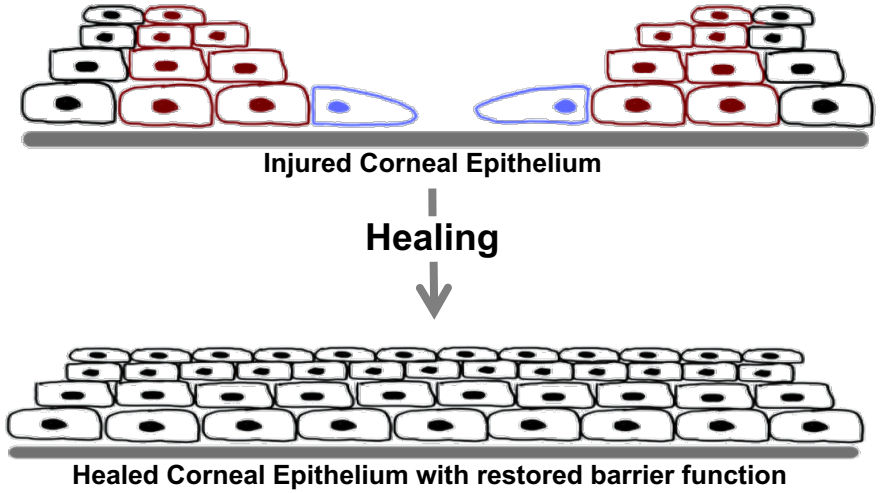
Like other chronic wound applications – major unmet need, few success stories …

Product	Company	Mechanism of Action	Development Status
Nexagon	University of California CoDa Therapeutics	Connexin 43 (gap junction protein) antisense gel for PCED	Phase 2 terminated April 2015 "drug manufacturer could not supply study drug"
DE-105	R-Tech Ueno (from Santen Pharma)	First stage substance P + IGF-1 for PCED	Ph 2 completed 2012 (No data published)
Thymosin ß4	ReGenTree	Acts by reducing inflammation. Promotes re-epithelialisation. Inhibits apoptosis	Phase 3 dry eye (non-persistent) initiated Nov 2016; 500 patients
EBI-005	Eleven Biotherapeutics	IL-1 inhibitor (dry eye)	Phase 3 failed (2015)
EyeGate OBG	EyeGate Pharmaceuticals	CMHA-S hydrogel	Phase I (surgical setting)

<u>Other treatment approaches:</u>

- Amniotic membrane grafting
- Autologous serum
- Umbilical cord blood serum
- Platelet-rich plasma
- Human growth hormone, insulin, nerve growth factor, EGF
- Limbal stem cell transplant
- Scleral contact lenses

Ocular Wound Healing



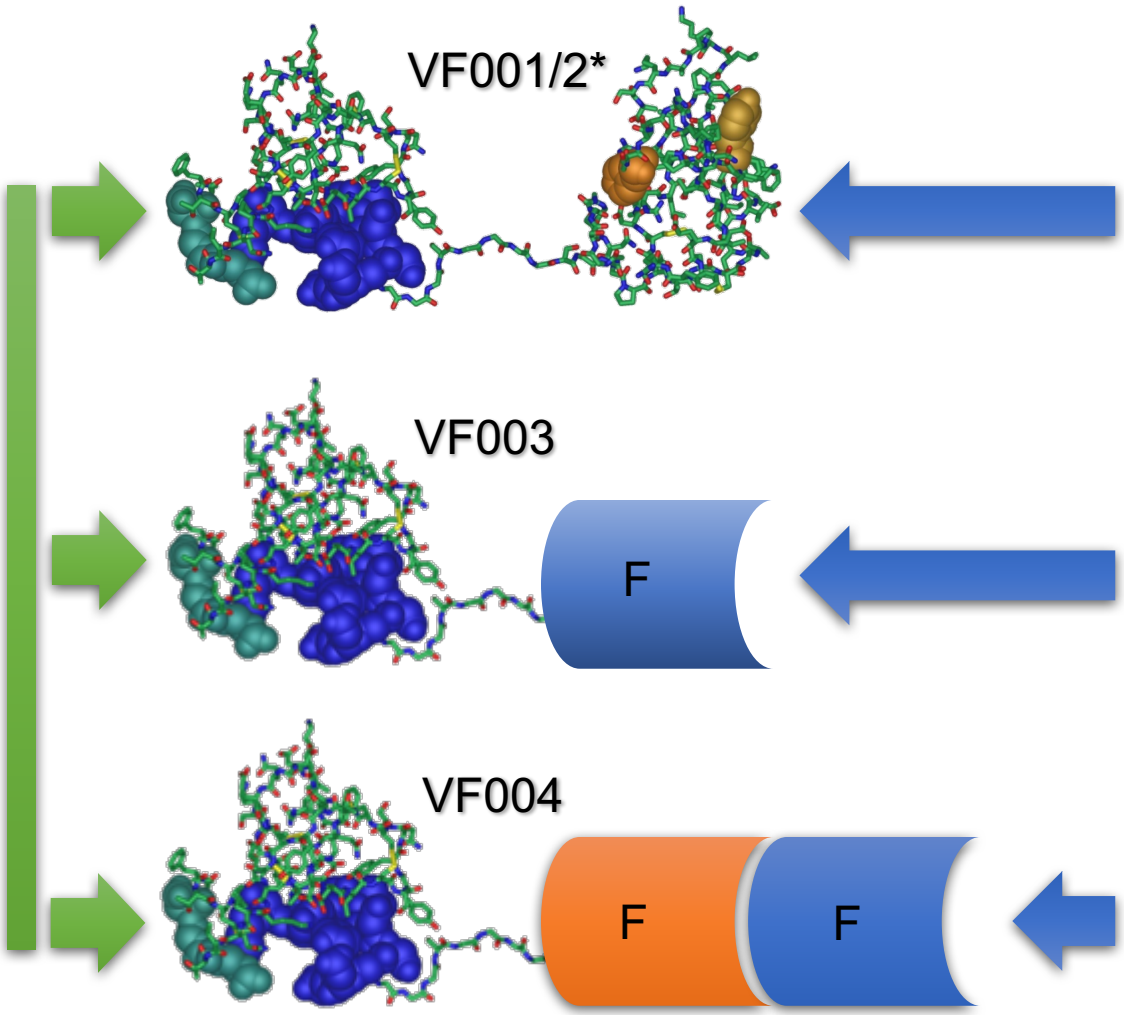
Stages:

1. Attachment & migration of adjacent epithelial cells to close the injured site
2. Proliferation of migrated cells to re-establish epithelial thickness
3. Differentiation of new epithelium to restore structure and function

Rationale for exploring Factor technology for PCED:

- Vitronectin-targeted growth factors ("VF") have the ability to rapidly adsorb onto exposed extracellular matrix and support epithelial cell migration over the wound base while stimulating cell proliferation

What are VF003 / VF004 ?



"V" *: Vitronectin peptide portion (collagen binding, cell adhesion)*

"F" : Growth Factor (IGF-1)

Alternative Growth Factor (Undisclosed)

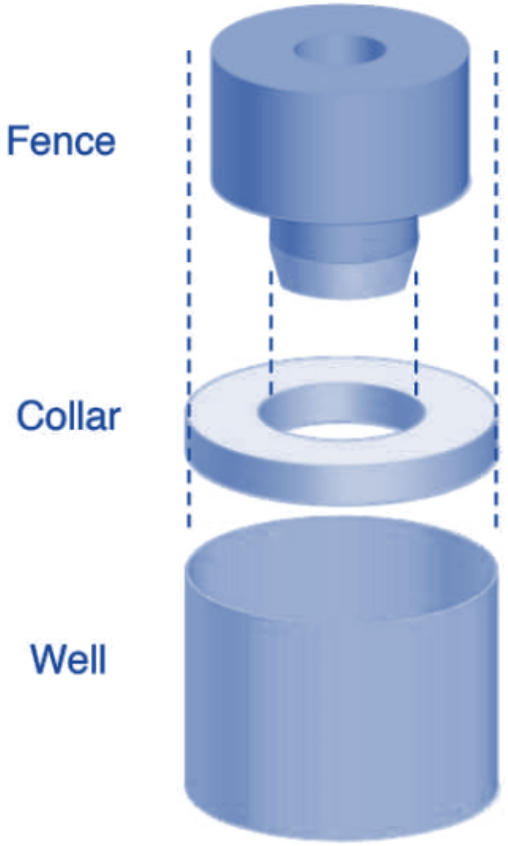
Dual Growth Factors (Undisclosed)

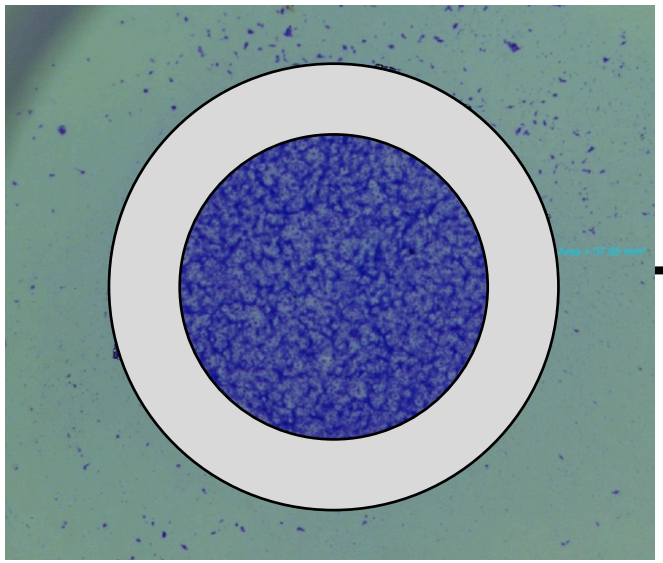
The growth factors used in VF003 and VF004 were chosen to theoretically optimise the migration and proliferation of corneal epithelial cells.

All of these constructs build on the core Factor vitronectin program. We have manufactured these new molecules at lab scale and evaluated their basic expression feasibility. This is a significant undertaking in its own right.

**VF002 is a high viscosity formulation of VF001*

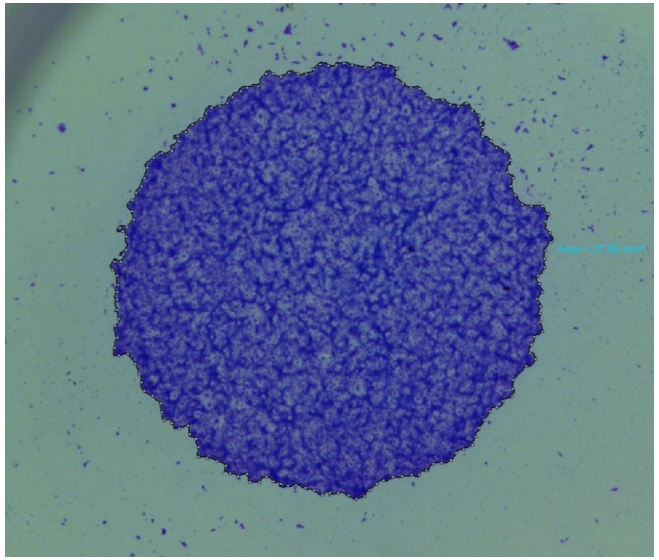
Tissue Growth Assay to Measure VF Potency





48h migration

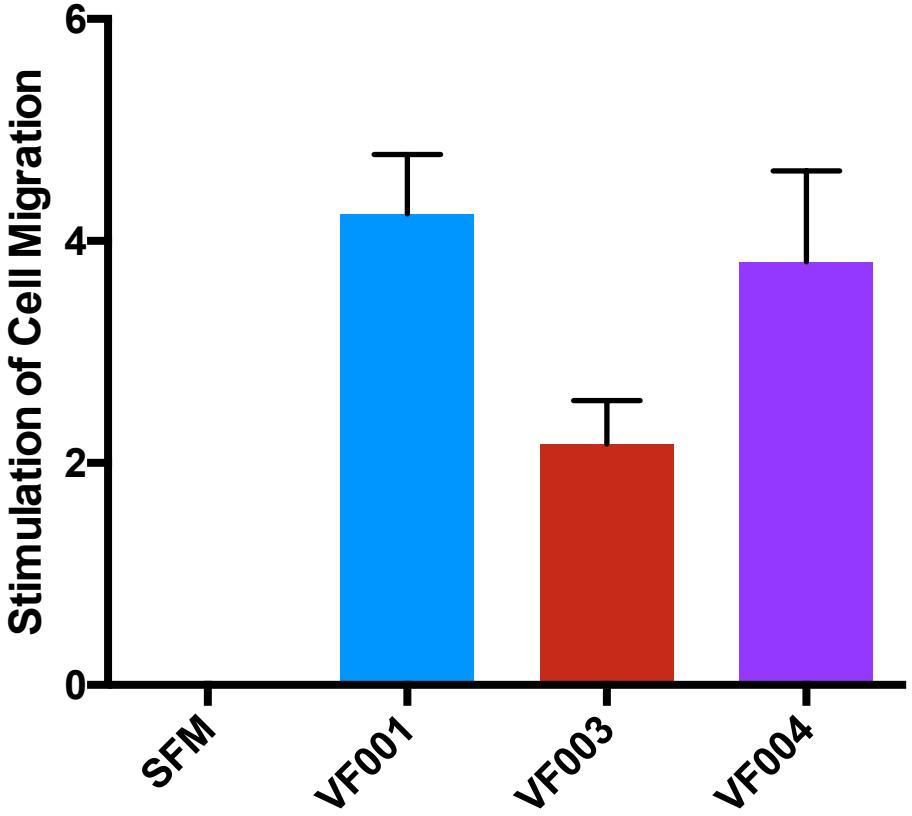
+ mitomycin-C to inhibit proliferation



- *In vitro* “Fence Assay” – tissue culture
- Cells seeded using fence and collar
- Cells attach over a defined circular area
- Fence and collar are removed and treatments added

- Surface areas measured
- Serum-free media (SFM) used to set baseline (normal) migratory response
- Area above SFM treatment response measures relative potency of VF candidates

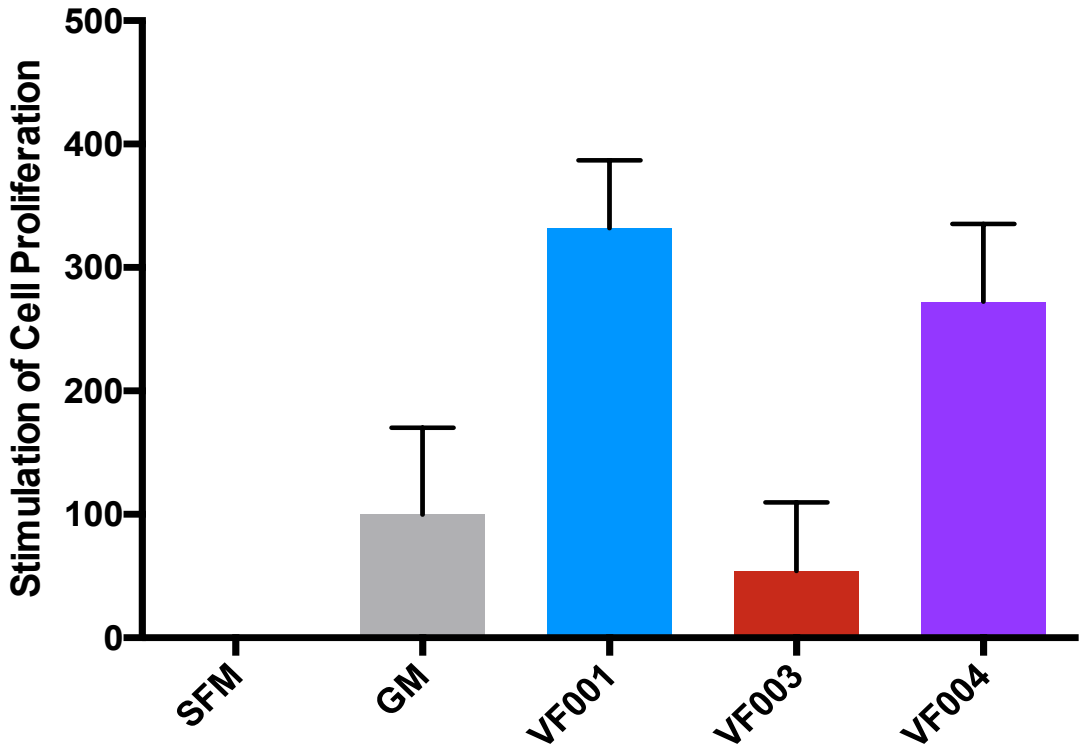
VF001 and VF004 are Potent Stimulators of Corneal Epithelial Cell Migration



SFM = serum-free media (control)
N=6, duplicates from 3 independent experiments

- Stimulation of cell migration based on the HCE-T human corneal epithelial cell "fence assay" over 48h
- Responses represent increases in cell surface area (mm^2) relative to serum-free media control (SFM)
- VF candidates were tested across a range of concentrations
  - 150nM data displayed on graph
  - Same trends across different concentrations
- ***VF001 & VF004 responses were equally strong at stimulating cell migration and significantly greater than VF003***

VF001 and VF004 are Potent Stimulators of Corneal Epithelial Cell Proliferation



SFM = serum-free media (control)
GM = growth media containing 10% serum (comparator)
N=9, triplicates from 3 independent experiments

- Stimulation of cell proliferation based on the HCE-T human corneal epithelial cell "fence assay" over 48h
- Relative assessment (to controls) with:
  - Response to SFM (serum-free media) set at "0 %"
  - Response to GM (growth media containing 10% serum) set at "100%"
  - GM is to measure normal cell proliferation
- VF candidates were tested across a range of concentrations
  - 150nM data displayed on graph
  - Same trends across different concentrations
- ***VF001 & VF004 responses were significantly greater than that of GM (~300% increase) while VF003 response was similar to GM***

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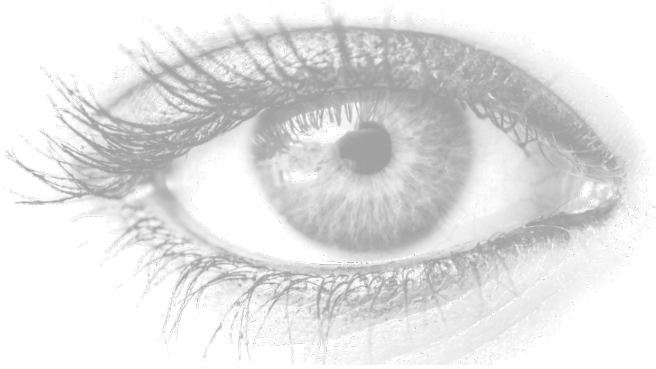
Clear Rationale for Clinical Translation



- VF001 appears to be a good candidate for the PCED application, building further value in our lead program
- We have plenty of bulk GMP drug available in inventory
- Currently VF001 is very simply formulated (in phosphate-buffered saline or “PBS”) and could be very quickly tested in patients as an ocular irrigation
- Existing clinical data and safety profile of VF001 supports rapid clinical evaluation of this new indication
- Existing validated manufacturing process and pre-filled syringe used in study VF00102 (VLUs[1]) could be utilised for a clinical study in PCED

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[1]Venous Leg Ulcers, the existing clinical indication under development for VF001

Provisional Patent Submission

- Provisional Patent drafted and submitted to Australian Patent Office (application number 2017902737) – July 2017. Data collection over the next 12 months will support PCT (international) applications
- Method(s) for treating or preventing a corneal epithelial wound
- Specification also claims new VF candidates (as composition of matter)
- **Broad Indications captured:** all ocular surface conditions that would benefit from a topical treatment that stimulates corneal epithelial cell proliferation and migration

Australian Government

IP Australia

Summary and Next Steps

- VF001 stimulates strong proliferation and migration in human corneal epithelial cells – evidence of potential for treating PCED, a high-value advanced wound care application with the potential to expand more generally to the post-surgical setting
- With the existing data and ongoing clinical evaluation of VF001, expansion into an ocular clinical development program could happen within 6-9 months, subject to financing
- Similar efficacy observed for VF001 and VF004, which we will investigate further before selecting our clinical candidate. There is a speed advantage in pushing VF001
- Currently preparing for IND-enabling *in vivo* studies based on appropriate models to further validate usefulness of lead VF candidates as ocular wound healing treatments
- ***Factor continues to build value in its core IP platform, including new indications and applications for the significant investment in VF001***