



# Investor Update

*Biotech Showcase  
San Francisco  
January 2017*

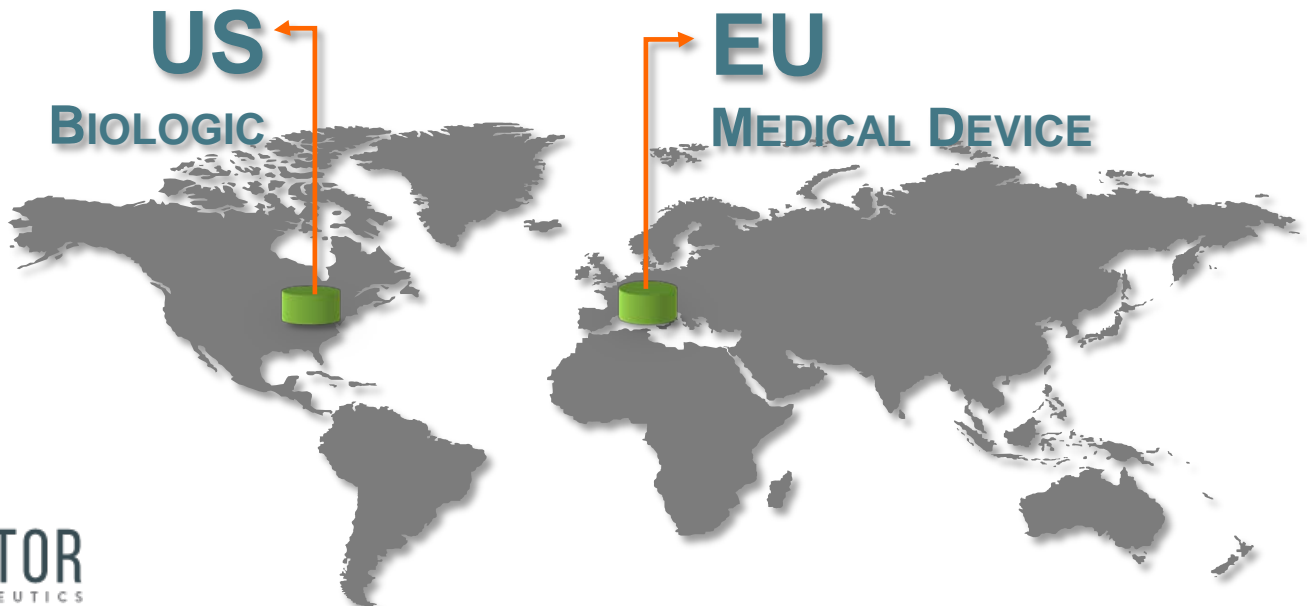
**Christian Behrenbruch, Ph.D**  
*Executive Director*

# Disclaimer

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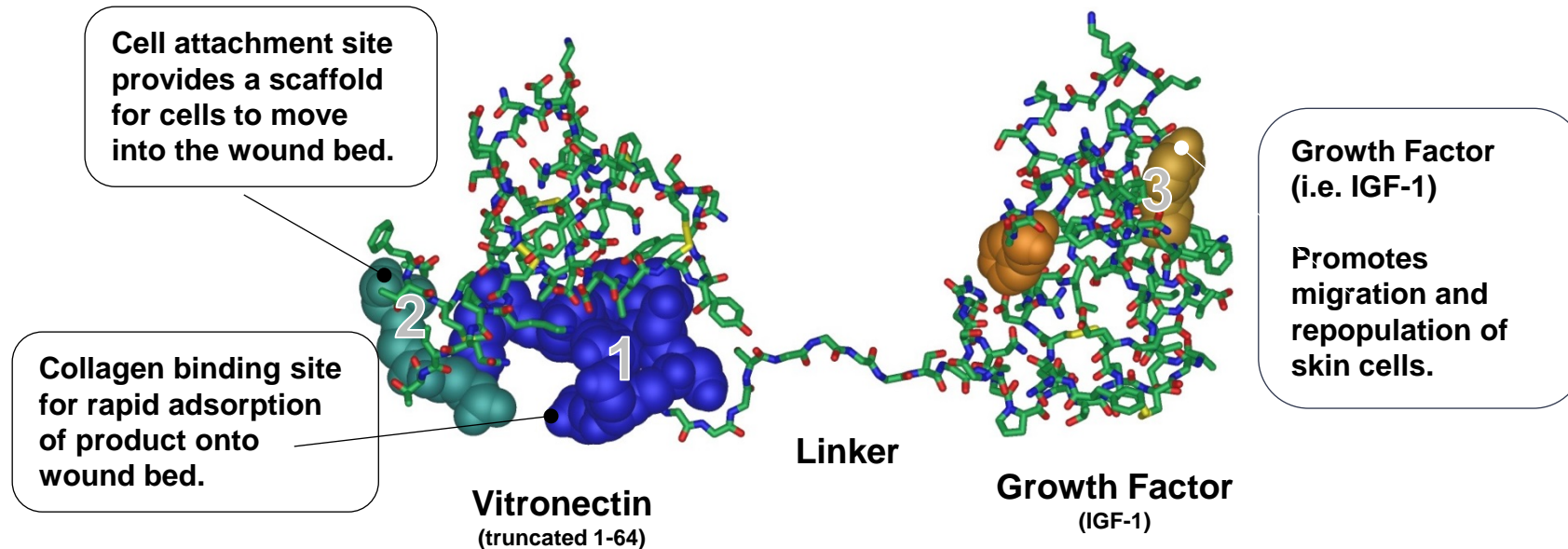
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# Dashboard



▲ \$0.06	
\$0.035 (Placement)	
<b>Mkt. Cap. A\$43m</b>	
(January 10)	
<b>Focus</b>	<b>Advanced wound care</b>
<b>Clinical Stage</b>	<b>Phase II US Pivotal EU</b>
<b>Issued Shares</b>	<b>724,328,499</b>
<b>Options</b>	<b>9.5m</b>
<b>Current Cash</b>	<b>AUD ~\$12m</b>
<b>Symbol</b>	<b>FTT</b>
<b>Exchange</b>	<b>ASX</b>

# Technology Recap : Molecular “Velcro” + Growth Factors



- Advanced biologic products for wound care using a targeted growth factor approach.
- Our products promote healing by 1) providing an anchor point for new cells and 2) providing growth factors to encourage the proliferation of skin cells.
- Proven potency and safety.
- A platform technology with multiple clinical applications.

# Our mission: Put Chronic Wounds onto a Healing Trajectory



## Economic Burden

Chronic wounds affect 6.5M people in the US, costs > US\$25B.



## Difficult to treat

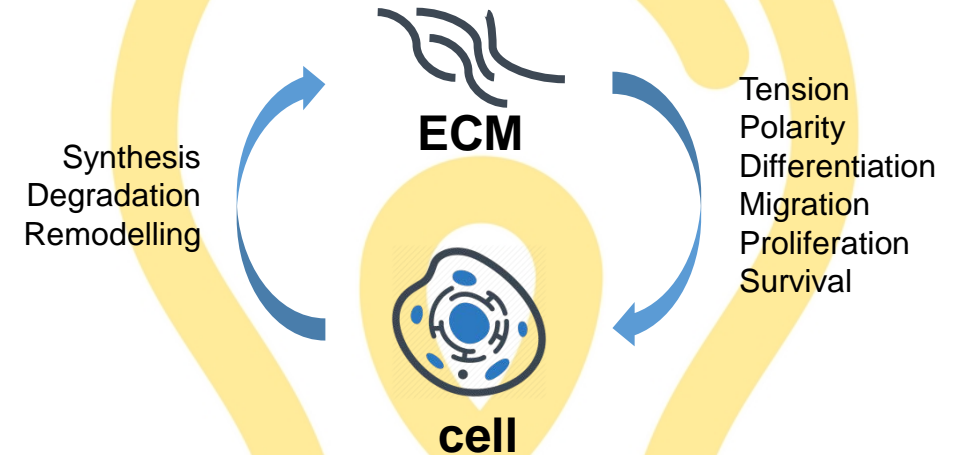
Chronic wounds are recurrent, prone to infection, painful and often associated with comorbidities



## Growing Problem

Increasing obesity and diabetes rates drive increase in incidence and prevalence

## FTT Solution: Convert non-healing wound into healing wound



Restore cellular connectivity on dysfunctional ECM  
Induce cells to lay down new functional ECM

# VF-001 Lead Program : a Major Opportunity

1/3 of treated patients experience 4+ recurrent episodes



Probability of healing in Mild and moderate patients is 93% and 65% respectively.

Persisting pain at dressing changes is common -

Associated with lower activity, depression, 73% disturbed sleep, 50% mood affect.

**Venous Leg Ulcers (VLU) affect 1.7% of the US population.**

(age 65 and older, prevalence is 600,000/year)

**\$\$\$ \$2.5-3.5B**

Annual cost of treating to the US healthcare system. VLU treatment costs ~\$9,600.



Over 1,000 outpatient wound centers in the US.



Current therapies fail to bind to collagen in the ulcer bed, hindering fast and effective wound healing

# The Investor Perspective ASX:FTT

Clear  
Mission

- To develop and commercialize a portfolio of advanced wound care products
- Lead Program : VF-001 in Venous Leg Ulcers

Progress

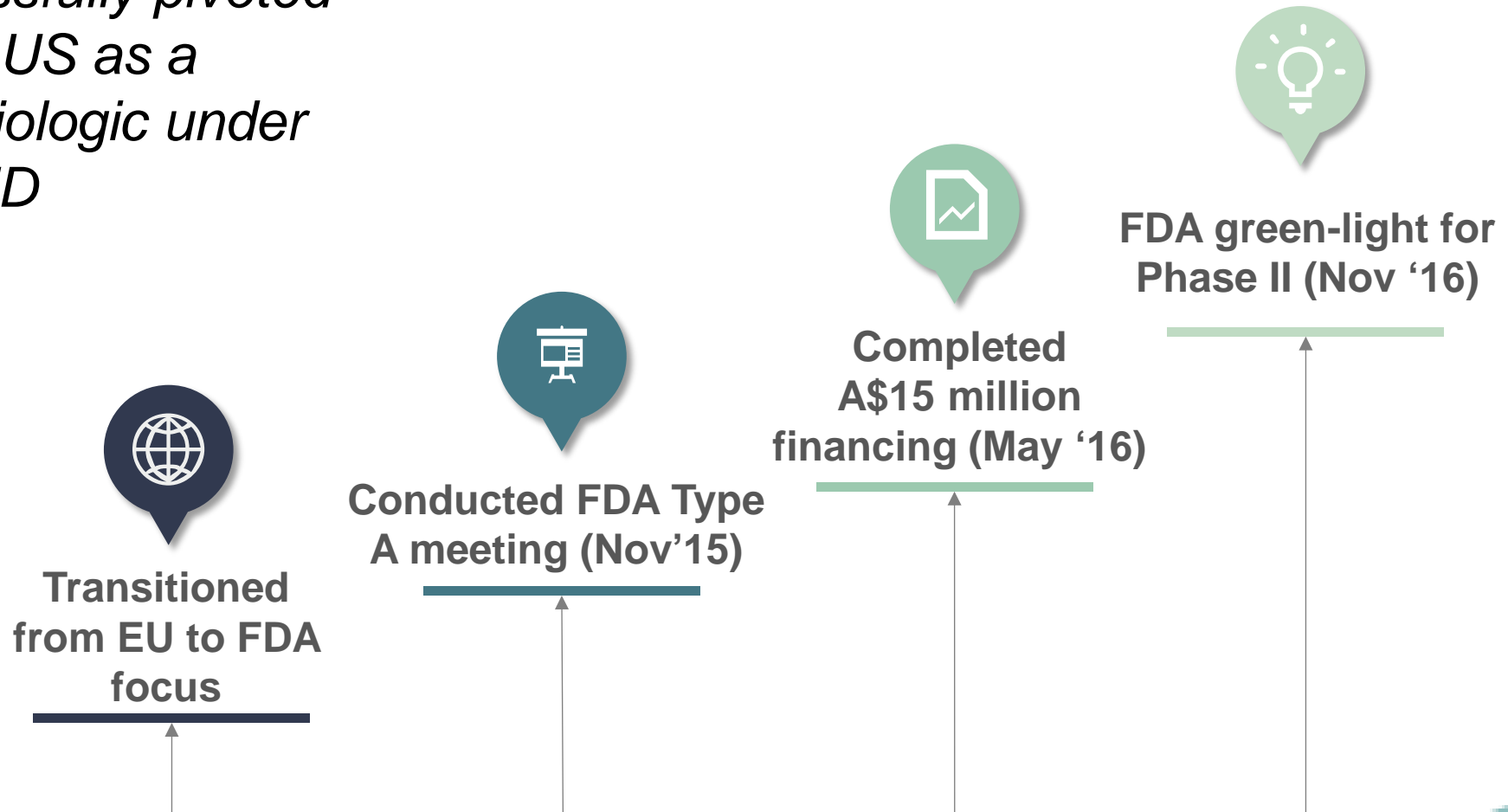
- Effective corporate turnaround, de-risked lead program
- VF-001 undergoing a significant Phase II trial in the US

Growth

- Near-term value inflection around regulatory and data catalysts, business development
- Long term market opportunity for VF001 across multiple indications

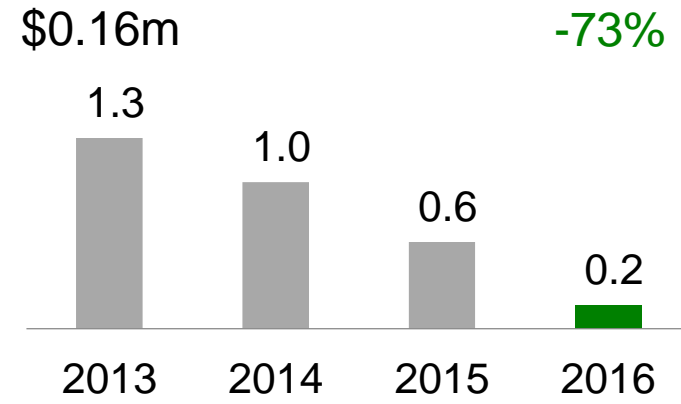
# FY16 : A Big Year, Major Turning Point

*We successfully pivoted  
VF-001 to US as a  
Phase II biologic under  
an FDA IND*

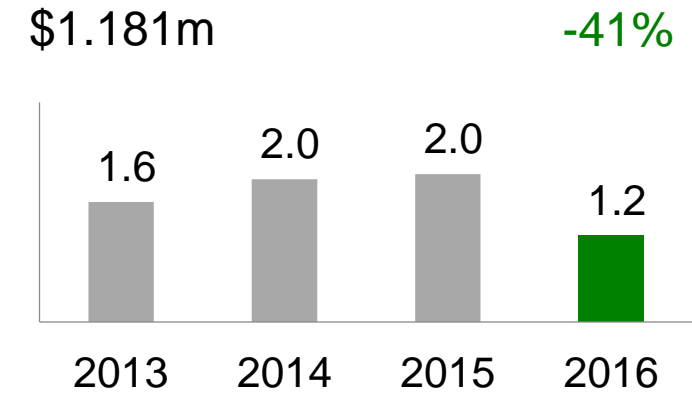


# Financial Re-Prioritization

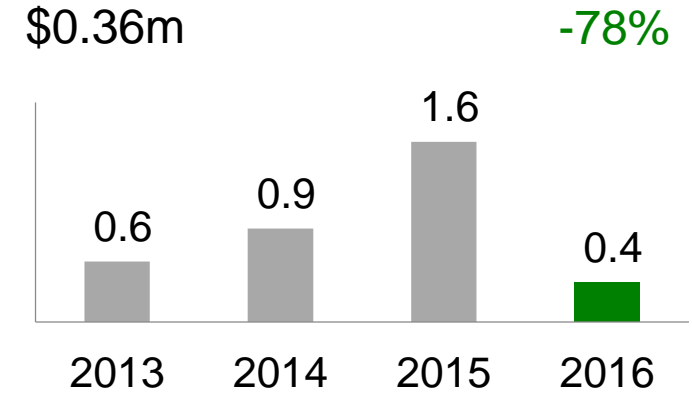
## R&D expense



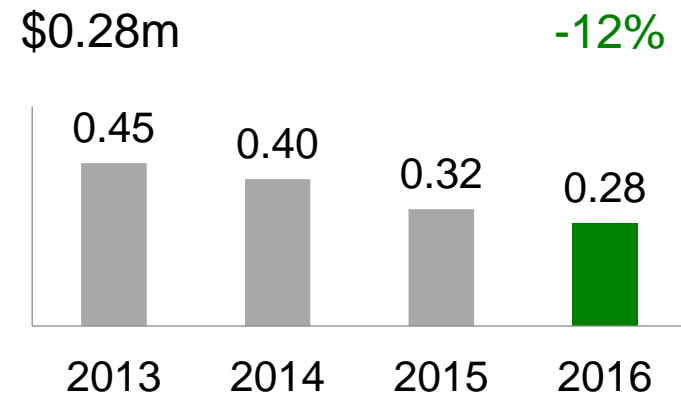
## Employment expense



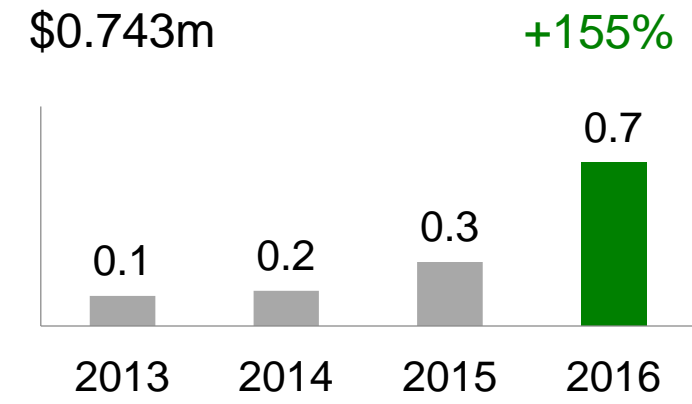
## Regulatory expense



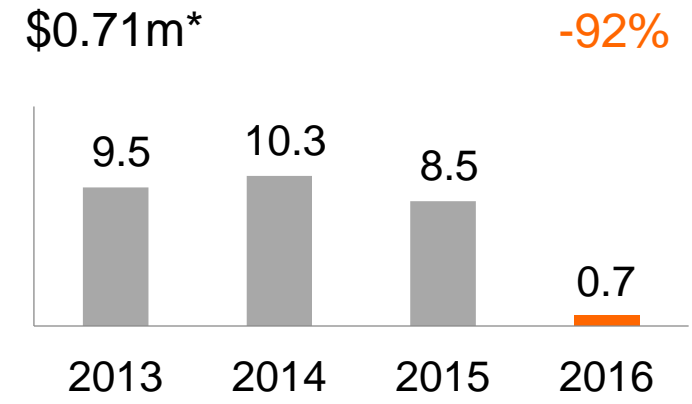
## IP expense



## Clinical expense



## Inventory



\*Appropriate revaluation: Regulatory shelf-life of registration lots precedes potential approval date

# Chronic Wound Care : A Mixed Track-Record of Success

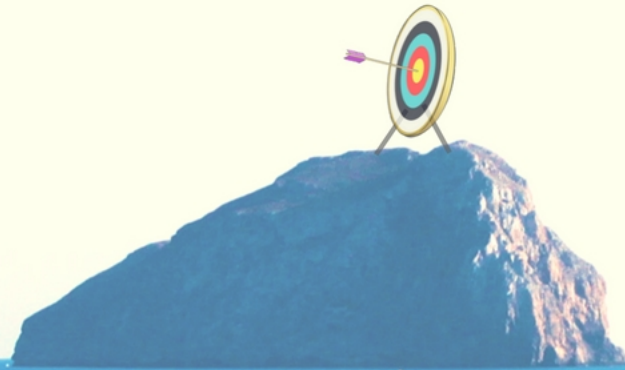
Product	Company	Clinical stage	Trial history	Design features
Regranex	<b>Smith &amp; Nephew</b>	Marketed, DFU	VLU study showed 46% closure for treated vs 39% placebo (not stat sig). Phase 2, n=228	n=132, 16 weeks
HP-802-247	<b>Smith &amp; Nephew</b>	Failed Phase 3, VLU	Phase 2: 70% in treated vs 46% control achieved complete wound closure, n=228, stat sig.	N=440, 12 weeks
CureXcell	<b>Macrocare</b>	Failed Phase 3	Phase 3 missed primary endpoint, terminated for futility.	N=252, 16 weeks
Nexagon	<b>CoDa Therapeutics</b>	Stalled Phase 2?	No results announced	N=300, 10 weeks

# SETTING THE TRIAL UP FOR SUCCESS

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## Importance of Patient Selection:

Exclude patients who confound efficacy



### Non-healers

Usually present with  
infections or other  
complications

### Rapid healers

>20% wound  
reduction during the  
run-in period

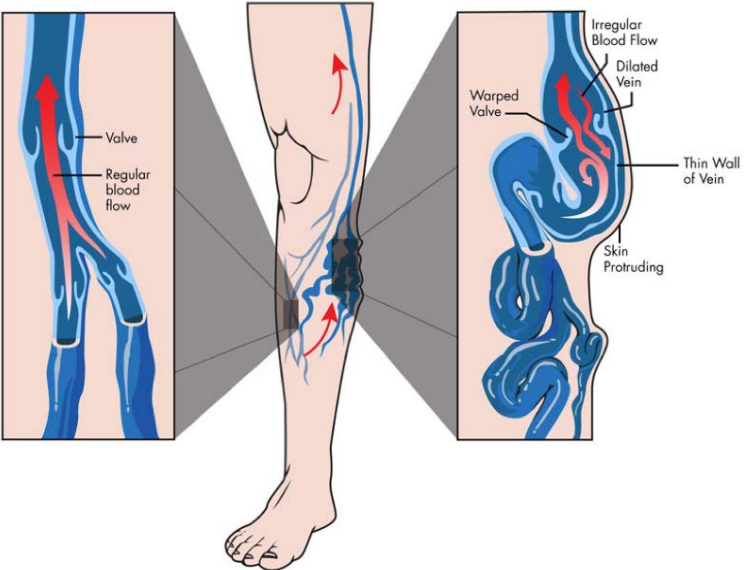
# NCT02973893 : Phase II Trial Synopsis

Duration	12 weeks (2 weeks screening, 12 weeks treatment, 12 weeks follow up)
Dosing	1:1:1 randomized into placebo, 14 mcg VF001+SC, 140mcg VF001+SC
Total patients	168 patients, 26 sites
Key inclusion criteria	Margolis predictive score of 1a or 1b at treatment initiation. Target ulcer exhibits <30% change in ulcer size with standard of care.
Primary Endpoint	% Reduction in study ulcer area
Key Secondary Endpoints	Proportion of patients with complete ulcer closure
	Time to ulcer closure
	Quality adjusted life-year survey
	Time to first instance of no ulcer study pain (VAS score)
	Time to meaningful pain reduction

- **Partnering Potential:** Successful Phase II is a major inflection point
- **EMA:** Serves as a second pivotal study for EMA (CE Mark)
- **FDA:** Successful Phase 2 and CE Mark could mean only one confirmatory Phase 3 would be required for approval, with a second Phase 3 in another indication

# Margolis severity scores

## Underlying Venous Disease



- Seminal work by epidemiologist and wound care expert, Dr. David Margolis (U. Penn) provides classification of venous disease
- Highest level of unmet need in Margolis 1 patients
- Highly relevant to considering the therapeutic potential of VF-001

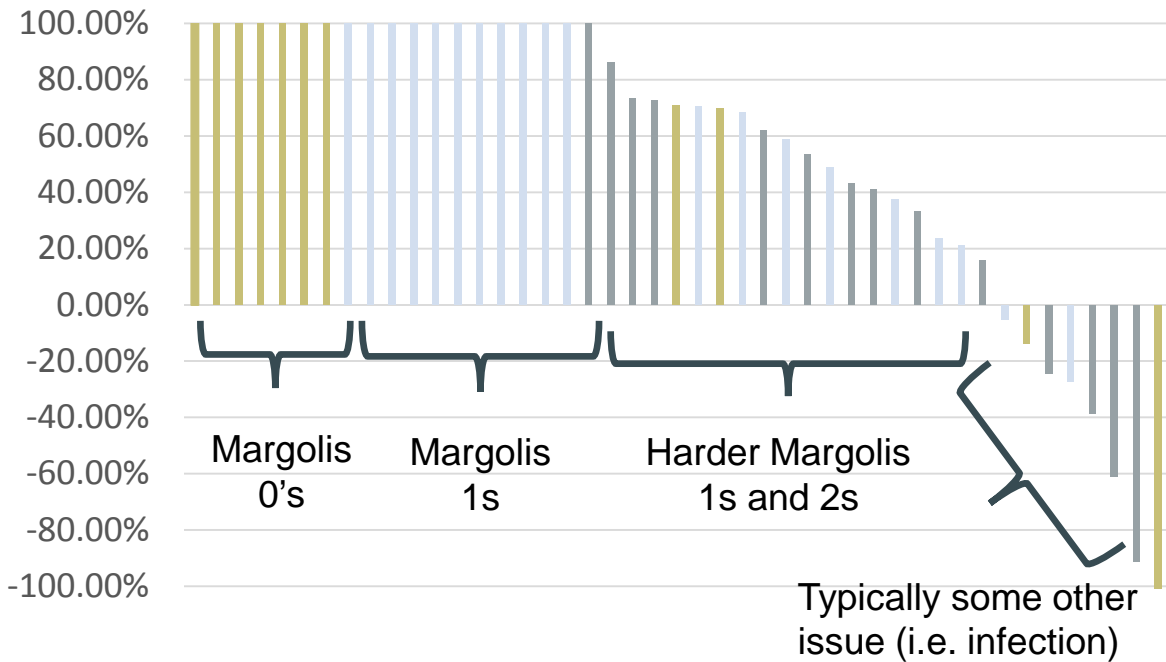
Severity	Proportion in the real world population	Probability of Healing within 24 Weeks with Limb Compression (%)*	Baseline Ulcer Area (cm <sup>2</sup> )	Ulcer Duration (months)
0 (least severe)	~ 69%	93.0 %	≤ 5	≤ 6
1 (middle)	~ 25%	65.0 %	≤ 5	> 6
			> 5	≤ 6
2 (most severe)	~ 6%	13.0 %	> 5	> 6

\* Margolis DJ, Berlin JA, Strom BL. Which venous leg ulcers will heal with limb compression bandages? Am J Med. 2000 Jul;109(1):15-9.

The vast majority of these patients will be treated in the community setting, not the specialty care setting

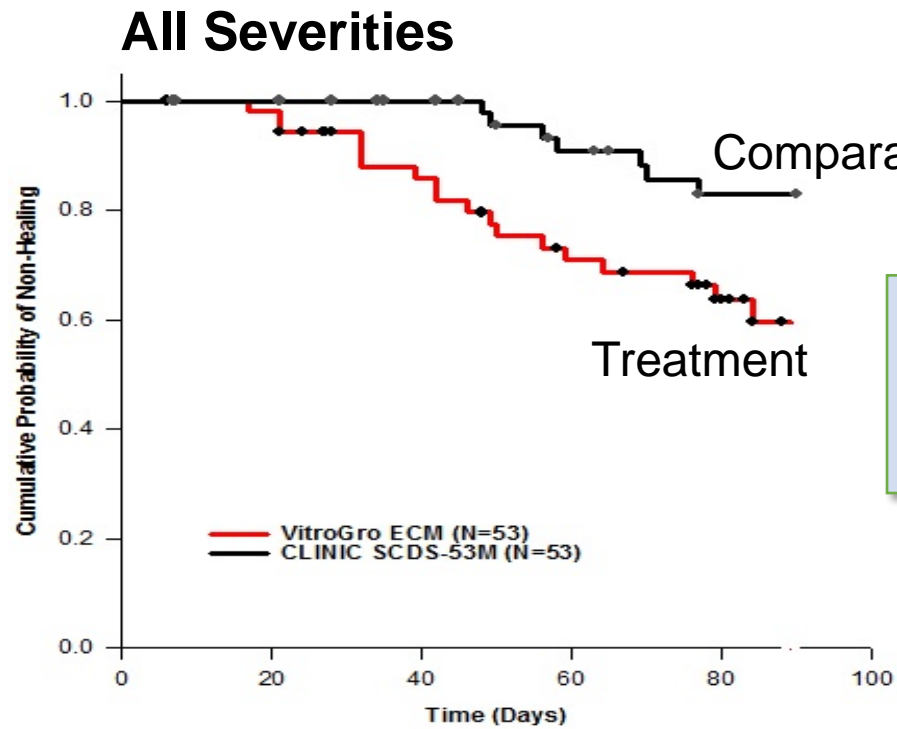


# VitroCard : Subset Analysis Highlights Efficacy

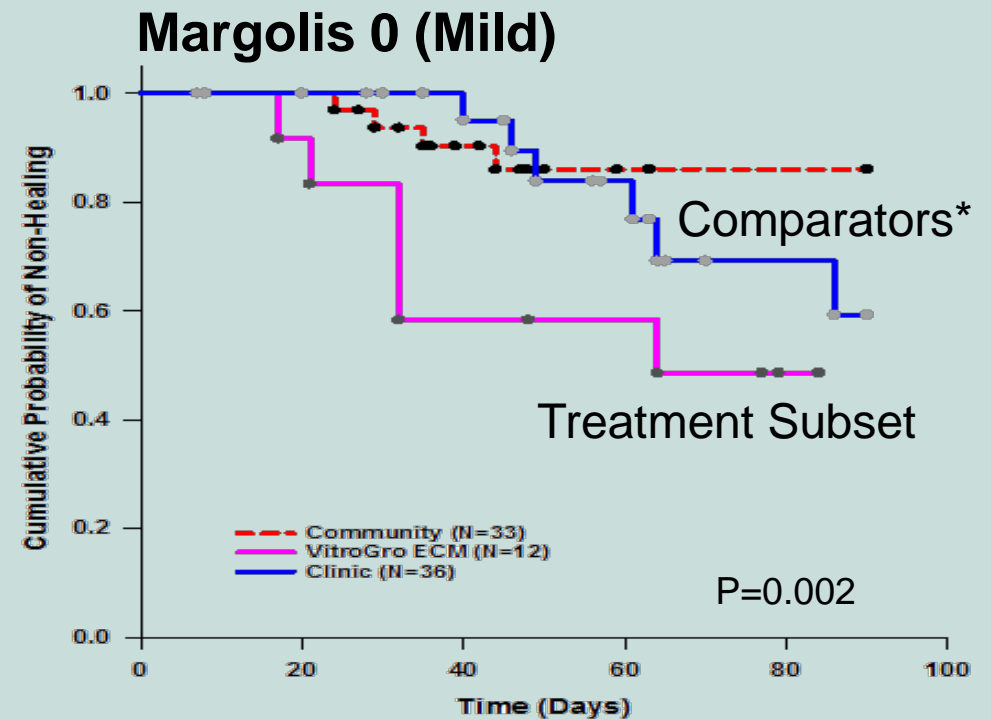


- 12 week data showed statistically significant wound area reduction from baseline ( $p=0.003$ )
- Differential, robust efficacy in Margolis 1's
- Moderate efficacy in harder Margolis 1's and 2's

# Margolis “0” : Modest, 10% Improved Probability of Healing

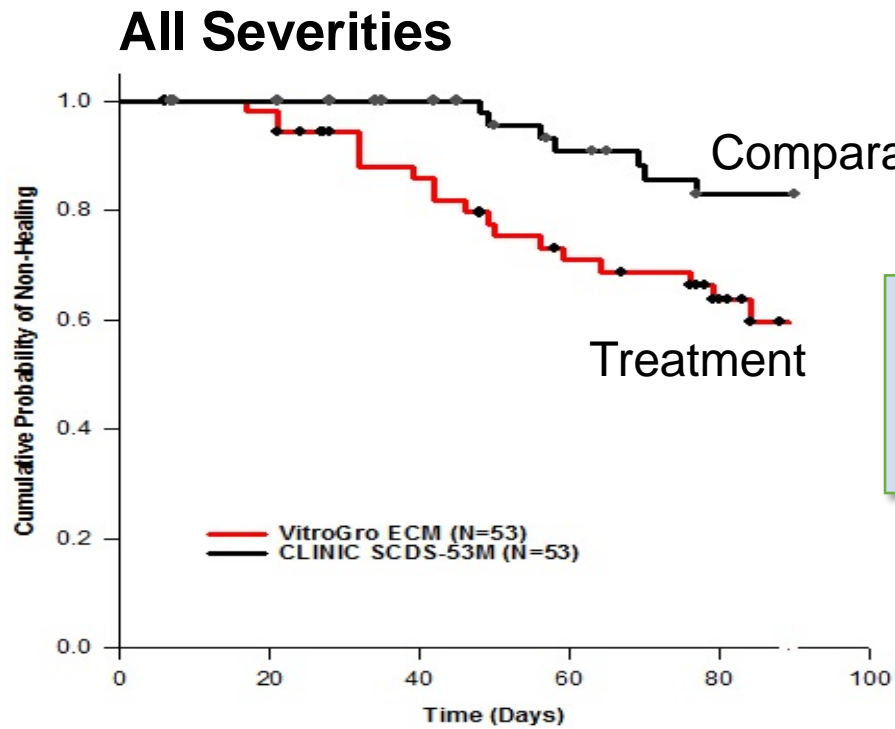


VF001 shows only modest improvement

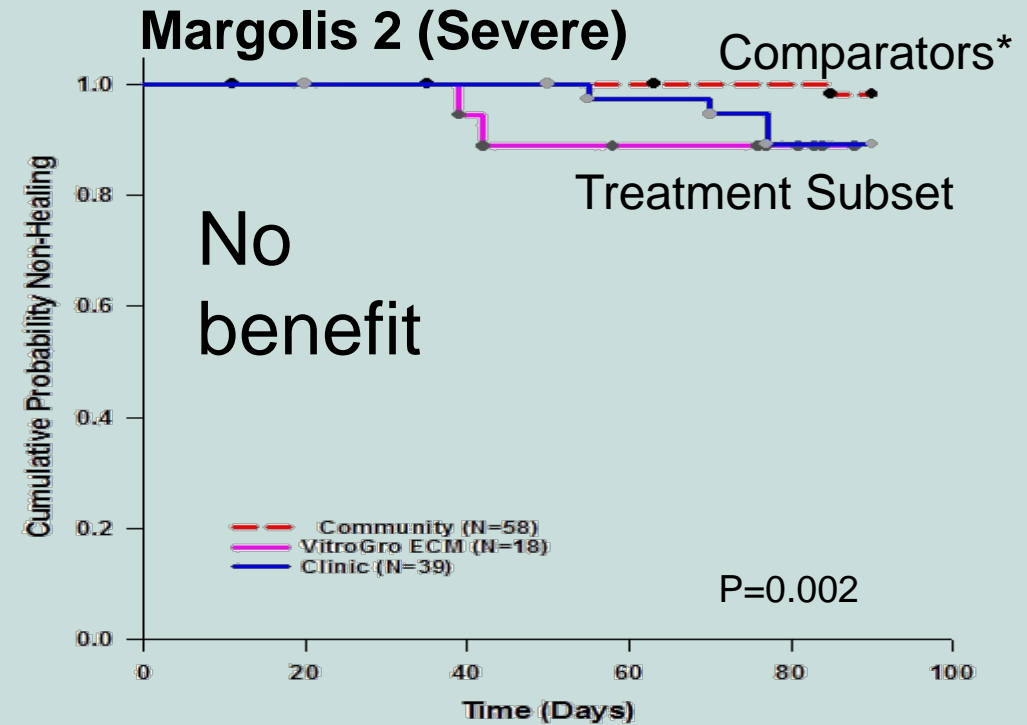


# Margolis "2"

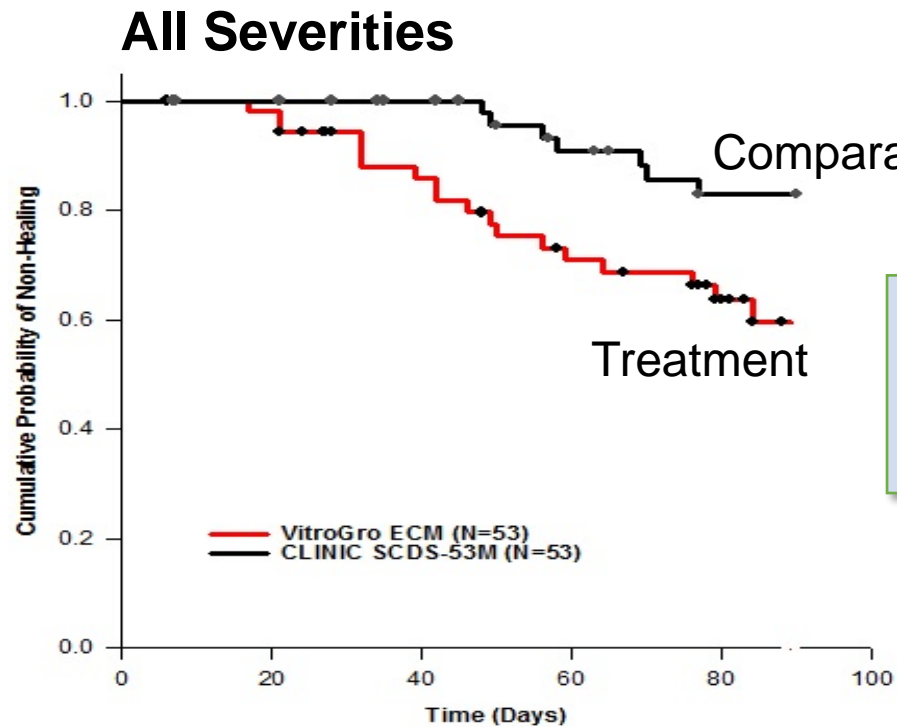
## No Improved Probability of Healing



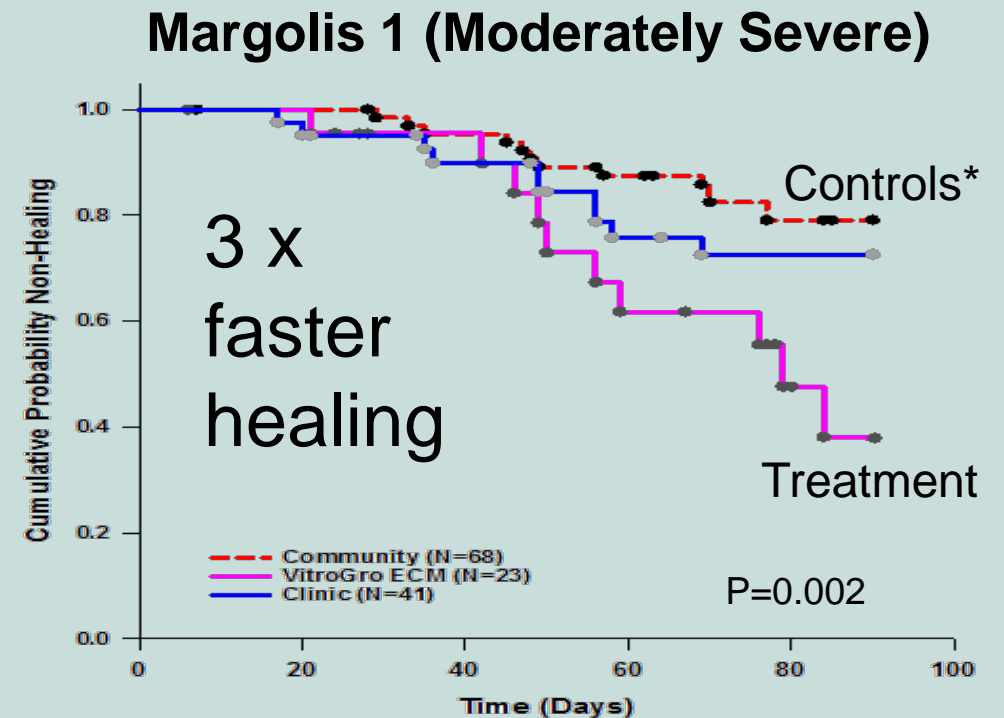
VF001 showed negligible benefit in Margolis '2's



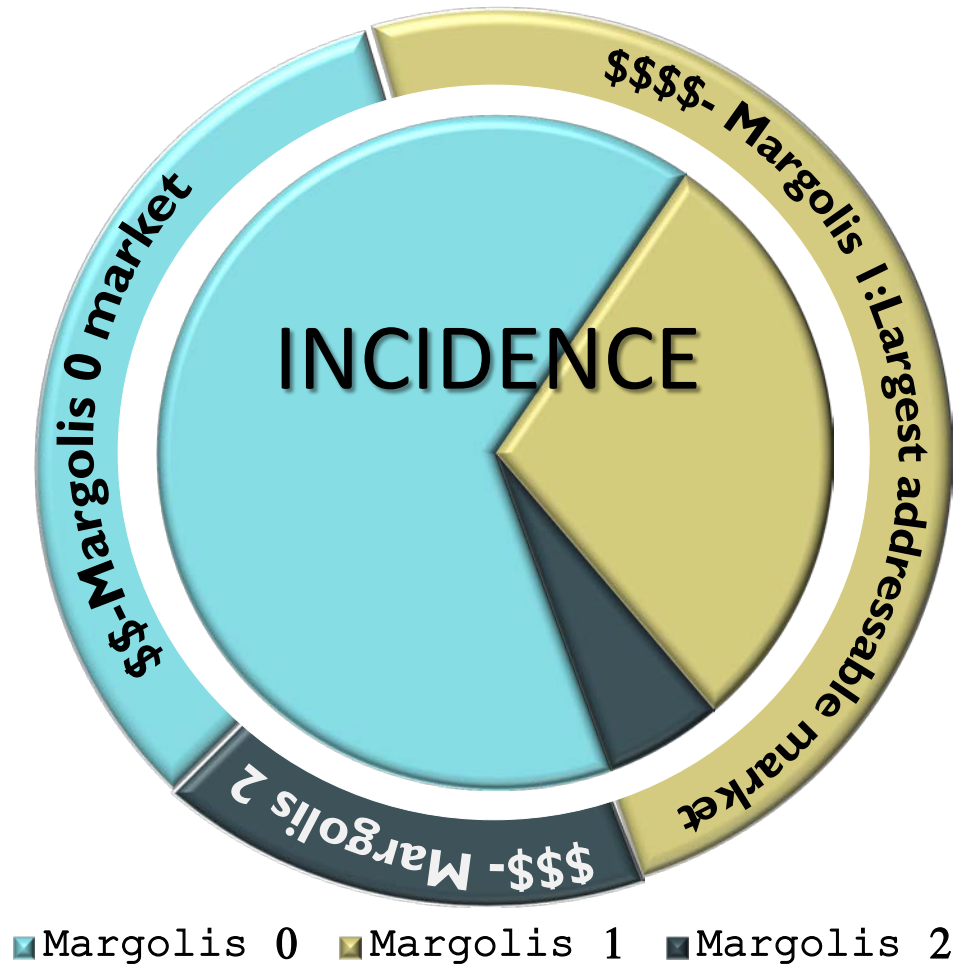
# Margolis "1" Significant (Best) Improvement



VF001 Converts non-healing wounds to healing wounds



# An Effective Market Segmentation Strategy



## Margolis type 0 patients:

- Mild disease – community care
- Compression bandaging, dressings
- Highly fragmented / congested market (low “value”/differentiation)

## Margolis type 1 patients:

- **Unmet clinical need**, low competition.
- A cost-effective treatment that can be used in the community setting would be a game-changer
- FTT target market

## Margolis type 2 patients:

- Severe disease, specialty care, congested.
- Expensive therapies (grafts, cell therapies, scaffolds) but cost-benefit supports these treatments.

# Label & Reimbursement

- **~\$1,000 - \$1,200 per treatment course is supported using pricing models**
- Targeted at patients in the community setting that do not adequately respond to standard care
- In line with pricing and reimbursement criteria for competing products

- For example, a 20% healing rate improvement would eliminate 6 weeks of standard care
  - Upside : potential of pain relief

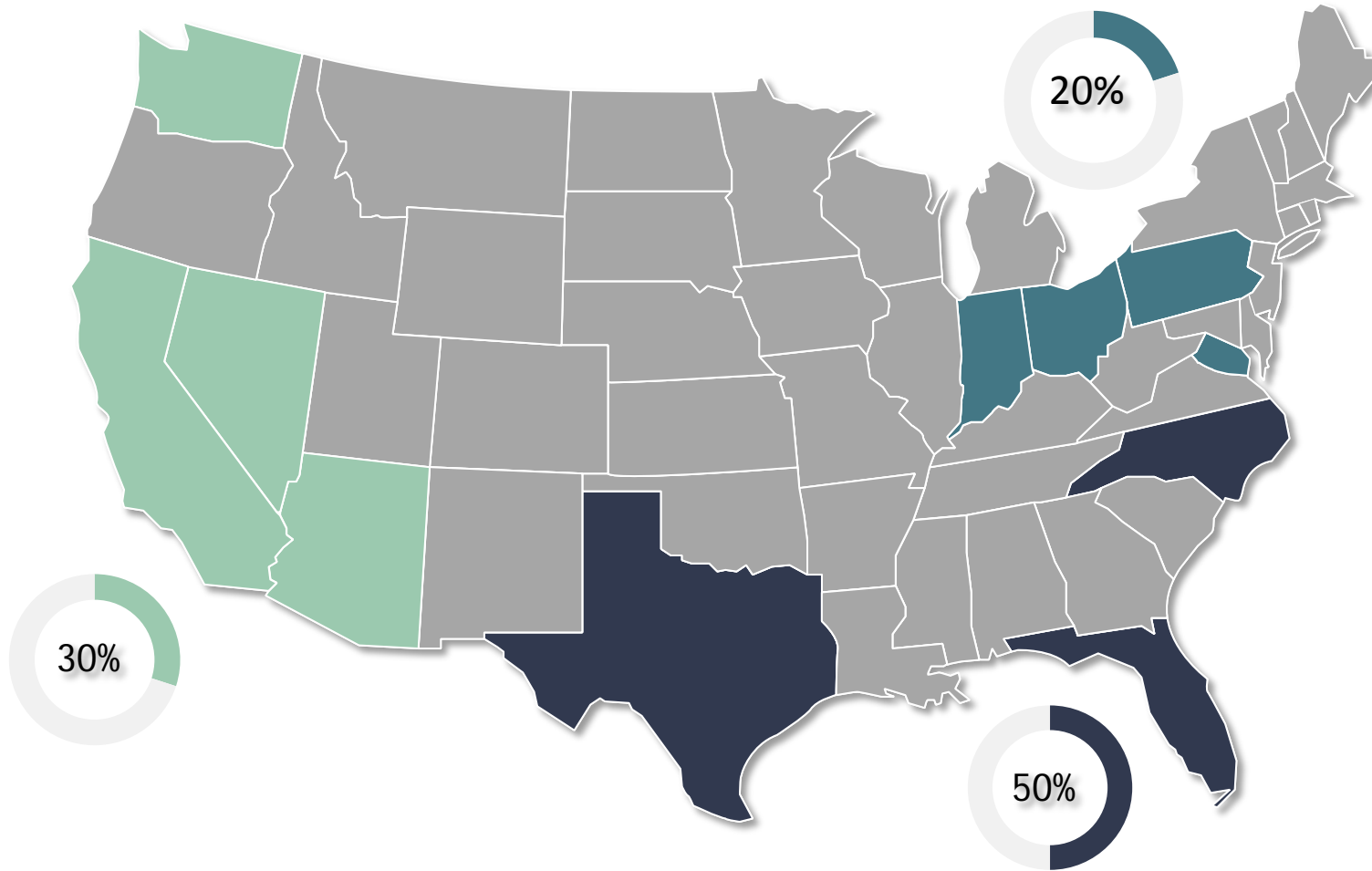
- VF001 is likely to be cost-effective based on EU data
  - £705 average UK cost-benefit / patient
  - €629 in Germany (15% improvement)



# Clinical Operations

## VF-001 in Phase II

✓ **Recruiting well**

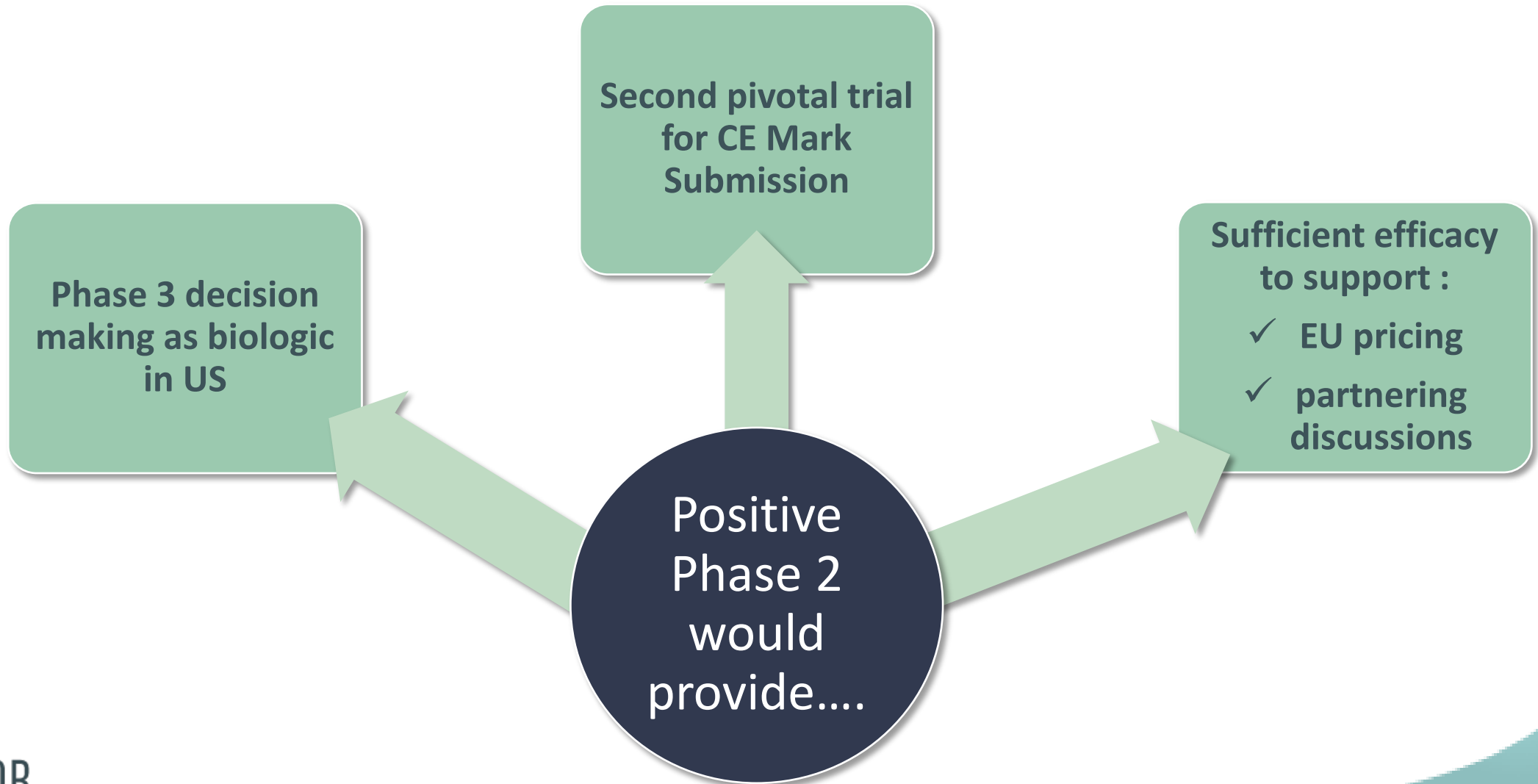


**SOUTH** KOLs & podiatry



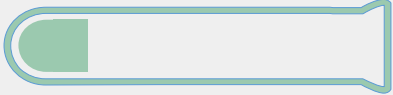
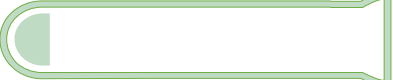
**NORTH** Specialty sites

**WEST** High throughput sites

# Poised for Clinical and Commercial Success



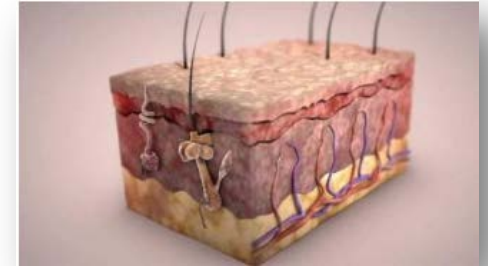
# Advancing the Pipeline

Program	Candidates	Progress
Chronic cutaneous ulcers Priority focus 	'001	<ul style="list-style-type: none"><li>• Phase II, Venous leg ulcers</li><li>• Preparing CMC for FDA end-of-phase 2 meeting</li><li>• Preparing return to European CE Mark process</li><li>• Evaluating indication expansion opportunities</li></ul>
High viscosity formulation 	'002	<ul style="list-style-type: none"><li>• Achieved necessary improvements in our CMC/analytical capability</li><li>• Engaged with potential collaborators to plan future path</li></ul>
Ocular 	'003/004	<ul style="list-style-type: none"><li>• R&amp;D manufacturing underway</li><li>• Potential proof-of-concept readout Jul 2017</li><li>• Planning <i>in vivo</i> collaboration</li></ul>
New opportunities 	'005 ....	<ul style="list-style-type: none"><li>• Monash collaboration in Harlequin Ichthyosis</li><li>• Other orphan indications</li></ul>

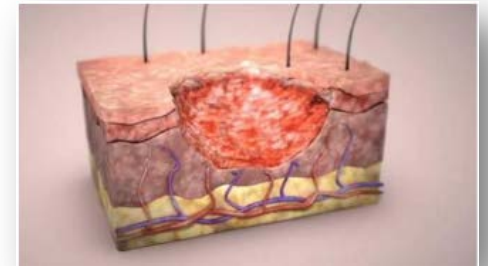
# Catalysts

Catalyst	Timing
Recruitment update	Quarterly, starting end-Q1
DFU IND update	End-Q1
Orphan strategy update	Early Q2
Completion of enrolment	End-Q2 / early Q3
Ocular program – first data	Q2
Top-line results from US Phase II	End-Q3 / early Q4

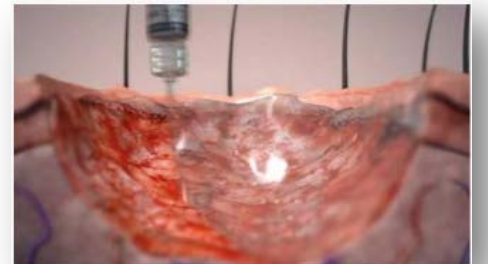
Healthy skin layers



Hemostasis



Application of VF-001



# Summary

- De-risked product with prior clinical experience demonstrated safety and efficacy
- Factor has achieved robust operational outcomes in corporate turn-around over the past 12 months
- Manufacturing is complete, off FDA clinical hold
- Clinical protocol has been significantly optimised
- Competitive advantage as a synthetic product, ideally suited to the cost and practicalities of treating patients in the community setting
- Exciting pipeline and indication expansion opportunities

