TISSUE THERAPIES

Annual General Meeting

Nigel Johnson
Chief Executive Officer

25 November 2015

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A Transformative 12 Months

Why the market has been disappointed with TIS:

- Mar-2015 : Notification of withdrawal from failed EMA* process.

Apr-15

Significant board and management changes commenced

Jun-15

Obtained scientific advice from EMA

Jul-15

Intellectual property assignment from QUT

Jul-15

Changed strategy to pharmaceutical

FDA Readiness

Key Trading Figures:

- Open $0.28, close $0.047, change ↓ (83.3%)
- Turnover 46.6%
- Daily average volume 383K
- 31 Oct 2015, cash $3.3M (+$426K tax asset)
- 31 Oct 2015, 302.88M shares, market capitalization $14.3M

*European Medicines Agency

A Transformative 12 Months

Key accomplishments – Summary

- Restructure for operational requirements in view of regulatory setback
- Effective engagement with FDA for transition to IND
- Intellectual property arrangement strengthened
- Rethink of corporate strategy in light of change from device to pharmaceutical pathway

We will deliver as we progress towards our goal

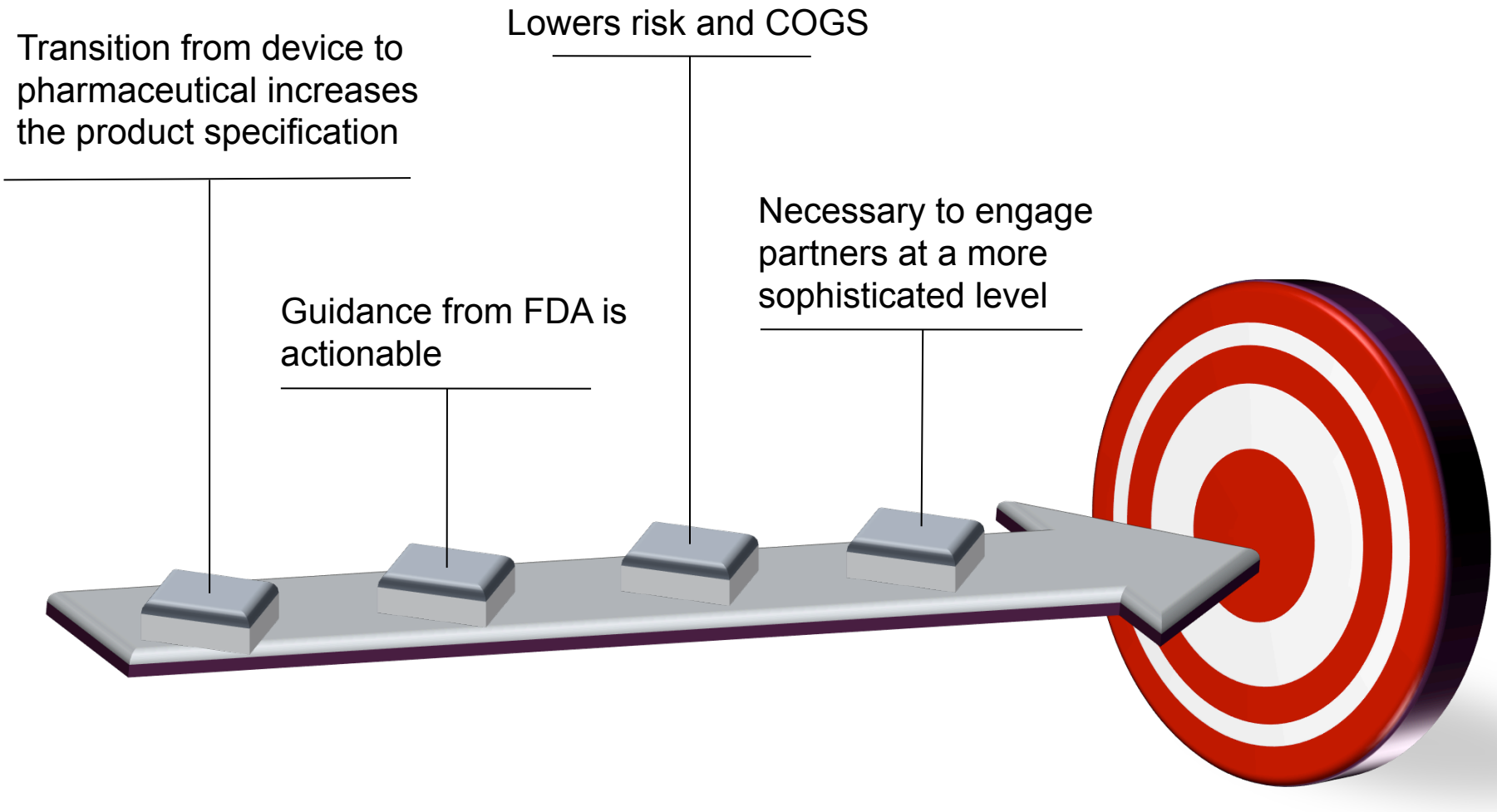
Reported Financials : Summary

Item	Guidance	Full year ($M)	Comments
Income	✓	0.5	$70K movement in R&D incentive after 30 June
Impairment of inventory	↑	(4.1)	Consequence of EMA outcome
Regulatory approvals	↑	(1.6)	Increased ~100% on prior year
Research & development	✓	(0.6)	Reduced ~40% Aligned with regulatory program
Selling, general & administrative	✓	(4.5)	All commercial launch activities ceased
Base burn rate per month	✓	(0.15) 31-Oct-15	Reduced from ~0.44M Oct-14

- Cash reserves, $3.3M at 31 October 2015 plus R&D tax credit ($426k).
- A limited number of EMA-related close-out costs are due by year-end.
- Significant experience and investment in development is recoverable for future

Historical Investment Benefits Future Development

- Resolved EMA objections
- Developing pharmaceutical quality (CMC) for stage of product development



Clinical Evaluation Fell Short

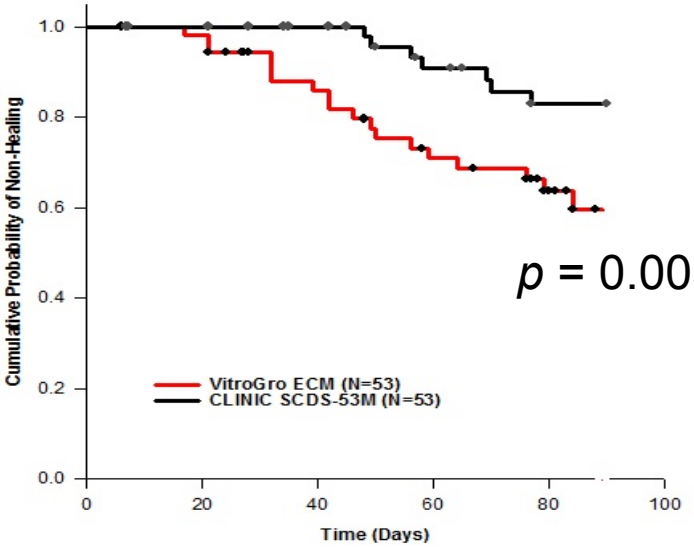
Company underestimated the extent of clinical trials required to satisfy the regulator

- EMA required a larger, comparative database to reliably assess risk : benefit
- The Notified Body had accepted that the clinical investigation establishes safety and performance
- Scientific advice from EMA provides clear guidance for future
- Major opportunity to reposition for a significantly larger number of addressable ulcers

We have significant data for future decision-making

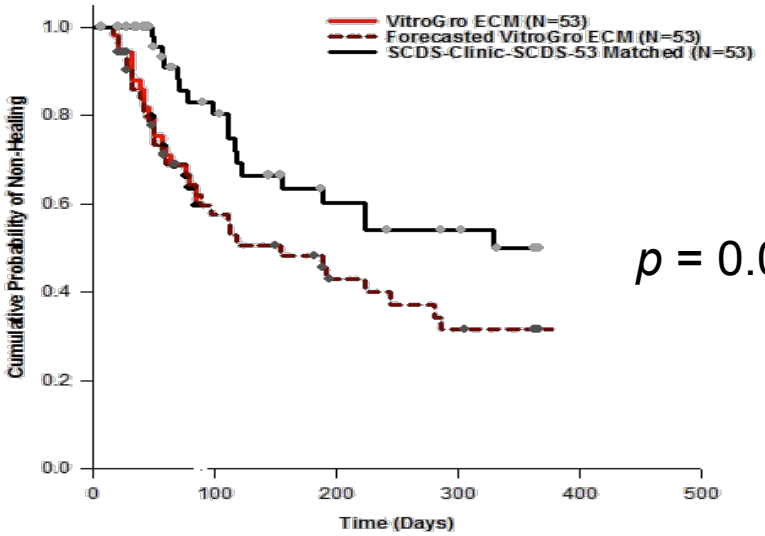
Clinical Experience to Date

- Evaluated in 53 patients to date. Wound care trials are notoriously difficult, but we have shown clear efficacy, indicating that VF-001* delivers significant clinical benefit to a very tough patient population
- VF-001 plus standard care (SC) compared to SC only - Day 90:
  - Cross-trial data - 1:1 propensity score matched from raw data on major prognostic factors for healing (ulcer area and duration) and age. Comparator is large published SC data set on chronic venous leg ulcers in the UK



$p = 0.003$

Group	Mean days to healing [95% Confidence Interval]
VitroGro® ECM plus SC	73.1 [66.4 – 79.9]
SC (weekly visits to clinic)	85.2 [81.4 – 88.9]



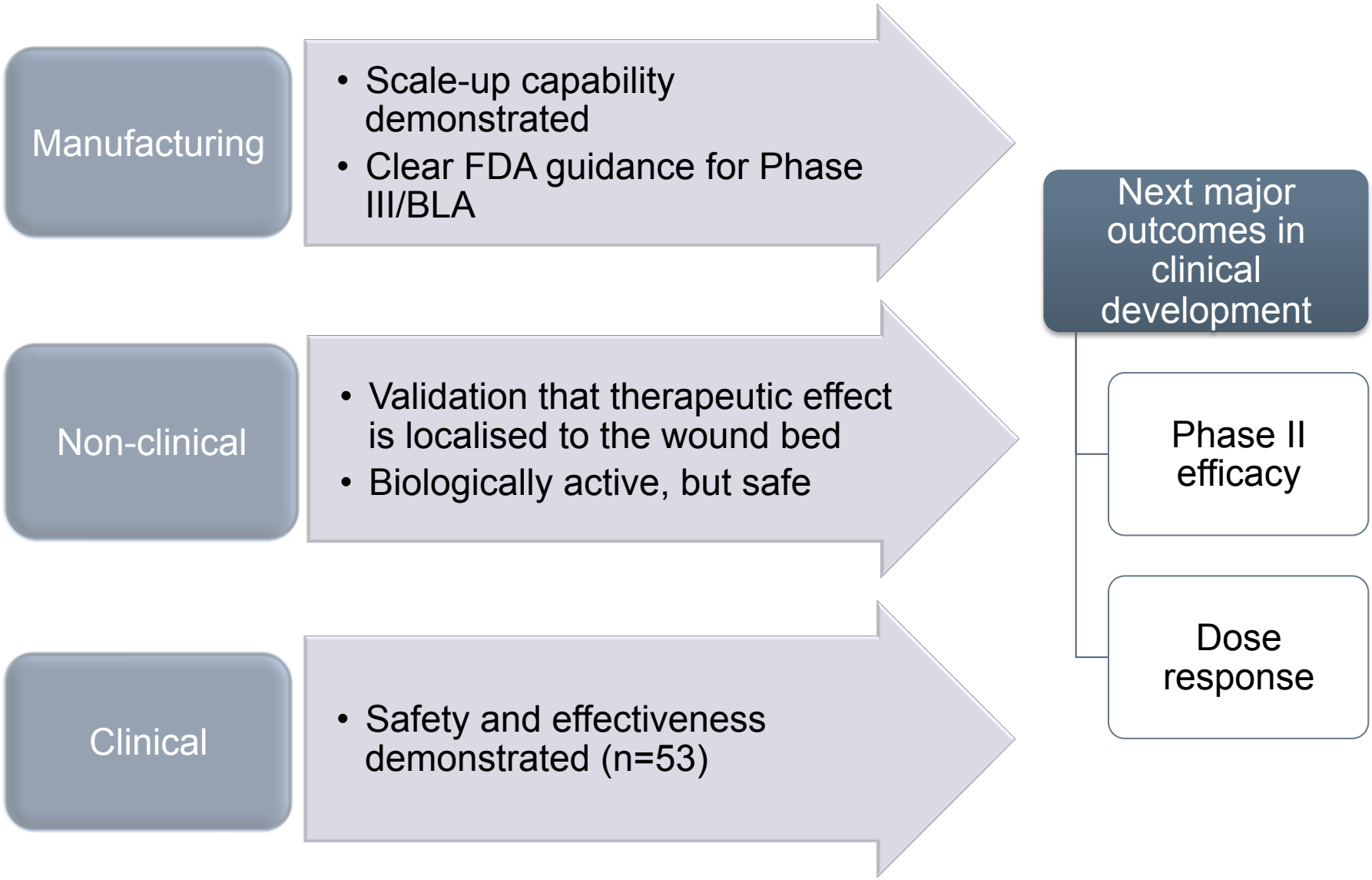
$p = 0.025$

Group	Mean days to healing [95% Confidence Interval]
VitroGro® ECM plus SC forecasted	198.9 [152.9 - 244.9]
SC (weekly visits to clinic)	249.9 [207.3 – 292.4]

Demonstrably faster healing trajectory with VF-001

** Formerly communicated as VitroGro®*

Lead Program: VF-001* Development Status



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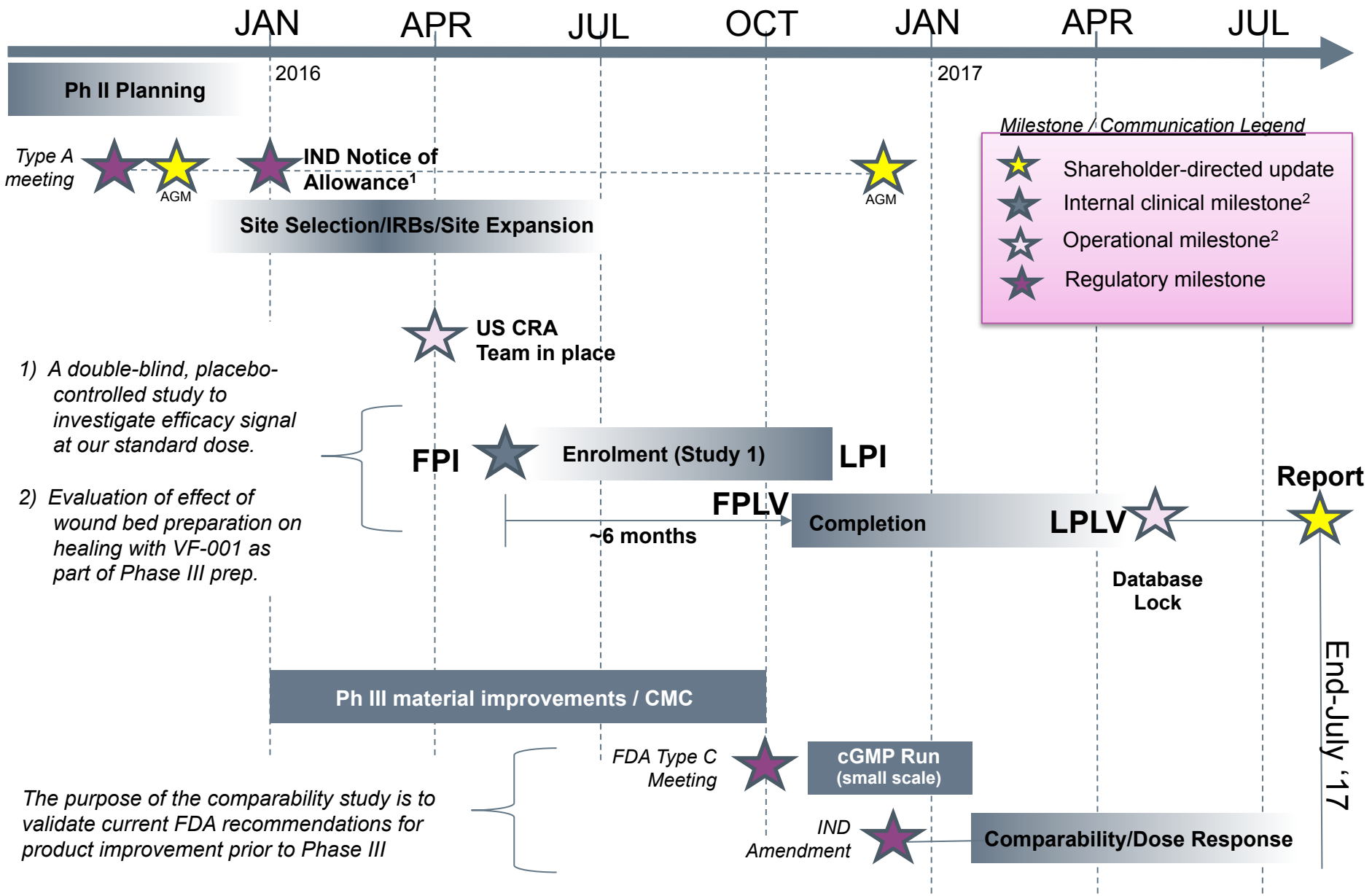
High-Level Clinical Plan (Lead Program)



[1]Based on management's estimate only, [2]May or may not be reported, FPI = "first patient in", LPI = "last patient in", FPLV = "first patient, last visit", LPLV = "last patient, last visit"

Strategy change targets greater value

Pharmaceutical route offers advantages

The wound care market continues to experience an unmet need for improved efficacy and cost effectiveness

Future path managed with clear guidance

- Size
- Homogeneity

Establishment of reimbursement in premarket phase

Pharmacy access versus primary care

TISSUE THERAPIES

What Next?

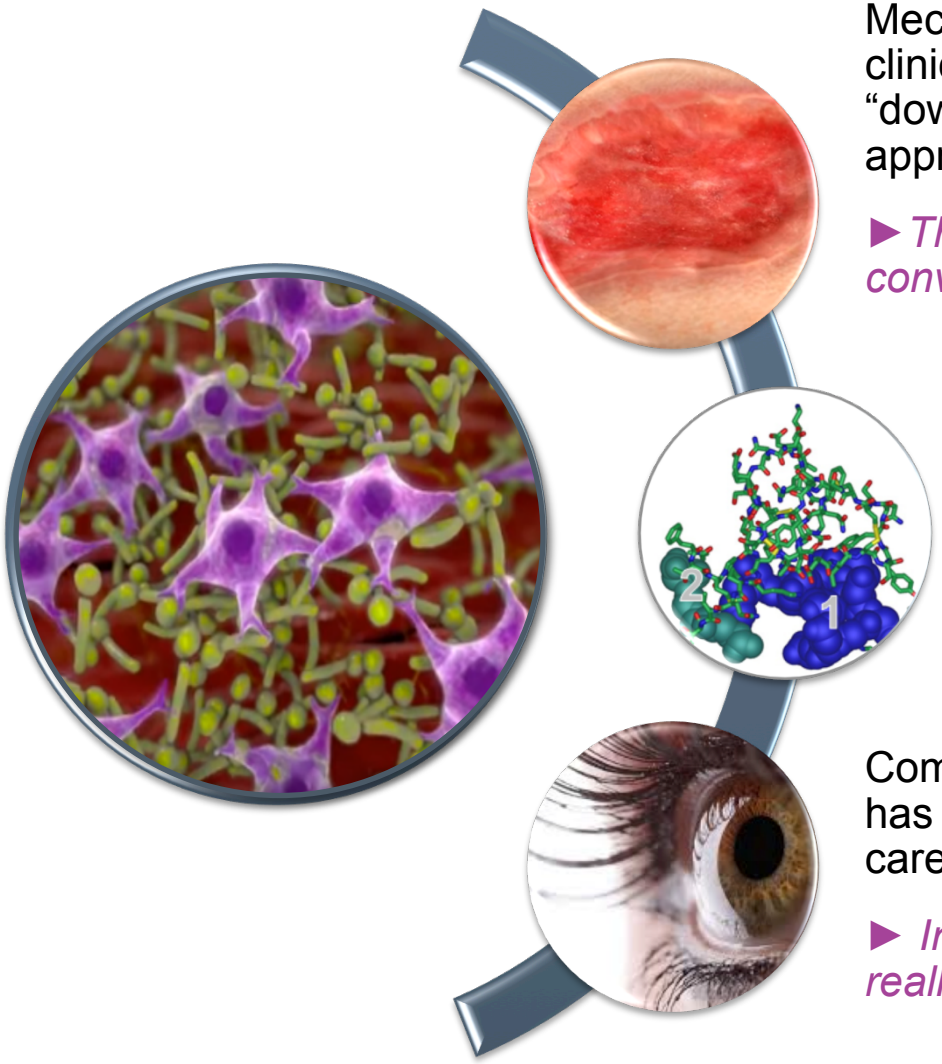
Christian P. Behrenbruch
Executive Director

25th November 2015

Major Challenges – and Major Opportunities

Challenge	Opportunity
Device route not proven to be feasible for the company.	Pharmaceutical route enables much larger market opportunity / superior price point.
Clinical development rolled-back to Phase II.	Company will have necessary efficacy signals to engage partners in a higher-value way.
Transition from EMA to an FDA-focused process.	A larger, more homogeneous market opportunity for the company.
Additional manufacturing requirements to prepare for Phase III.	Existing scale-up experience can be largely “re-used”, better product control = lower COGS, stability, etc.

Powerful Technology : Historically Under-Articulated



Mechanism of action is well understood and clinically validated yet was historically "downplayed" due to decision to pursue device approval route.

► *This considerably limited sophisticated conversations with potential partners.*

Company's technology platform consists of multiple potent constructs with robust international IP protection.

► *We see the potential for a pipeline of relevant wound care products with distinct and commercially significant application areas.*

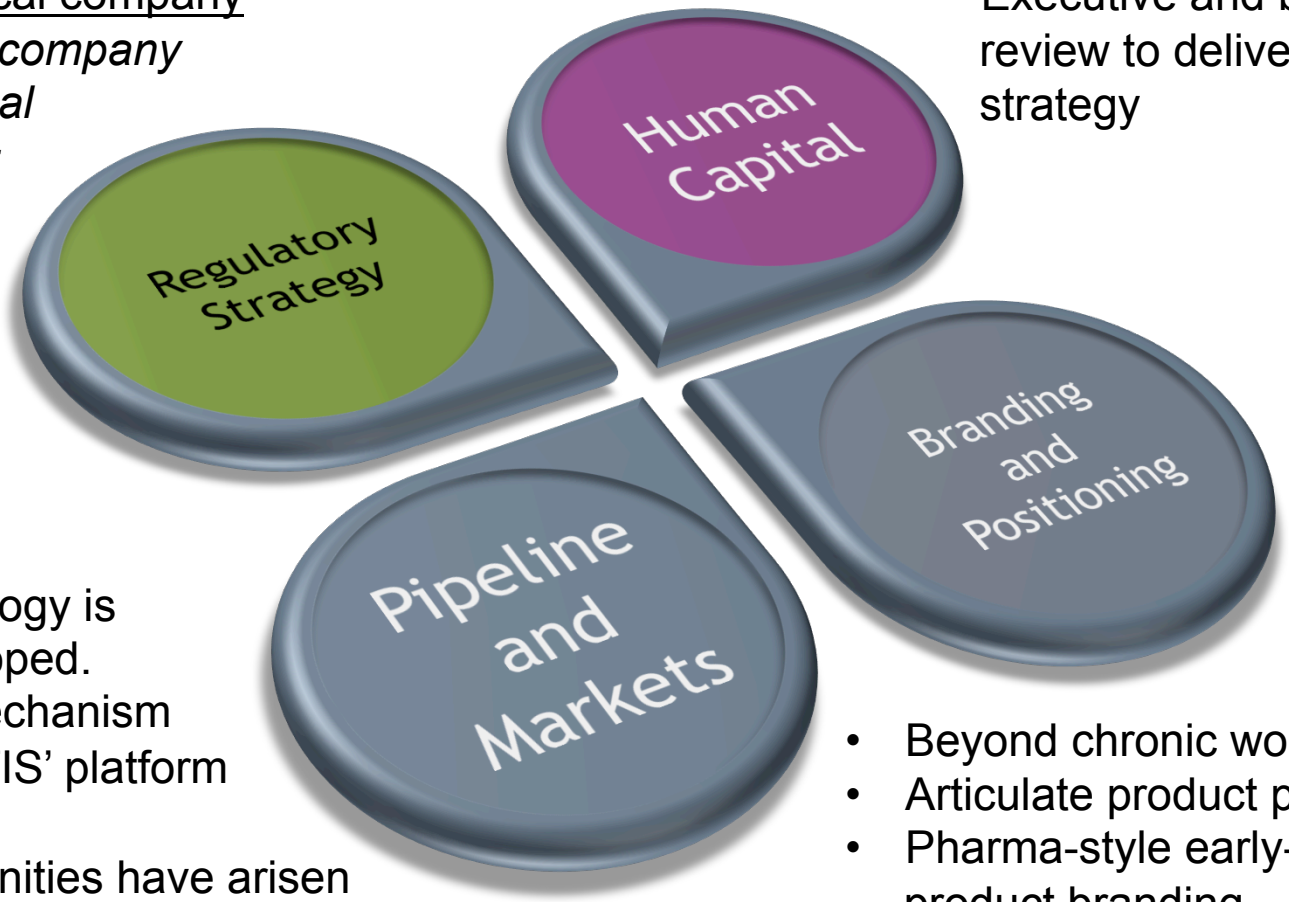
Company's fundamental wound care technology has broad application beyond chronic wound care.

► *Including significant new markets that are only really starting to take shape*

Transformation Strategy : Four Parts

- US/FDA-centric strategy
- Product development as a <u>pharmaceutical company</u> *not a device company*
- *Robust clinical development*

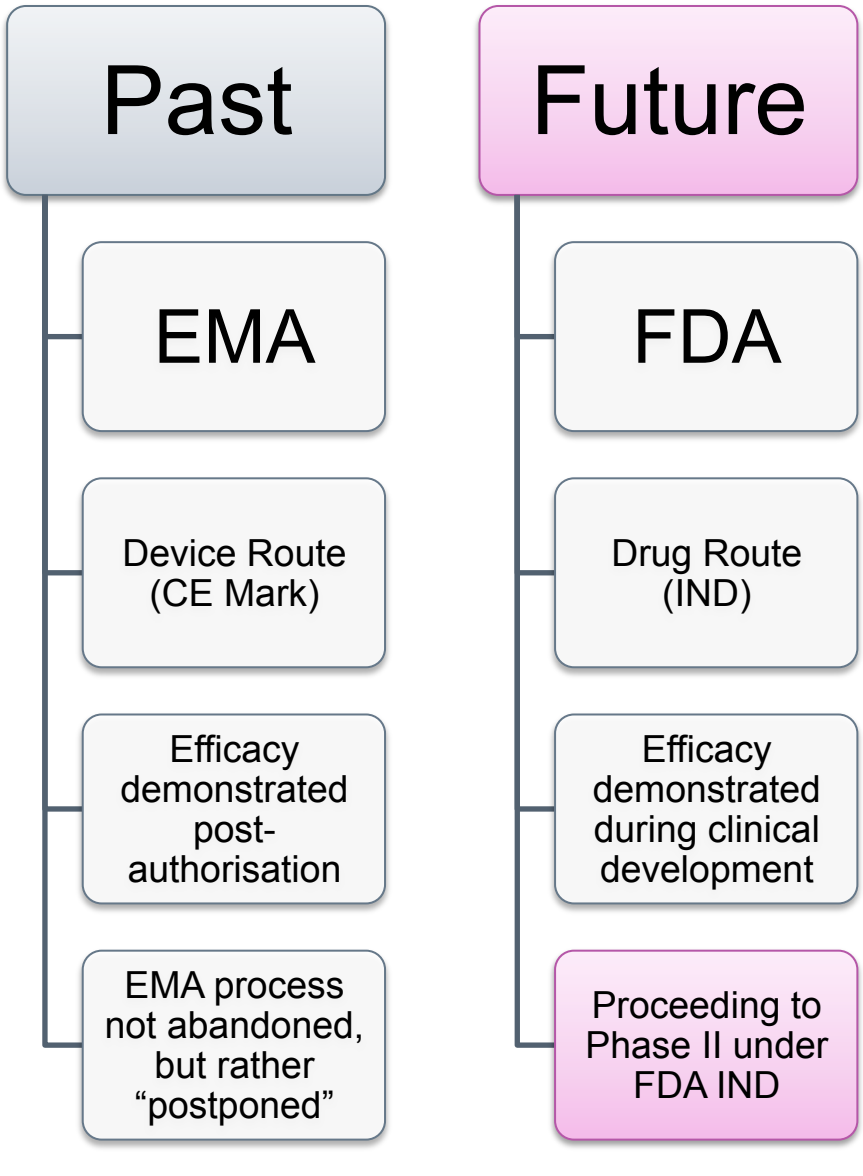
- US clinical and executive recruitment a priority
- Executive and board skills review to deliver our new strategy



- Core technology is under-developed.
- Focus on mechanism of action of TIS' platform technology
- New opportunities have arisen that have significant valuation impact

- Beyond chronic wound care
- Articulate product potency
- Pharma-style early-stage product branding
- Overhaul of company brand
- Improving communication

Regulatory Game Plan

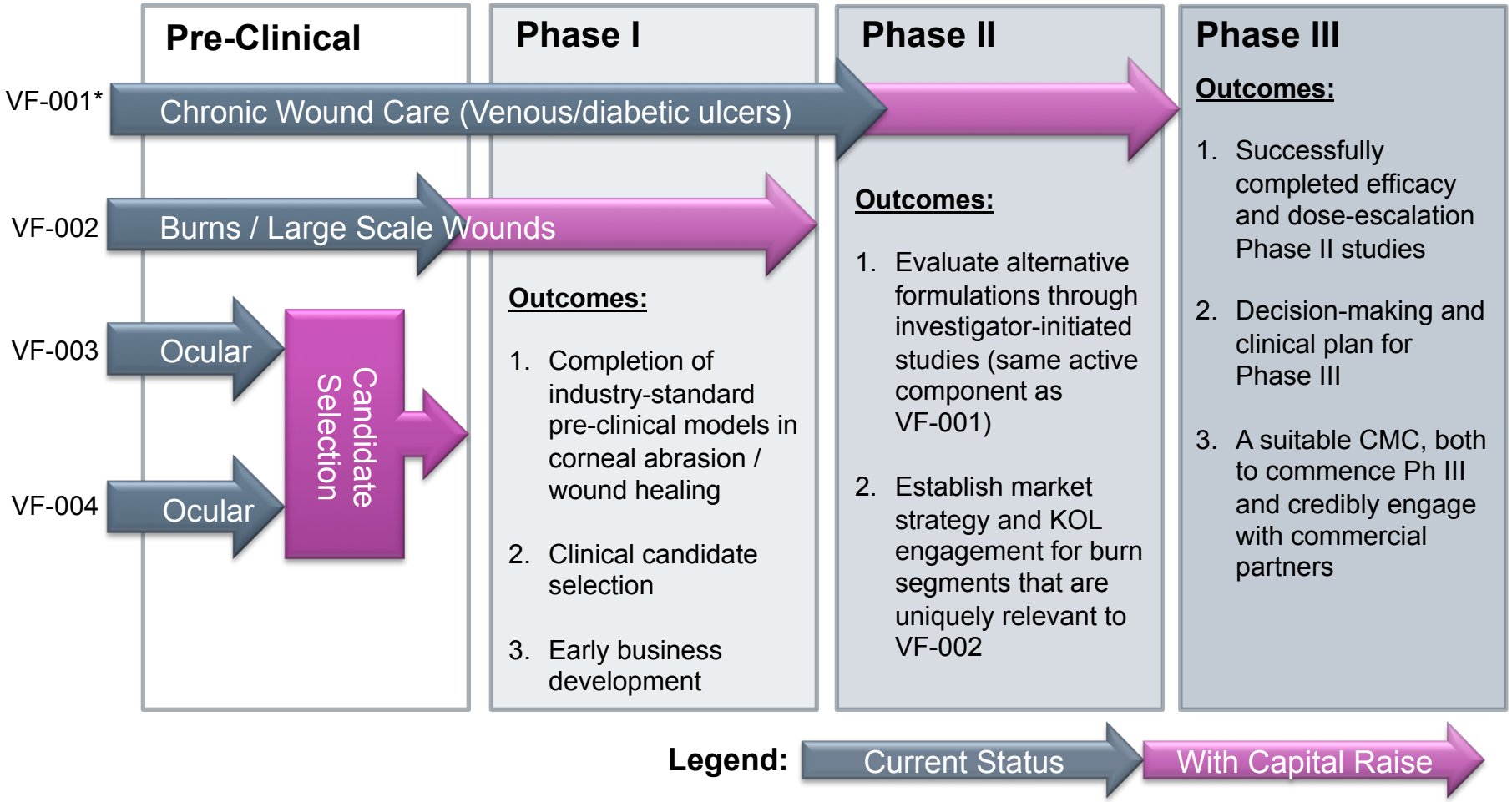


Significant team effort to transition from device to IND pathway.

- ✓ Sophisticated and detailed gap analysis in collaboration with a top-tier CRO.
- ✓ Manufacturing / product characterisation taken to a superior level.
- ✓ Effective re-engagement with the FDA (Type A meeting), with planned ongoing engagement.
- ✓ Clinical plan well-defined for a multi-centre Phase II US clinical trial that will pave the way to Phase III.
- • ***Clear guidance from the FDA on characterisation requirements for Phase III.***

Pipeline Management : Next 18 Months

- 90% of investment will focus on the lead program (VF-001*).
- Strategic re-evaluation of the key application areas of our technology.
- We plan to cost-effectively explore larger-area wounds / burns through investigator-initiated studies with a more viscous/barrier-oriented formulation (instead of irrigation, appropriate for chronic ulcers).
- Accomplish clinical candidate selection for an ocular wound care product targeted at post-surgical healing.



** Formerly communicated as VitroGro®, KOL = Key Opinion Leader*

Business Development

Lead Program (VF-001):

- Have already re-engaged with major wound-care players
  - Goal : to provide a progress update
  - Eliminate perceptions of “stasis”, introduce new leadership
- New regulatory strategy means that the optimal time for partnership discussions are at the end of Phase II

Ocular Program (VF-003/4):

- Already interest
- Major unmet clinical need and an well-identified market opportunity by the major ophthalmology players. Very low level of competition.

Significant business development opportunities exist for our pipeline but excellent clinical data at the end of Phase II will maximise the company’s value in partnership discussions.

Capital Requirements & Use of Proceeds

AUD $15m, three main investment areas:

1. Multi-centre Phase II study : **$6.5 - $7m.**
   - Larger number of sites for rapid recruitment (typically 1.2 patients / month / site).
   - US-centric, readiness / site qualification for Phase III a key consideration.

2. Manufacturing / CMC : **$3m.**
   - Further develop bioprocess to meet needs of Phase III and beyond as a pharmaceutical. Includes comparability studies.
   - Will not include Phase III manufacturing scale-up.

3. Indication / pipeline expansion : **$1.2m.**
   - Further develop core technology into new indication areas, future value capture.

✓ + Basic working capital – keeping basic burn as low as possible.

✓ Effective CMO/CRO usage to keep costs / team size down.

✓ Target runway of 18-24 months.