Navigating Requirements Ambiguity and Volatility
One Step at a Time
-or-
Why Culture Matters
Culture is the base on which success is built.
Orpyx delivers wearable medical and health tools that quantify biometrics and provide decision support to optimize health outcomes.
The Problem
Epidemic of Diabetes & Diabetic Foot Care

Over 30% or

1 in 3 North Americans
136 million people are diabetic or pre-diabetic.

Diabetic Peripheral Neuropathy

- 1M ulcers per year in the US
- 25% of people with diabetes develop ulcers during their lifetime.
- 120,000 lower extremity amputations / year
- Leading cause of hospitalization related to diabetes.
Foot ulcers requiring acute care can result in treatment costs of up to **US$70,000 per event**, varying with the severity of the wound.

*Journal - Advanced Skin Wound Care 14: 297-301*
A Priority Solution
Management of Diabetic Foot Ulcers

SurroSense Rx® (V1)

- Designed to work in standard running or walking shoes. Sized to fit full complement of shoe sizes.
- Replaces plantar protective sensation.
- Flexible. <0.7mm thin.
- Patient portal collects and interprets uploaded plantar pressure data.
- Plantar pressure and foot movement measured in real-time via sensors.
- Alerts and feedback provided via mobile app or smartwatch.

International patent coverage
Registered medical device with FDA, Health Canada
First peripheral neuropathy compliance monitor
A Digital Health Solution

Orpyx → Actionable Data → Reduced Ulceration

IMPACT: Reduction in ulceration

Pre-Clinical Studies
- Extensive third party external validation of sensor performance against gold-standard lab instruments.

Pilot & Case Studies
- Demonstrated 83% relative risk reduction in callus and ulcer formation in high-risk patients
- Economics studies showed 70% cost savings
- Case studies examine SSRx’s utility in non-diabetic neuropathy

Multi-Site RCT
- 3-year multi-site RCT (UK-based)
- Preparation of multiple publications underway
Timeline – Key Events

1st Employee
Travis Joins
Orpyx B-Day
RCT Start
LogR™
RCT End
You are here

- Trial End
Key Challenges

- First Mover – No predicate device
- Preventative – System is treatment based
- Evidence Based Medicine
- Regulatory & Reimbursement Hurdles
Navigating Uncertainty

- Accept it - you’re wrong about everything.
- Be system – not goal oriented
- Measure what matters
- Get the right people at the right time
- Build and evolve the culture
Process

- Accept it - you’re wrong about everything.
  - Identify and validate assumptions ASAP and continuously.

- MVP - Minimum Viable Process
  - What are you process/business requirements?
  - Constantly evaluate and evolve
  - Beware the downside risks
  - Must fit people and culture

- Process matters when the stakes are high.
Example – Orpyx Product Dev

- **SCRUM Like Process**
  - System oriented
  - Cross-functional
  - Weekly Iterations - Low Churn, Effective, Transparent
  - Integrated into our QMS System

- Focus on rapid/cost effective prototyping

- Built for uncertainty
“Quantitative” Methodology For Evaluating IP

IP are scored across 6 categories by a group.

IP is ranked and prioritized based on score.

Process is repeated for new and old items regularly.

Outcomes are fed back into the process.

FEELS QUANTITATIVE
Effectiveness should be gauged by “quantitative” measures.

Are we measuring the right things?

Orpyx example – Iron Triangle

Other example – Quality Example

Problem:

How do we account for long term objectives?
Process Conclusions

- You are probably wrong – your process should help with this.
- Process matters when the stakes are high.
- Never stop evolving your process – feedback loops and incrementalism are great.
- Process and metrics should long and short term focused.
The People

- People Over Process
  - Agile Manifesto
  - Toyota
- People can make all the difference
  - Jimmy Garoppolo, Steve Jobs
- Culture and People are linked.
  - Every person is a culture microcosm.
  - Vibe Tribe
The People

- Get the right people at the right time
  - The Alliance – Reid Hoffman
  - Cultural fit is critical
- People are “Predictably Irrational”
  - Behavioral Economics
  - This should/does affect your requirements
  - Know thy bias
- The Orpyx Example
The People Conclusions

- Build systems to optimize for your people
- Never underestimate the power of the individual
- Cultural fit is critical
- Beware of your bias
The Importance of Culture

“Culture Eats Strategy for …”
Culture is your organizations guiding light.
Values matter – but you have to live them.
Employees shape the Culture and Vice Versa
Culture can be explicit or implicit
– Example - Orpyx is “Sciencey”
Culture affects everything
1\textsuperscript{st} Law - A culture in motion tends to stay in motion acted upon by an unbalanced force (Inertia).

2\textsuperscript{nd} – Culture equals people multiplied by time.

3\textsuperscript{rd} – For every action there is likely an opposite over reaction.
Culture and Requirements

- Requirements and Values Alignment/Misalignment
- Fossilized Requirements – “We’ve always done …”
- Requirements gathering and validation.
- Requirements and prioritization.
Conclusion

- Culture Eats Everything.
  - Be aware of this.

- People, Culture and Process are interdependent and reinforcing
  - Understanding is critical to exploiting it.

- Be explicit about your culture
  - Live your values

- Accept it - you’re now a little less wrong about everything.
  - Identify and validate assumptions ASAP
THANK YOU

For more information, please contact:

Dr. Breanne Everett, CEO
Orpyx Medical Technologies Inc.

+1 403 460 0216
breanne@orpyx.com