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# BioMelbourne Network
# Devices + Diagnostics Lab

## Lessons Learned About Commercial Partnerships

*Mr. Rick Legleiter – Chief Executive Officer*

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# My Background

***Sales and Service General Management***

- ***16 years in Healthcare***
- ***Senior management roles in Sales and Customer Service***
- ***Lived and worked in U.S.A., Germany and now Australia***
- ***Global experience across Asia, Europe and the U.S.***
- ***Experience in start-up, small-cap, mid-cap to Fortune Global 100 companies***
- ***Education***
  - *B.S. Mathematics, Kansas State University*
  - *B.S. Nuclear Engineering, Kansas State University*
  - *M.B.A., Harvard Business School*



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# UBI Rowville Corporate Headquarters

*Research Laboratories, Engineering, Manufacturing and Administration*

## Administration

## Manufacturing

## Research Laboratories, Engineering

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# Novel Electrochemical Cell Technology

*High Performance, Low Cost, Platform Technology*

| Conventional Strip Technology - Coplanar electrode system | UBI Strip Technology - Opposing Electrode System |
|---|---|
| | |

| Key Features of Coplanar Electrode | Key Features of Opposing Electrode |
|---|---|
| - *Complicated electrode structure* | - *Simple electrode structure* |
| - *Requires a larger blood sample* | - *Requires only a small blood sample* |
| - *Challenge to eliminate interferences* | - *Lower interferences* |
| - *Labour intensive batch manufacturing* | - *Automated continuous manufacturing* |



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# Case Study #1
# LifeScan, a Johnson & Johnson Company
# UBI Breakthrough Idea

***Early Days***

- ***Opposing electrochemical cell technology application***
- ***Breakthrough idea to marry the technology with blood glucose testing as a superior alternative to optical sensors and existing co-planar electrochemical technology***
- ***Identified LifeScan as preferred partner: relationship, technology, and market knowhow***
- ***Bootstrap feasibility project in San Diego***
- ***Founders raised funds:***
  - *Solve the manufacturing challenge*
  - *Carry technical development risk*
  - *Pursue regulator approval*
  - *Partner formation*

**LifeScan - OneTouch® Verio®**

LIFESCAN
a Johnson & Johnson company

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# Case Study #1
# LifeScan, a Johnson & Johnson Company
# UBI Breakthrough Idea

***Early Days***

- *J&J purchased Medisense diabetes business from Inverness Medical Technology in 2001 for their co-planar plane electrochemical technology*
- *UBI incorporated in Delaware in 2001 and establishes Universal Biosensors Pty Ltd subsidiary in Australia*
- *LifeScan Business Development head becomes UBI's internal champion*
- *LifeScan Business Development funding creating the UBI "partner funded development" model*
- *UBI signs LifeScan development agreement in 2002 to develop new blood glucose test*
- *No room for failure!*



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# Case Study #1
# LifeScan, a Johnson & Johnson Company
# UBI Breakthrough Idea

***Early Days***

- ***Project on and off the back burner***
- ***LifeScan personnel changes except for Business Development***
  - *Group leadership*
  - *R&D*

**LifeScan - OneTouch® Verio®**

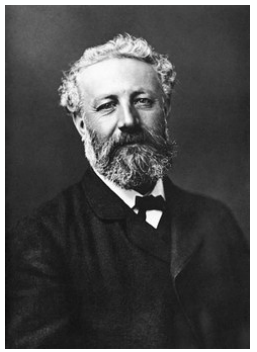
- ***2006 UBI ASX IPO and begins biosensor manufacturing in Rowville***
- ***2009 OneTouch® Verio®, receives initial regulatory clearance to sell in Europe***
- ***2011 OneTouch® Verio® receives U.S. Food and Drug Administration 510(k) clearance***
- ***Ten years from company founding to U.S. and Europe regulatory approval***
- ***LifeScan sells 1.7 billions strips globally in 2017***
- ***UBI $20.0 million revenue in 2017***

# Case Study #2
# Daverci Solutions
# Technology Application

***Right Drug, Right Time – Anywhere***

- *Founded 2001 at Intel's Internet Health Division*
- *Intel spin-out in 2003 with Rohan Coelho, founder and CEO*
- *Started with small, founder team of which I was a member*
- *Business model: medication supply chain automation between pharmacies and long-term care facilities*

**Daverci Solutions**



*Jules Verne*
*Creative vision*

*Leonardo da Vinci*
*Technical genius*

- *Value proposition: reduce costs; automate tedious, manual, paper processes e.g. fax orders; cut medication administration errors; report generation*
- *Target customer segment: pharmacy and Pharmacy Benefit Managers (PBMs)*
- *Target user: long-term care facilities as small as 20 beds*
- *Designed TOCCARE' eMAR: electronic Medication Administration Record*

# Case Study #2
# Daverci Solutions
# Technology Application

***Right Drug, Right Time – Anywhere***

- *U.S. PBMs consolidation until today three major players: Express Scripts, CVS Health, and United Health/OptumRx/Catamaran*
- *Landing the whale*
- *Find your customer at church*
- *Angel funding*
- *Les Fahey, Chairman*
- *2007 Marc Cameron named CEO and Rohan Coelho continues as EVP*
- *March 2007 employed 30 staff; eMAR used by over 1,000 caregivers at 50 long-term care facilities in eight states; and processing 1.5 million medications administrations per month*
- *Thru June 2007 raised US$5.5 million with Series A, A2, A3 and late stage rounds*
- *PolyCare acquires Daverci in 2009 for an undisclosed price*
- *Six years to exit*

# Case Study #3
# Siemens Healthineers Point of Care
# Opening a New Market Segment

***Coagulation Testing***

- *UBI identified market opportunity for coagulation testing*
- *Initiated internal development for PT/INR (prothrombin time/international normalized ratio) coagulation test*
- *2011 Johnson & Johnson relationship enabled us to license technology to other partners for coagulation market*
- *Approached global healthcare companies*

**Siemens Healthineers – PT/INR Coagulation Testing**

- *Telephone calls, emails and ultimately a meeting in Chicago with CEO for Siemens Point of Care*
- *Technical review, analyzer demonstration, and scientific data presentation*
- *Filled segment gap*



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# Case Study #3
# Siemens Healthineers Point of Care
# Opening a New Market Segment

***Coagulation Testing***

- ***2011 signed Siemens product development and commercialisation agreement***
- ***2014 CE Mark and Siemens launch of Xprecia Stride™ Coagulation Analyser in Europe***
- ***2016 Xprecia Stride™ receives U.S. FDA 510(k) Clearance***
- ***$4.1 million revenue in 2017***
- ***Five years from agreement to U.S. and Europe regulatory approval***

***Xprecia Stride™ Coagulation Analyser – Safety and Accuracy, Simplified***

Test strips use the same Dade® Innovin® reagent as Siemens laboratory analysers

The Xprecia Stride uses small samples of 6µL for easy testing

A test strip eject button reduces biohazard exposure



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# Lessons Learned About Commercial Partnerships Avoid Small Thinking Trap

*Flying Solo is the Best – Are You Sure?*

- *Why add more risk with partners*
- *I have sole authority for decision making*
- *We are more creative and innovative alone*
- *We only have internal accountability*
- *"Corporation" is a dirty word*
- *Sell-out*
- *Sell your soul*
- *Give up your freedom and autonomy*
- *Lose your identify*
- *Giant wants to buy-in and exert control*
- *If you dance with elephants you'll be crushed*
- *Just pay me money and leave me alone*

**Avoid Small Thinking Trap**

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# But Think About It…

***Balance the Risks and Benefits***

- *You MUST have company plan for strategic relationships*
- *Envision the future*
- *Understand what do you want: what are your needs and strengths*
- *Understand what your partner wants: opposite or complementary to you*
- *Be careful of being seduced*
- *Study Principal-Agent Theory… you will need it*
- *Study Game Theory… you will need it*
- *Study Negotiation Theory… you will need it*
- *Partners MUST be in your strategy wheelhouse*

**Balance the Risks and Benefits**

# What Do You Need?

***Define Your Benefit Objectives Upfront***

- *Capital*
- *R&D risk managed with partner funded development*
- *Access to foreign markets*
- *International trade: import/export expertise*
- *Supply chain processes*
- *Large distribution system*
- *Sales and marketing expertise*
- *Service network*
- *Purchasing power to lower costs*
- *Market credibility*
- *Research and development knowhow and resources*
- *Project management*
- *HR knowhow and staff sourcing network*
- *Healthcare*
  - *Regulatory experience*
  - *Clinical trial experience*

**What Do You Need?**

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# Benefits

***Assess Your Partner Before Engaging in Courtship***

- ***Cash flow***
  - *Partner funded development*
  - *Internal partner VC*
  - *Internal partner capital fund*
- ***Increase revenue***
- ***Faster market penetration***
- ***Established customer base: customers want to buy from a company with a track record, well financed, staying power and quality***
- ***Intangibles***
  - *Survival of your business*
  - *Visibility for your products*
  - *Growth ramp-up*
  - *Validity and credibility in the marketplace*
  - *Cost to build a brand*

# Risks

***Construct a Survivability Plan***

- *Expect reorganizations and turnover of management and contacts – build a network within the partner organization and avoid single threading*
- *Company politics*
- *Decision making: more players, more reviews, more approvals, more stakeholders*
- *Small revenue is irrelevant in their P&L*
- *IP and trade secret rights*
- *Timelines*
- *Structured plans and execution burden*
- *Hire someone with experience in both large corporations and small companies to understand inner workings and manage the partnership*

# Understand Partner Expectations

***This is THE Time to Bring your "A" Game***

- *You are not a partner of equals*
- *Your financial stability is a qualification criteria*
- *Your organization stability is a qualification criteria*
- *Your capacity to scale and deliver the big order*
- *Entrepreneurial vs. professional management style*

**Balance the Risks and Benefits**

- *Professional slides: dress up your documents to your partner's level*
- *Professional financial models: spreadsheets*
- *Professional processes, documents and certifications e.g. ISO*
- *You must adapt to the partner – e.g. Sustainability in the Supply Chain*

# Partner Check List

***Avoid Desperation – Rigorously Evaluate Decision***

- ***Do not over value the channel…"we have hundreds of feet on the street that will sell your product"***
  - *What is the channel structure?*
  - *How do you gain sales team's attention and "share of mind"*
  - *Is the Sales force selling many products?*
  - *How is sales compensated?*
  - *What are the sales incentives?*
  - *What is the average selling price of your product vs others in the product line?*
  - *Who does sales training?*
  - *What is the marketing and advertising plan?*
- ***Internal champion***
- ***Understand the partner's culture***
- ***Reference check their other partnerships***
- ***Slow pay warning – billing and invoice payments***

# Avoid Contract Hell

***Own the Agreement***

- *Difficult to predict outcomes and develop contingencies*
- *Protracted negotiations*
- *Company speed limit - slow, slow, slow*
- *Endless provisions*
- *Legal chain of command*
- *New players = new demands*
- *No response/slow response*
- *Low priority*
- *Decision making lacking*
- *On whose terms*
- *Design an "out" clause*

**Avoid Contract Hell**

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# In Conclusion

***Your Value Proposition is Your Life Blood***

- ***Keep promises and commitments***
- ***Keep the spark alive***
- ***Keep your creative edge***
- ***Keep innovating***
- ***Keep flexible***

**Your Value Proposition is Your Life Blood**

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## Lessons Learned About Commercial Partnerships

*Devices + Diagnostics Lab*

# Thank you BioMelbourne Network!



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