

# PCIERD Anniversary June 2014

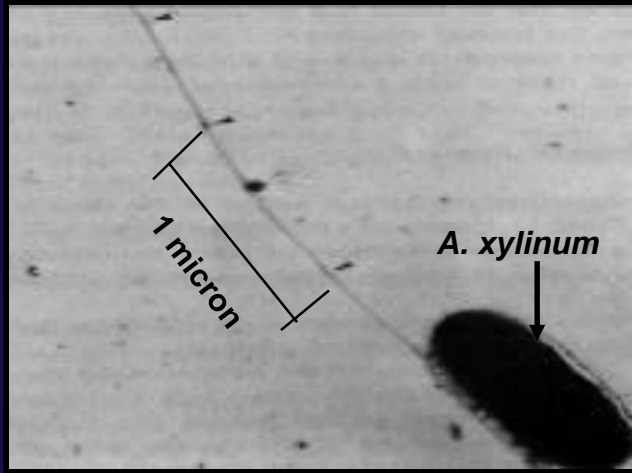
## How to Start, Grow and Sell a Biotech/Medical Device Company in United States :The Xylos Story

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# ***Presentation Outline***

- **Pre Start-up (1993-1996)**
- **Starting the company (1996-1998)**
- **First Product Launch (2000-2003)**
- **Growing the company (2003- 2012)**
- **Selling the company (2007-2012)**

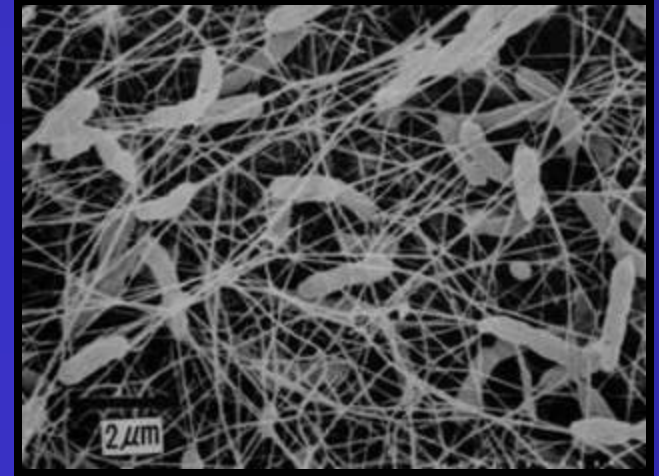
# Bacterial Nanocellulose



Cellulose Fiber  
(1-10 nanometers width)



Active Culture



Top View

***Acetobacter  
xylinum***



Full Pellicle

***Biocellulose***

# *How I got involved with BC?*

- **Nata de Coco boom of 1993 in the Philippines**
- **Focused on biopolymer production optimization**
- **Completing PhD in Chemical Eng'g in RPI**
- **Filed 1<sup>st</sup> Patent in 1995 in U.S. granted in 1999**

# *How Xylos got started?*

- **Met an RPI Alumni business partner at university enterprise forum in 1995**
- **Founded Xylos in August 1996**
- **Received NIH SBIR grant for bacterial cellulose wound dressing in 1997**
- **Received first FDA clearance in 1998**

# *Initial Technical Challenges*

- **Shift from research to product development**
- **Expand knowledge of potential applications**
- **Identify the first product and its advantages**
- **Complete regulatory requirements**
- **Develop clinical experience to help marketing**

# *Enterprise Challenges*

- **Recruiting early stakeholders- RPI**
- **Raising the first venture financing**
- **Completing management team**
- **Identifying path to market**
  - **marketing partner and clinical support**

# ***Key Milestones of 1st VC Funding***

- 1. Finish Wound Dressing development**
- 2. Biocompatibility testing *completed***
- 3. FDA application filed/cleared**
- 4. Successful animal testing and Clinical**
- 5. IP position testing expanded**



# *First Product Launch 2003*

- **5 year to launch and 3 partnerships**
- **Scaled up Manufacturing and CE mark**
- **Expanded multi-center clinical testing**
- **Second FDA product : antimicrobial dressing**

# *Scientist's Changing Roles*

- **Technology Pitch**
- **Competitive advantage**
- **Regulatory Clearance**
- **Pre-clinical and Clinical testing**  
**focus on best application**
- **Providing marketing support**

# ***First Implantable Product 2003***

- **Focus on permanent implant**
- **Completed prototype and safety testing**
- **Animal effectiveness testing**
- **Search for product Champion**
- **1<sup>st</sup> CRADA with a corporate partner**

# ***Expand Implantable Applications***

- **More human body locations (2006-2012)**
- **High-strength tissue reinforcement**
- **Soft tissue adhesion prevention**
- **Vessel Guard applications**
- **Complete regulatory requirements bioresorbable**
- **Develop clinical experience to help marketing**

# *At the end of 16 year adventure*

- **Five distinct product groups**
- **7 FDA products cleared/ 2 CE approved**
- **FDA Registered - ISO Facility**
- **Received 10 U.S granted patents and 20 IP**
- **Sold Topical and Implantable to partners**

# *On Selling the company*

- **Expanding Technology/Clinical Use**
- **Proven Regulatory Pathway**
- **Worldwide Intellectual Property**
- **High Market potential**
- **Easy Manufacturing Scale up**
- **Reduce the RISKS!**

# *Method of Analysis: TRIM<sup>3</sup>*

- **Technology focus/advantage**
- **Regulatory Pathway**
- **Intellectual Property**
- **Market potential**
- **Manufacturing Scale up**
- **Money – is it worth doing it?**

**ROI (Return on Investment)!!!**

# *Some Lessons Learned*

- **Dare to dream**
- **One cannot have too many friends**
- **You cannot do it all**
- **Control is an elusion**
- **Failure is not option**



# *Acknowledgements*

- **Xylos employees**
- **Venture Capital Groups**
- **Product Champions- Doctors/Nurses**
- **Marketing partners- Corporate**
- **Early supporters, NIH-SBIR and RPI**

*Thank You!!*

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