



IME Medical Electrospinning **International Business Development in the Medtech & Pharma industry**

Judith Heikoop
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IME Medical Electrospinning



IME is provider of fiber-based medical devices – a revolution in the industry

- Nanofibers are >100 times smaller than a hair
- Nanofibers come in many shapes and forms
- Nanofibers mimic the extracellular matrix and can be used to generate innovative solutions for medical devices and drug delivery

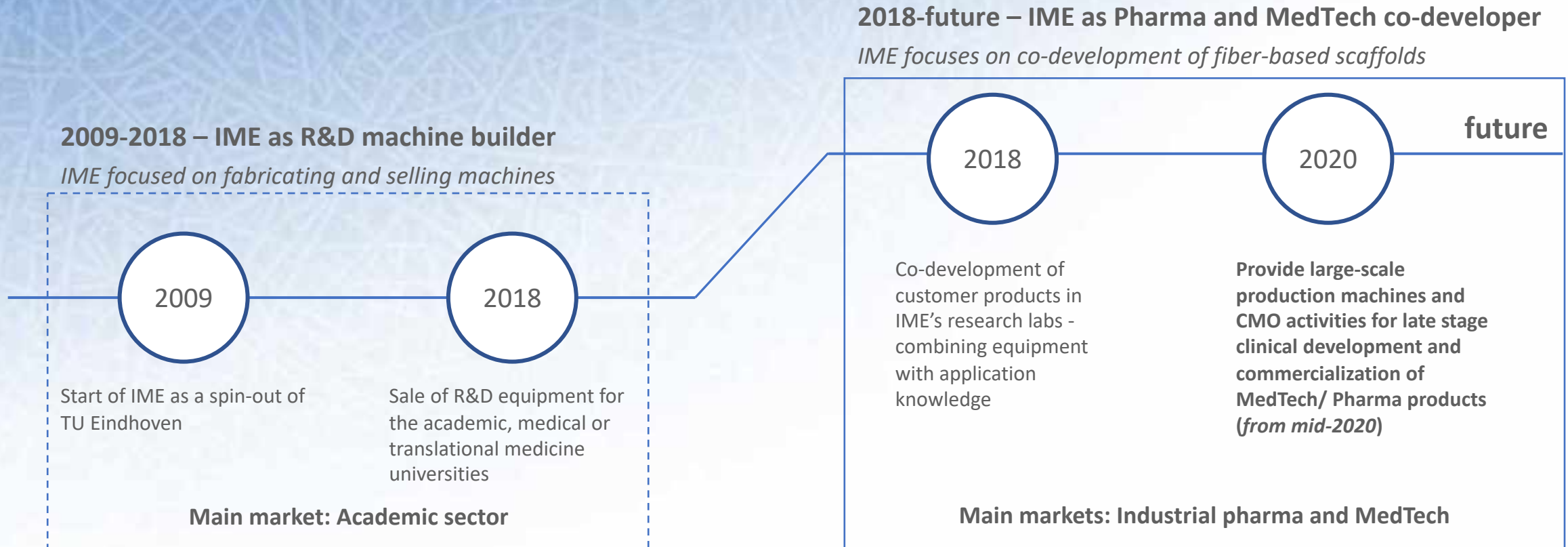


Medical devices are currently causing significant problems

- Nano- & microfibers provide natural scaffolds for living cells:
 - No rejection
 - No scar tissue
 - No pain



IME is the leading technology provider for fiber-based scaffolds



IME has developed the MediSpin[®], the platform for industrial Medical Electrospinning



- **Industrial platform for fiber-based scaffolds**
- **Wide variety of Pharma and MedTech applications**

Key characteristics and benefits:

- ✓ **Rigorous control** of all the crucial parameters of the electrospinning process
- ✓ **Ultimate automation** to eliminate operator influence and optimize efficiency
- ✓ **Process data capture** to provide detailed manufacturing data for traceability of individual products
- ✓ **Reproducibility** of the fibers that are required for registration/market admission of a medical device/ pharma product
- ✓ **Scalability** to large scale production with the MediSpin[®] platform

IME's Medical Electrospinning is the most promising technology for fiber-based scaffolds worldwide

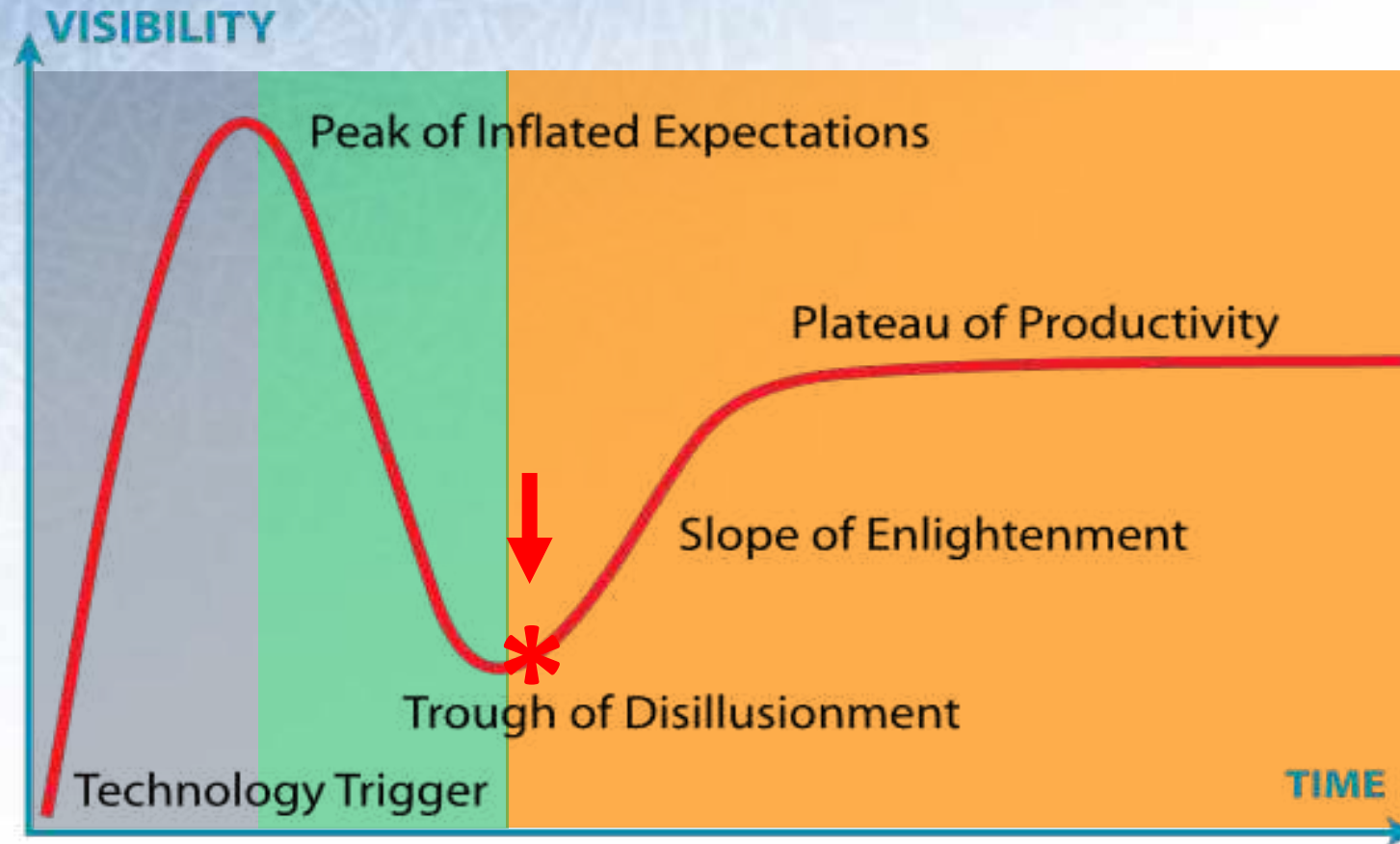
- IME is recognized as one of the key players in the fiber-based scaffold industry (Garcia et al, J. Biomed Mater Res. 2019) and the **only equipment provider** in this list
- Alternative technologies for fiber-based scaffolds are lagging-behind many years; it is questionable if they ever will make it to industrial scale production machines



The market for Medical Electrosinning

Electrospinning went through the Gartner hype cycle due to a lack of quality and scalability of fiber-based scaffolds

- Reproducibility issues
- No/ inferior tissue formation
- Limited scalability of the process



Electrospun products are groundbreaking solutions for patient needs

Xeltis heart valve



International Conference of Tissue-Engineered Heart Valves



Xeltis trials show promising function of living heart valves restored in children

February 14th, 2020 | [Latest News](#)

[FOR MORE ON THE DATA, PLEASE CLICK HERE](#)

CEO ANNOUNCED CONTINUATION OF THE CLINICAL TRIAL PROGRAM FOR THE PULMONARY VALVE IN EU, ASIA AND USA

Clinical trial results of Xeltis pulmonary valve (PV) show promising functionality of the living valves developed in patients as a result of its restorative implants. The recent trial data have been presented today at the International Conference of Tissue-Engineered Heart Valves (ICTEHV) as part of the 2020 Heart Valve Society scientific meeting. The data showed promising outcomes of Xeltis pulmonary valve at one-year follow-up in six U.S. pediatric patients and two-year follow-up in 12 pediatric patients enrolled in EU and Asian trial sites.

IME is co-writing the NIST standards for fiber-based scaffolds

Characterization of Fiber-Based Scaffolds

Project Partners: ASTM International, BioFabUSA, the National Institute of Standards and Technology (NIST), and The SCB Tissue Engineering Sector Working Group

Fiber-based scaffolds have the potential to more closely mimic the properties of a functional tissue than a scaffold with a regular repeating pattern. As a result, they are being used and considered for a wide variety of tissue engineering applications. To ensure their quality and safety, the regenerative medicine community would benefit from establishing standards for measuring the structural, mechanical, and biological properties of fiber-based scaffolds. ASTM held a May 2013 workshop on standards and measurements for tissue engineering scaffolds to identify the needed standards in this area, including specific needs for standardizing characterization of fiber-based scaffolds.

To re-energize this 2013 scaffolds standards and measurement effort, SCB is coordinating a working group of 28 experts from industry, government, and academia to identify fiber-based scaffold standards gaps and develop an ASTM International standard focused on the characterization of fiber-based scaffolds.



A scientist wearing a blue lab coat, a blue surgical cap, and a light blue face mask is working in a laboratory. The scientist is wearing purple nitrile gloves and is focused on a piece of equipment inside a biosafety cabinet. The equipment has a white label with the text "GENERAL SYSTEM" and "Max 20-01". The background shows a clean, modern laboratory environment with blue accents.

International Business Development

IME helps its Pharma and MedTech customers to innovate

MedTech

- Novel treatments to reduce the total cost of care due to less complications & side-effects
- Products to provide an alternative to donor tissue, e.g. tendons, cornea etc.

Pharma

- Novel treatments or extensions of product life cycle based on existing API's

...for the benefit of patients with unmet needs

IME has entered into co-development deals with MedTech/ Pharma companies

- Several co-development deals have been signed in MedTech
 - ✓ VC backed advanced pioneer in the US
 - ✓ Top 5 MedTech company in the US
 - ✓ MedTech company in China
- First co-development deal has been signed in Pharma
 - ✓ VC backed advanced pioneer in the US

Business development will focus on creating an industrial market for Medical Electrospinning

- **Implement the MediSpin®** for launching customer(s) to get out of the Gartner hype-cycle
- Focus on strategic co-development alliance to **validate technology** with large Pharma/ large MedTech companies
- Source co-development projects based on mesh-like and tubular products in most promising markets to further **develop application expertise**

IME's proprietary technology is well protected through a three-fold IP protection strategy

1 Patents	2 Internal know-how	3 Contracts
<ul style="list-style-type: none"> ▪ Patent portfolio focusing on reproducibility, scalability and quality control of fiber-based scaffolds. ▪ Most patents are electrospinning equipment related and focused on protection of key aspects of IME's equipment. ▪ Co-development contracts with MedTech & Pharma partners facilitate further IP building. 	<ul style="list-style-type: none"> ▪ IME's equipment contains know-how based on IME's and knowledge in IME's supplier network ▪ Co-developments projects with MedTech & Pharma partners based on specific applications create a broad knowledge base applicable in a wide variety of products: <ul style="list-style-type: none"> – Polymer spinnability & application knowledge – Tooling & techniques for specific shapes & forms – Pre- and post-electrospinning techniques (e.g. material preparation, cutting, annealing) 	<ul style="list-style-type: none"> ▪ Co-development & production contracts with IME's MedTech & Pharma customers to protect IP ▪ NDA's & strategic collaboration contracts with IME suppliers and equipment development partners, e.g. BKB, NTS, GBO & PCT

New co-development projects are sourced by creating awareness

- Present on international conferences
- Publish articles in international media
- Communicate progress by press-releases



Thank you!