



**Innovative Start-up, Spin-off UniPi**

**Serena Giusti, co-founder**

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**[www.ivtech.it](http://www.ivtech.it)**



**Eng. T. Sbrana**

**PhD in Biomedical Engineering**

**Resercher at Research Center "E. Piaggio", University of Pisa**

**Expert on design, development and characterization of bioreactors. Involved in the technology transfer**



**Prof. A. Ahluwalia**

**Professor of Bioengineering**

**Director of the reserch group "MultiD in-vitro models group" at the Center "E. Piaggio", University of Pisa**



**Eng. G. Mattei**

**PhD student in Materials Chemistry**

**Expert on scaffolds, biocompatible materials for 3D cell cultures and optically transparent bioreactors**



**Eng. S. Giusti**

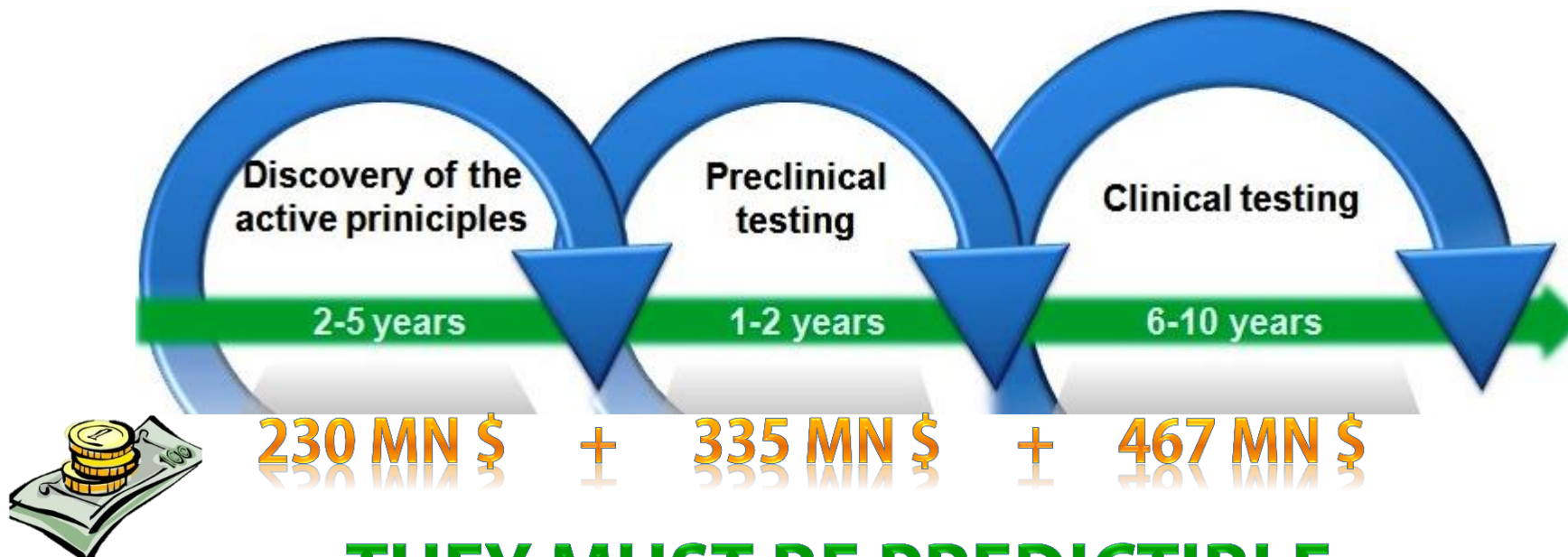
**PhD student in Biomedical Engineering**

**Expert on design and development on smart bioreactors with environmental control.**  
**Winner of TR-35 Young Innovator 2013**



**THEY MUST BE PREDICTIBLE**

**The company is legally liable for all drugs on the market**



## THEY MUST BE PREDICTIBLE

**The company is legally liable for all drugs on the market**



- removed from worldwide circulation in 2001
- 52 deaths between 1998-2001
- class action against Bayer
- \$1170 million spent in settlements

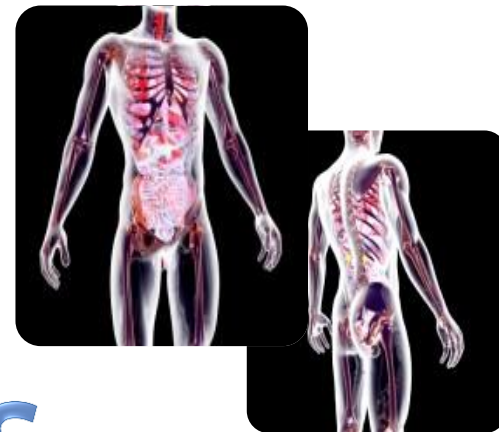


VS

VS

**ARE THEY  
REPRESENTATIVE???**





**VS**

**VS**

***In-vitro tests***  
2D  
Static  
Single culture

***In-vivo tests***

- \$ 900 Mln/year worldwide
- Time costs
- Ethical issues

***Clinical tests  
on humans***

- Study & test of new drugs
- Cosmetic products tests
- Tissue engineering
- Regenerative medicine
- Toxicology
- Base cellular biology
- Alternatives techniques



**USA**

**United States National Academy of Sciences  
proposed "Toxicity Testing in the 21<sup>st</sup>  
Century: A Vision and a Strategy"**



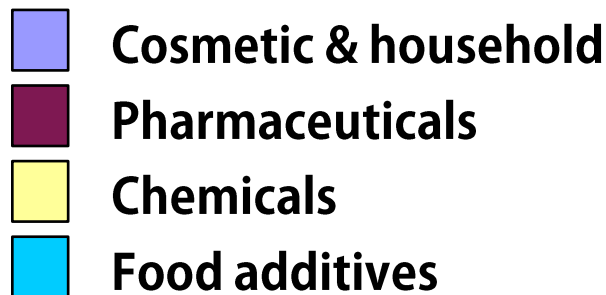
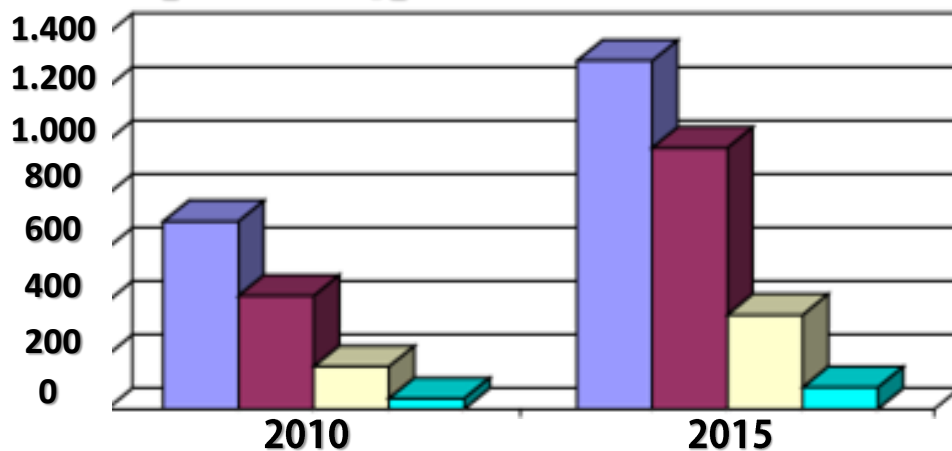
**CE**

**EU directive 655/2013  
prohibits the commercialization of  
cosmetic products tested on animals.**

**Need of  
representative  
*in-vitro* models**

- Study & test of new drugs
- Cosmetic products tests
- Tissue engineering
- Regenerative medicine
- Toxicology
- Base cellular biology
- Alternatives techniques

**Estimation of global market for  
*in vitro* toxicology, 2010-2015  
[milions \$]**

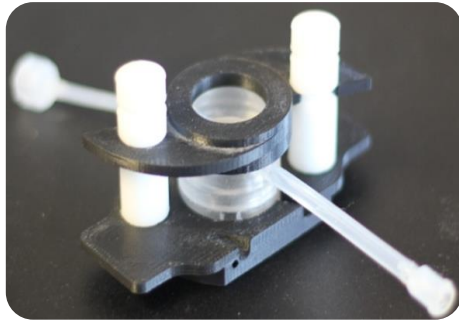


**Need of  
representative  
*in-vitro* models**

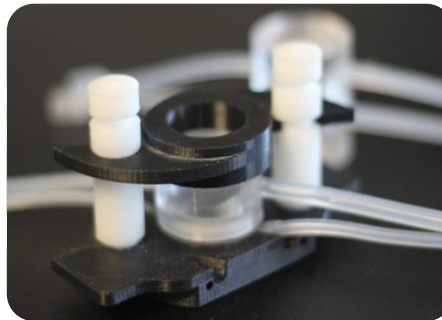


Customers	Turnover	Market volume	Interest in training
R&D in pharmaceutical and cosmetrical companies (n. <b>9000</b> global)	high	High	yes
Centers for TESTING of MEDICAL DEVICES	high	Mid-high	yes
UNIVERSITIES; RESEARCH CENTRES; ISTITUTION & FOUNDATIONS ( <b>500</b> global)	limited	Mid-high	yes

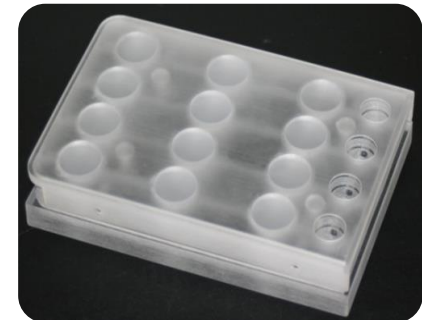
1. **Commercialize innovative technologies** for highly representative *in-vitro organ models* of human physio-pathological conditions



LIVE BOX 1  
Single flow bioreactor



LIVE BOX 2  
Double flow bioreactor

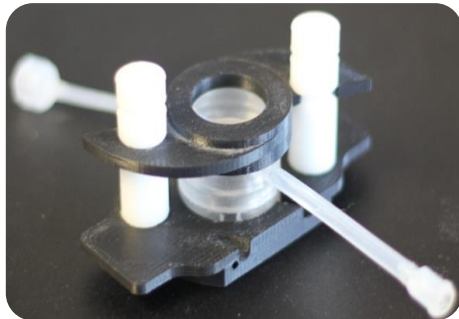


MULTUDYN  
Smart multiwell

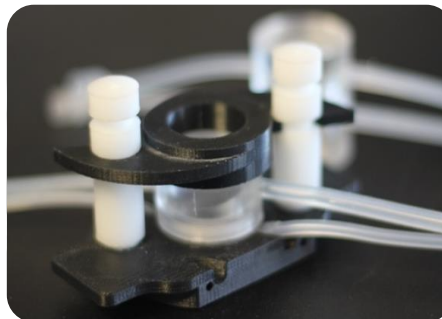
2. **Product Customization** based on customer's needs

3. **Workshops and trainings**

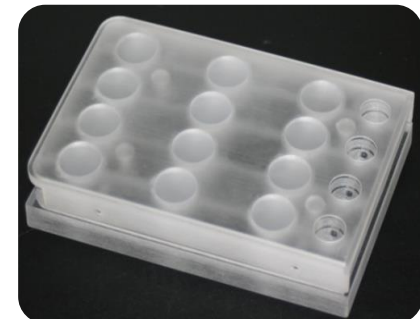
# 1. Commercialize innovative technologies for highly representative *in-vitro organ models* of human physio-pathological conditions



LIVE BOX 1  
Single flow bioreactor

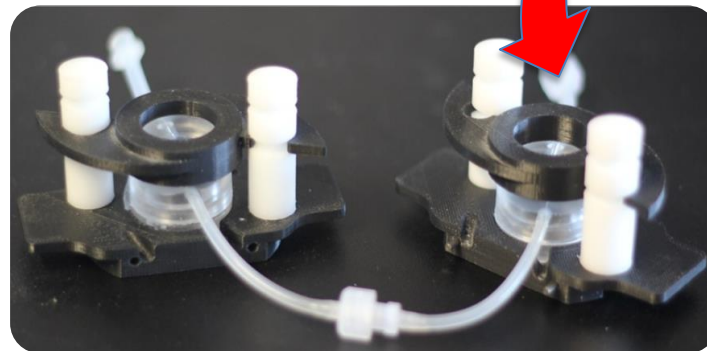


LIVE BOX 2  
Double flow bioreactor

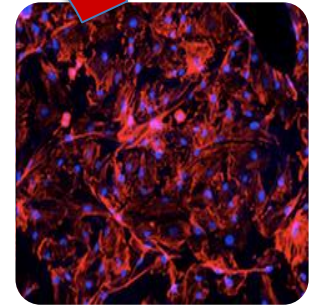


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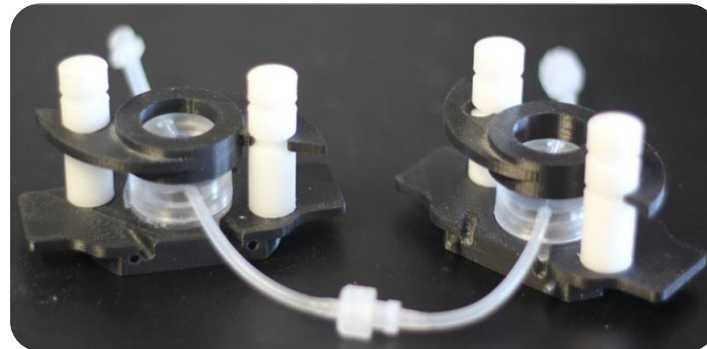
- In-vitro liver model using microfabricated scaffolds in a Modular Bioreactor, *Biotechnology J*, 2010
- Modular bioreactor for primary human hepatocyte culture: Medium flow stimulates expression and activity of detoxification genes, *Biotechnology J*, 2011
- In vitro toxicological screening of nanoparticles on primary human endothelial cells and the role of flow in modulating cell response, *Nanotoxicology*, 2014



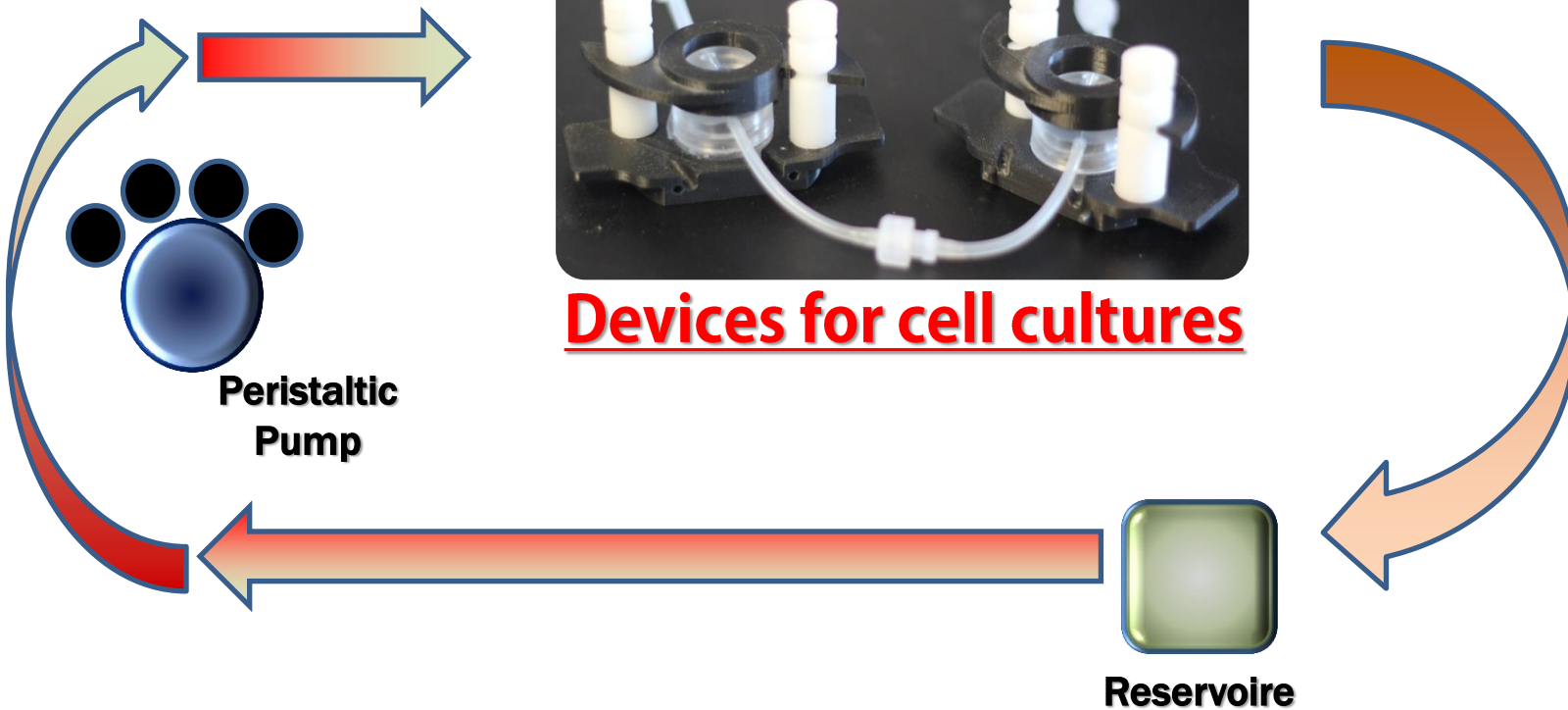
**Devices for cell cultures**

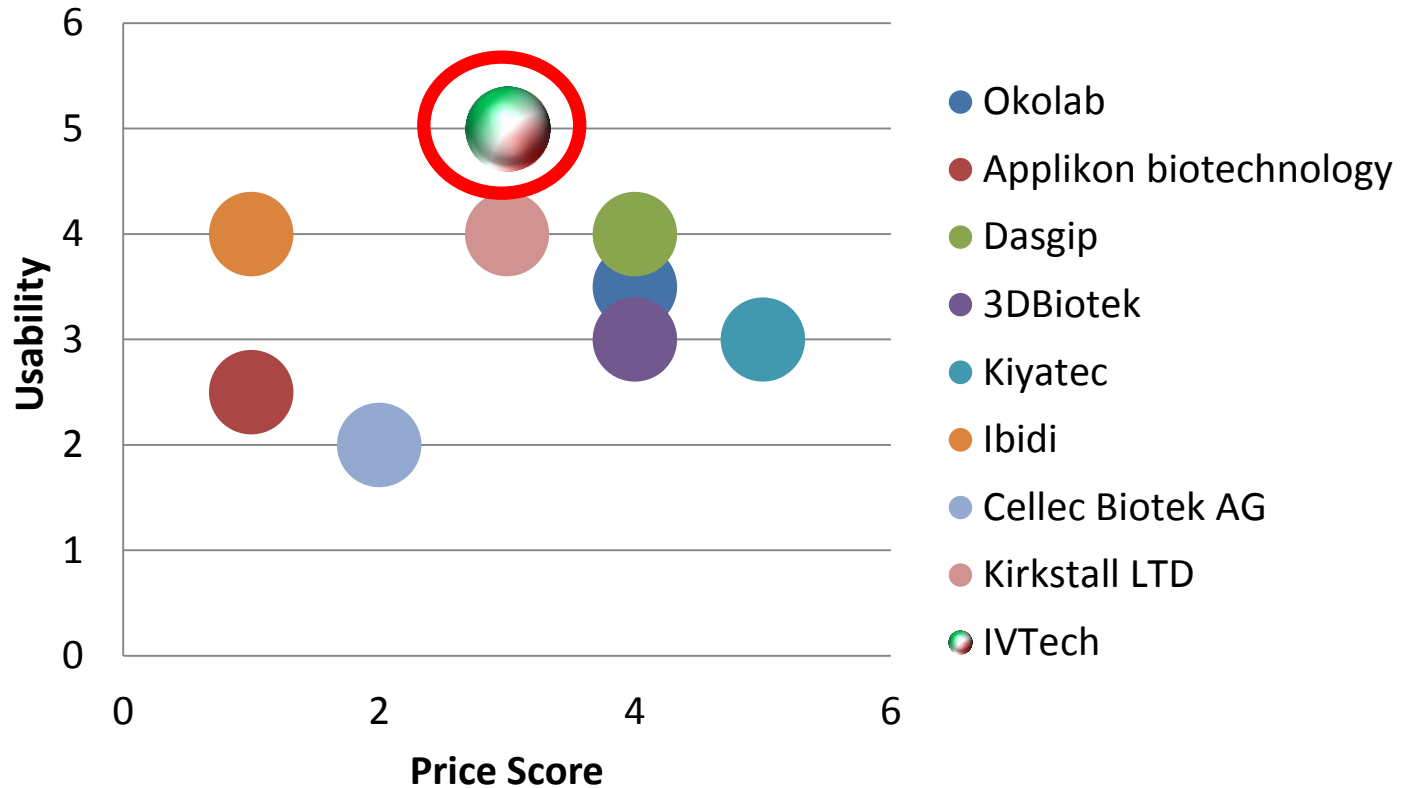


**3D Scaffolds  
colonized  
with cells**



**Devices for cell cultures**





**Usability** = Versatility + handling + modularity + efficacy  
(1 --> high price or low usability, 5 --> low price or high usability)





Our systems are **the only one** that combine:

- 3D structure
- Dynamic conditions
- Multi-organ models (connected)
- Real-time imaging
- Usable as *in-vitro* standards tools

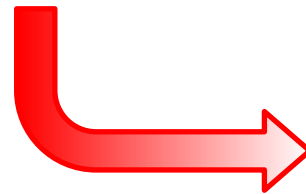


- **More representative**
- **More predictive**
- **High efficacy (less test requires)**



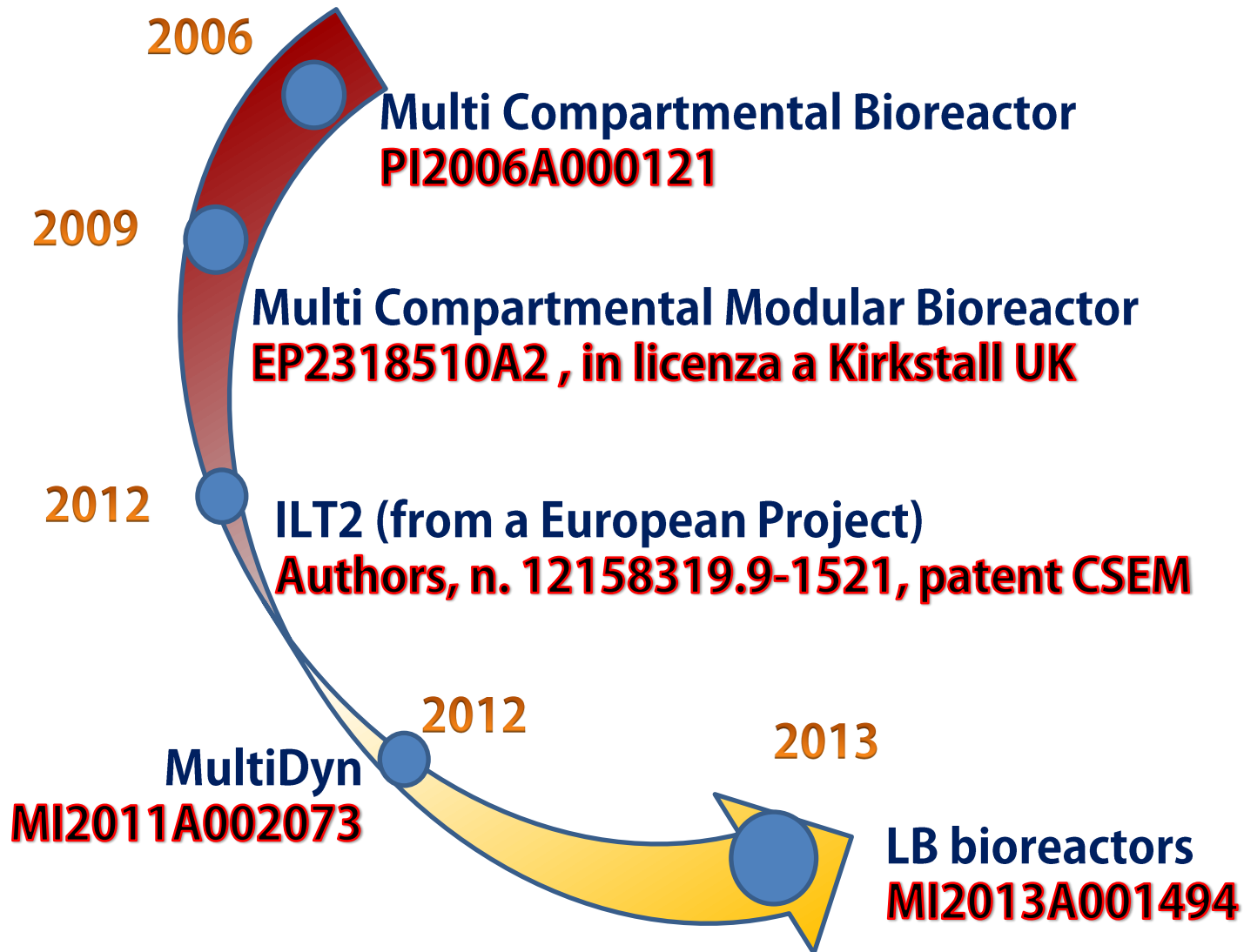
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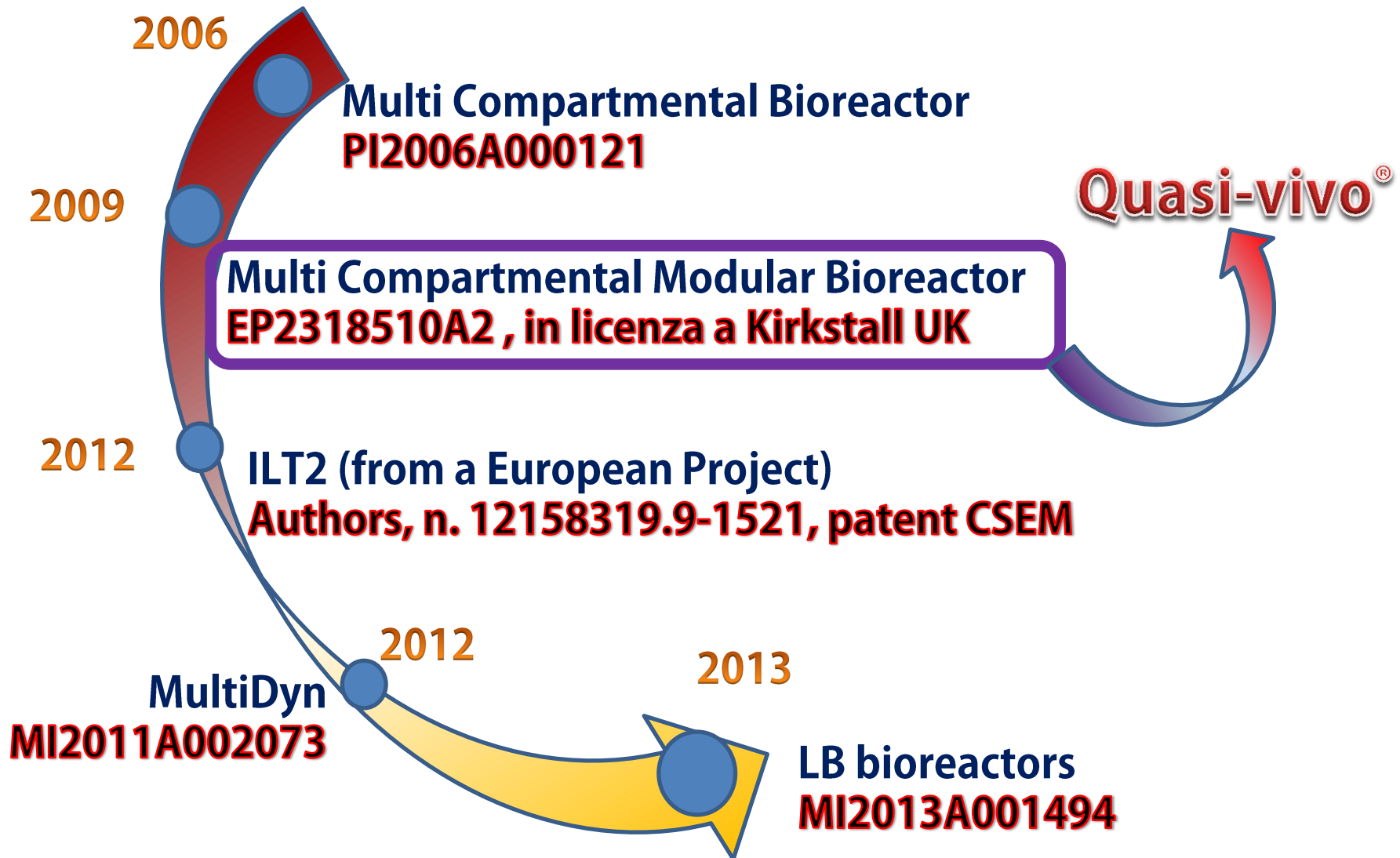
- 3D structure
- Dynamic conditions
- Multi-organ models (connected)
- Real-time imaging
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- More representative
- More predictive
- High efficacy (less test requires)

## Save MONEY and TIME (300 Mln/year)





2006

**Multi Compartmental Bioreactor**  
**PI2006A000121**

2009

**Multi Compartmental Modular Bioreactor**  
**EP2318510A2 , licenced to Kirkstall UK**

2012

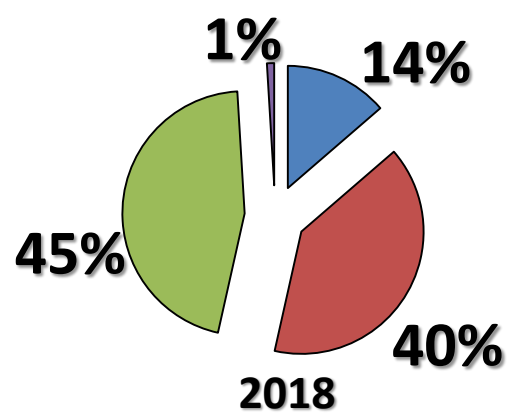
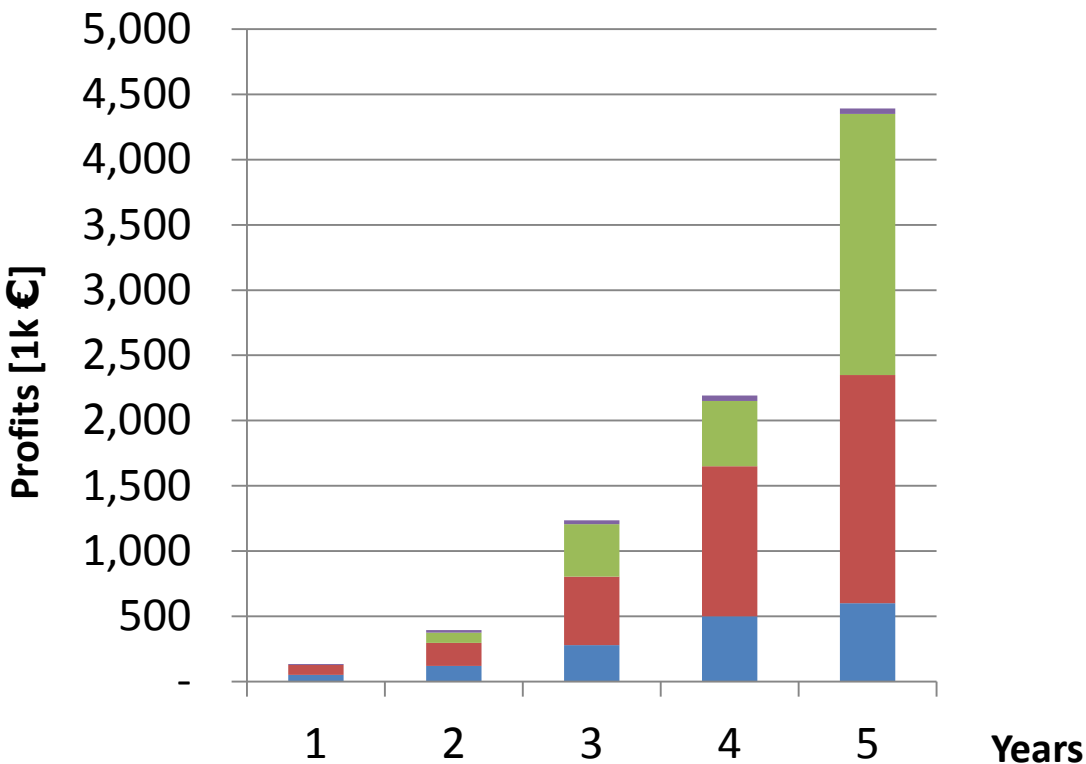
**ILT2 (from a European Project)**  
**Authors, n. 12158319.9-1521, patent CSEM**

2012

**MultiDyn**  
**MI2011A002073**

2013

**LB bioreactors**  
**MI2013A001494**



<b>Mould</b>	<b>2,000</b>	<b>200,000</b>	-	-	-
<b>Production</b>	<b>15,860</b>	<b>12,800</b>	<b>31,546</b>	<b>31,546</b>	<b>31,546</b>
<b>Staff</b>	-	<b>26,200</b>	<b>52,400</b>	<b>206,200</b>	<b>206,200</b>





- **First place at  
Arscentia 2012-13 (MultiDyn)**
- **Third place  
StartCup Toscana 2012-13**
- **Finalist PNI Cube 2013**
- **First place Premio Marzotto 2013  
“Dall’Idea all’Impresa”**



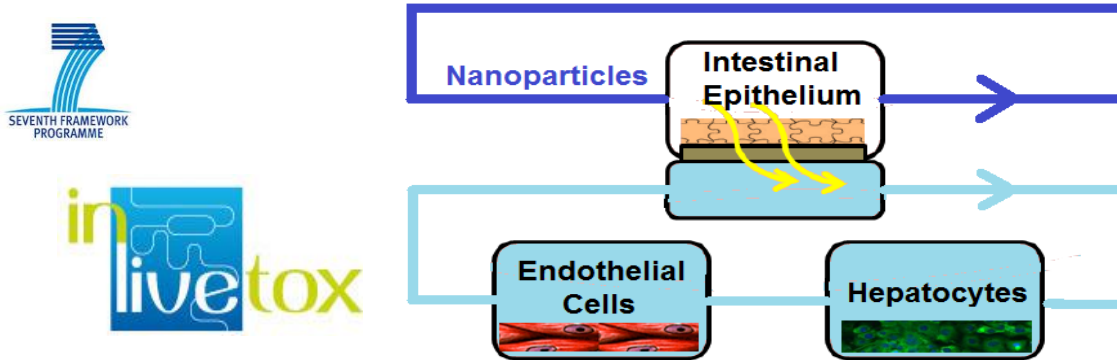
Soft incubation at  
Fondazione Filarete (MI)



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- **Low translocation of nanoparticles** (InLive Tox Project, FP7),  
Premio Farindustria 2013 N. Ucciferri (Ucciferri et al., Nanotoxicology, 2014)



- **Endothelial inflammation signal is dependent on the adipose tissue level**  
(Iori et al., PlosOne, 0034704, 2012)

