Il ruolo della proprietà intellettuale nell’evoluzione della giovane Start-up

Med-Tech start-up, spin-off of University of Sannio, Benevento ITALY

Andrea Cusano (a.cusano@unisannio.it)
Our startup

*Often Medical* was founded in 2018 by a multidisciplinary research team from:

**Optoelectronics and Photonics Group at the Department of Engineering of the University of Sannio** in Benevento
*(decades of experience in developing advanced fiber optic sensors for industrial applications)*

**Department of Medical Surgical Sciences and Medicine Translation of the University of Rome Sapienza**
*(experts in algology and invasive and mini-invasive techniques in pain therapy)*

in collaboration with *DayOne*, incubator of high tech start-ups from European research centers

The mission: reshaping the future of Epidural Anesthesia
The most commonly performed procedure for pain relief

**The epidural Anesthesia**

Failure rates up to 30% in clinical practice

*British Journal of Anaesthesia 109, (2) 144-54 (2012)*

In Italy, Extra cost of about 300M/year for the National Health Service

Andrea Cusano (a.cusano@unisannio.it)
It is estimated that each year about 3% of people undergoes an epidural.

**Number of people receiving epidurals annually**

<table>
<thead>
<tr>
<th>Region</th>
<th>A= # people</th>
<th>B= # epid/yr</th>
<th>B/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>319 M</td>
<td>11 M</td>
<td>3.4%</td>
</tr>
<tr>
<td>ITALY</td>
<td>60 M</td>
<td>1.6 M</td>
<td>2.6%</td>
</tr>
<tr>
<td>EUROPE</td>
<td>740 M</td>
<td>22.2 M</td>
<td>3%</td>
</tr>
</tbody>
</table>

*quote from the New England Journal of Medicine in July 2014*

**GLOBAL EPIDURAL ANESTHESIA SYSTEMS MARKET, BY PRODUCT TYPE 2017-2028 (USD MILLION)**

<table>
<thead>
<tr>
<th>Product</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
<th>2025</th>
<th>2026</th>
<th>2027</th>
<th>2028</th>
<th>CAGR 4%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheters</td>
<td>351.4</td>
<td>391.1</td>
<td>429.1</td>
<td>470.0</td>
<td>514.1</td>
<td>561.3</td>
<td>612.0</td>
<td>665.1</td>
<td>721.8</td>
<td>782.3</td>
<td>846.5</td>
<td>914.7</td>
<td>8.68%</td>
</tr>
<tr>
<td>Needles</td>
<td>395.1</td>
<td>441.0</td>
<td>485.4</td>
<td>533.4</td>
<td>585.2</td>
<td>641.0</td>
<td>701.0</td>
<td>764.4</td>
<td>832.1</td>
<td>904.5</td>
<td>982.0</td>
<td>1,064.5</td>
<td>9.02%</td>
</tr>
<tr>
<td>Accessories</td>
<td>206.6</td>
<td>230.9</td>
<td>254.5</td>
<td>279.9</td>
<td>307.4</td>
<td>337.1</td>
<td>369.0</td>
<td>402.8</td>
<td>438.9</td>
<td>477.6</td>
<td>519.0</td>
<td>563.1</td>
<td>9.13%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>953.1</td>
<td>1,063.9</td>
<td>1,169.0</td>
<td>1,283.4</td>
<td>1,406.7</td>
<td>1,539.4</td>
<td>1,682.0</td>
<td>1,832.3</td>
<td>1,992.9</td>
<td>2,164.5</td>
<td>2,247.5</td>
<td>2,542.3</td>
<td>8.92%</td>
</tr>
</tbody>
</table>

*Source: Trade Associations, Annual Reports, Government & Regulatory Bodies, Paid Databases.*

Andrea Cusano (a.cusano@unisannio.it)
Competitors

Passive devices

Episure®

Epidrum®
- http://www.exmoorinnovations.co.uk/index.php/epidrum/epidrum-what-is-it

Tuoren LOR®

Active devices

CompuFlo®

APAD®

EPI Detection®
- http://saeummeditec.com/

No catheter placement monitoring!

- Simple
- Visual feedback
- High compatibility with standard kits and procedures

- Visual/acoustic feedback
- Injection record database (except Epidetection)
- Compatibility with standard kits and procedures

Armando Ricciardi (info@often-medical.com)
We developed an innovative system based on a proprietary **optical fiber sensor technology**

Our smart needle measures in real time the pressure during the insertion making the whole procedure objective and less operator-dependent
• **Idea**: The project is aimed to meet a clear *clinical need raised by anesthesiologists*

• **First patent**: we recognize that the idea is new and compatible with an industrial device able to have a strong impact in the specific medical sector with an *interesting market*-> this pushed us to write a patent (deposited in Italy, one year priority worldwide ) but...:

• **Critical issue**: the patent is written with a strong focus on the concept more than on the technical aspects that are still undefined

• **First prototype**: a preliminary mock-up is fabricated and first test are carried out on an epidural phantom tissue used for training purposes.
Our story

- **First tests on animal (in-vivo)**: our prototype is tested on animals (study authorized by Italian Ministry of Health). Phanotm and Animals studies help us to recognize that the original idea and prototype need a significant review.

- **Second Patent**: we give up with the first patent and prepare, in collaboration with leading European intellectual property firm, a new draft of the patent including all the technical specifications collected during tests performed on both phantom tissue and animals.

- **The second patent focuses on the device instead of the concept** and it is much more detailed than the first one.

- Based on our experience, the technical details are the real value of the intellectual property.
• The second prototype is developed according to all the inputs received by anestesiologists (our partners and opinion leaders) who used our device. Phantom tests confirm our performance expectations and the advances in respect to the first prototype.

• International Patent: the second patent works so that we decided to go for a PCT.
Our team meets a **startup incubator (Day One srl)** during the event «User-driven innovation: a new way to develop technologies and startups together with large companies» organized by Unisannio;

*The presence of the patent is of fundamental importance to win the selection process.*

- Thanks to the collaboration with the incubator we prepared a **business plan** and started to look around for fundings.

- We apply to the call **“Bando supporto allo sviluppo di spin-off e startup innovative”** - POR Campania FESR 2014-2020 (project value 500k, co-financing 35%)

*The availability of an (international) patent gives scores and positive comments during the process evaluation.*
Proof of Concept Animal Study

**Fully functional prototype**
Successfully tested on

1. **Epidural phantom tissue**
2. **In-vivo test on pigs**

64 procedures 100% of accuracy

**In-vivo tests on animals**
authorized by Italian Ministry of Health (auth. N. 554/2017)

1. Needle placement
2. Catheter placement

**Publications on scientific journals**

- Best Poster Award
  - Chemical, Environmental, Biological and Medical Sensors

- **Optical Guidance Systems for Epidural Space Identification**
  - Benito Carotenuto, Alberto Micco, Armando Ricciardi, Elio Amorizzo, Marco Mercieri, Antonello Cutolo, and Andrea Cusano

- **Optical fiber technology enables smart needles for epidurals: an in-vivo swine study**
  - Benito Carotenuto, Armando Ricciardi, Alberto Micco, Elio Amorizzo, Marco Mercieri, Antonello Cutolo, and Andrea Cusano

**sensors**

**Andrea Cusano** (a.cusano@unisannio.it)
• The project is funded and finally the startup is established.

• New projects are submitted to the ERC (European Research Council) -> we obtain the 'seal of excellence' certificate that will give us the possibility to win new public grants...

• Again, the availability of an (international) patent gives scores and positive comments during the process evaluation.

• We start to meet Venture Capital (VC) firms at both national and international level
Often Medical is financed by the **Vertis Venture 3 Tech Transfer**, a venture Capital fund managed by Vertis SGR and Venture Factory (seed fund 575k).

*During negotiations, the investors considered the presence of an international patent a *conditio sine qua non* for the equity injection. **Often Medical has the exclusive license of the patent.**

In the mean time the patent is granted in Europe (20 countries), United States, Canada and China.

**Patent costs incurred to date are about 100Keuro / Patent manteinance expenses are about 20k/per year**
Our future
Go to market

2020 ...

01/21

Phase 1: R&D
Product engineering

Design freeze

01/22

Phase 2: Regulatory pathway
Animal Study First on Humans Multicentric Clinical trials

CE Marketing Clearance

01/23

Phase 3: Product launch (Educational Version) for the training market
Customers: Teaching Hospitals and Master Schools

Phase 4: Product launch (Clinical)
Customers: Distributors Public and Private Hospitals

...2023

1 M€ 4 M€
estimated total need of future investments

Recently, Often Medical was the first among the startups that can be financed within the call “Campania Start Up 2020” - PO FESR 2014-2020 (project value 420k, co-financing 30%) Again, the availability of an (international) patent provides higher score and positive comments during the process evaluation.

Andrea Cusano (a.cusano@unisannio.it)
Our project has been endorsed by

Dr. Ezio Amorizzo

Dr. Marco Mercieri

Dr. Enrico Barbara

Dr. Andrea Tognù

and many others...
Thank you for your kind attention.
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