Critical factors for a Start-Up in developing disruptive medical devices

Max Ostermeier, Founder and General Manager
• **Implandata Ophthalmic Products** – Combining medical technology with digital health for improved glaucoma care and remote patient management

• **January 2010** – Founded in Hannover/Germany

• **August 2014** – Formation Implandata Ophthalmic Products, Inc. in Delaware

• **Funding** – €6.2m Seed, Series A and B so far... €6m Series C next

• **Mid of 2016** – CE mark and initial market launch

• **Reimbursement** – NUB in 2017 for inpatient, out-of-pocket pay for outpatient

• **USA** – PMA HDE in 2018 and provisional reimbursement code

• **Exit** – in two to three years
Glaucoma: Number 1 reason for irreversible blindness worldwide
Problems in glaucoma patient care
Current IOP measurement methods miss real pressure situation

Real IOP higher, but undetected: Visual field loss!

Real IOP lower, but undetected: Risk of retinal detachment!

5mmHg 10mmHg 15mmHg 20mmHg 25mmHg

12 months

In office applanation tonometry
Solution: EYEMATE® for telemetric IOP measurement and glaucoma monitoring

Implantable EYEMATE® micro-sensor, telemetrically powered and read out by patient hand-held MESOGRAPH device.

IOP measurement data is transferred to cloud-based database, accessible by the eye doctor.

EYEMATE® patient app displays pressure history and reminds patient to take medication, while patient can control therapy success.
Various versions for various patient situations and surgeon preference required

**EYEMATE®-EO Versions**
Phakic glaucomatous eyes

**EYEMATE®-IS**
intrascleral

**EYEMATE®-ES**
episceral

**EYEMATE®-SC**
suprachoroidal

**EYEMATE®-IO**
Pseudophakic or aphakic glaucomatous eyes
- POAG patients with cataract surgery (primary or secondary implantation)
- Secondary glaucoma at keratoplasty patients
- Secondary glaucoma at keratoprosthesis patients
Next disruptions on the horizon...

combining EYEMATE® sensors with therapeutic devices

...like glaucoma drainage devices

...IOL's

and sometimes in future, ...establishing closed loop therapeutic devices
Over a period of 6 months 572 single IOP measurements have been acquired. The median IOP was 21 mmHg, while the IOP varied between 12 and 43 mmHg.

- Post-operatively after three months: Corticosteroid side effect and elevated IOP (*). Altering medication to reduce corticosteroid reaction and IOP with combination of Dorzolamid and Timolol.

- Some weeks later: Patient detects in the morning hours of 5 from 7 days a paradoxical IOP elevation of 8 to 12 mmHg two hours after applying IOP reducing medication (**). The increased IOP could be confirmed by GAT measurement. Swelling of the ciliary body due to Dorzolamid was suspected. Dorzolamid was replaced by Clonidin and Prostaglandin medication was added. This resulted in a significant IOP recompensation.
But what’s the point?
Observing strong IOP fluctuation, amended medication get IOP under control

- Prescription of brimonidine medication results in strong and unwanted IOP fluctuation and elevated IOP for this patient
- On May 27, 2015 brimonidine eye drops are replaced by latanoprost medication; resulting in immediate reduction of IOP fluctuation and lowered IOP
How is EYEMATE® disrupting glaucoma care?

- Introduction of self measurement; gives patient peace of mind, when glaucoma is under control and empowers them to take action when it is out of control; reduced number of office visits => better quality of life for patients and their families

- Monitoring and early recognition of elevated IOP enables eye doctors personalize treatment and titrate medication, before patient loses more vision; focus on patients who really need attention => enables doctors to provide better care to their patients

- Better economics: Solution supports prevention of blindness, makes care more efficient and helps to keep patients at less costly early disease stage => cost savings for patients, families, health care systems and economies
Critical factors in developing disrupting medical devices
Understand market needs and market trends

- What are underserved areas and who are the stakeholders?
- What is really needed, now and in future?
- What is the benefit you can offer and is it not just incremental?
- Who are potential enemies?
- What are potential boundaries?
- What is going on in other areas?
- Sounding with experts: Users and industry
Establish strong network with researchers, users and industry, also in neighboring areas

Important not only for product development, also for market intelligence, funding...

➢ Involve thought leaders and champions
Understand your market: Size, adoption, design requirements

<table>
<thead>
<tr>
<th>Product version, combined...</th>
<th>D: # of cases/Revenues</th>
<th>EU: # of cases/Revenues</th>
<th>USA: # of cases/Revenues</th>
<th>WW: # of cases/Revenues</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EYEMATE®-IO with/keratoprosthesis</strong></td>
<td># of cases: 80/0.36</td>
<td># of cases: 450/2.0</td>
<td># of cases: 750/3.4</td>
<td># of cases: 1.500/5.3</td>
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<td>Price/unit: 4.50</td>
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<td>Price/unit: 4.50</td>
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<tr>
<td><strong>EYEMATE®-IO w/keratoplasty</strong></td>
<td># of cases: 2.700/8.1</td>
<td># of cases: ~25,000/75.0</td>
<td># of cases: ~20,000/60.0</td>
<td># of cases: ~120,000/180.0</td>
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<tr>
<td></td>
<td>Price/unit: 3.00</td>
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<td>Price/unit: 1.500</td>
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<tr>
<td><strong>EYEMATE®-IO w/cataract at POAG patients</strong></td>
<td># of cases: 50,000/60.0</td>
<td># of cases: ~250,000/300.0</td>
<td># of cases: ~300,000/360.0</td>
<td># of cases: ~1,200,000/720.0</td>
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<tr>
<td><strong>EYEMATE®-EO w/canaloplasty</strong></td>
<td># of cases: 1.500/3.8</td>
<td># of cases: ~8,000/20.0</td>
<td># of cases: ~6,000/15.0</td>
<td># of cases: ~17,500/38.5</td>
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<td>Price/unit: 2.500</td>
<td>Price/unit: 2.200</td>
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<tr>
<td><strong>EYEMATE®-EO w/other surgery (valves etc.)</strong></td>
<td># of cases: 8,000/20.0</td>
<td># of cases: ~30,000/75.0</td>
<td># of cases: ~40,000/100.0</td>
<td># of cases: ~120,000/240.0</td>
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<tr>
<td><strong>EYEMATE®-EO w/cataract at PEX glaucoma</strong></td>
<td># of cases: 10,000/12.0</td>
<td># of cases: 50,000/60.0</td>
<td># of cases: 50,000/60.0</td>
<td># of cases: 300,000/180.0</td>
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<tr>
<td><strong>EYEMATE®-EO stand alone</strong></td>
<td># of cases: ~10,000/20.0</td>
<td># of cases: ~30,000/60.0</td>
<td># of cases: ~30,000/60.0</td>
<td># of cases: ~200,000/200.0</td>
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<td></td>
<td>Price/unit: 2,000</td>
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<td>Price/unit: 2,000</td>
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# of cases: per year today, future growths not considered
Price/unit: in USD
Revenues: in million USD/year

* Assuming that just one percent of the glaucoma patients are ready to undergo a stand alone procedure for better IOP monitoring
What do want/need to accomplish and can be accomplished?
  - Proof of concept?
  - Market approvals?
  - Exit?
  - Sustainable business?

Develop strategies accordingly
Don’t listen to naysayers and don’t accept boundaries so easily