We fill therapeutic gaps by combining new technologies with regenerative therapies to provide novel minimally-invasive treatments.
Problem

Peripheral artery disease is estimated to affect 202 million people worldwide.

Patients with CLI face a high risk of limb loss—between 10% to 40% at 1 year, and at 5 years, the mortality rate reaches 50%.

Most common cause of CLI is BTK disease where there are no optimal endovascular treatments and this is an important unmet clinical need.

Solution:

The Oath team has developed a bioabsorbable stent which can be targeted by regenerative therapies.

Our most recent milestone was successful preclinical studies in CAD culminating with $6M in support from European Grant funding.

We are seeking funding to rerun preclinical studies targeting CLI as the space is more attractive to enter.
Dissolvable Platform with Magnetic Targeting

Secured Patents:
PCT/US2016/025328 Title: FERROMAGNETIC PARTICLES BOUND TO POLYMERIC IMPLANTS
PCT/US2015/023880 Title: IRON PLATNIUM PARTICLES FOR ADHERENCE OF BIOLOGICS ON MEDICAL IMPLANTS

1.

Adult progenitor cells from the patient’s own bone marrow are tagged with an ultra-small iron-oxide nanoparticle using a commercially available cell selection system. Our team has successfully practiced this technique across 1,000 patients.

2.

The stent is placed in the artery using the normal technique with a delivery balloon. We then infuse the tagged progenitor cells into the artery containing the magnetized stent via a standard catheter.

3.

The iron tagged progenitor cells are attracted to the magnetised stent where they promote rapid endothelialisation. Cells that are not captured pass to the distal vascular bed where they promote an increase in blood supply.

4.

The bioabsorbable stent then dissolves leaving the new endothelial lining to regenerate the artery itself and to give protective agents to the artery and organs downstream.
Completed Bioreactor Studies

Experimental Setup

Nanomagnetic Cell Capture

Number of Cells Infused

Seeding Concentration

Flow Rate

Retained Cells on First Pass
Visualization of Stent and Cell Capture
RCA injection of 2.6 x 10^6 In-111 (0.42 mCi) labeled CD34+ cells
Magnetic and non-magnetic Stents RCA

Completed Preclinical Studies

in vivo OCT

Magnetic Stent

Visualization of Stent and Cell Capture
RCA injection of 2.6 x 10^6 In-111 (0.42 mCi) labeled CD34+ cells
Magnetic and non-magnetic Stents RCA
Global Market Size by 2023

**FIRST INDICATION**
Critical Limb Ischemia

- Procedures per year: 900,000
- Average stent selling price: $1,181
- Growth Rate Next 5 Years: 6.5%
- Global Market Value: $2.23 Billion

- In the US, between 150,000 and 300,000 cases are diagnosed each year.

Cardiac Stent Market

- Procedures per year: 1,800,000
- Average stent selling price: $1,419
- Growth Rate Next 5 Years: 8.7%
- Global Market Value: $7.75 Billion

- CAD market set to decline as recent data at AHA suggests no clinical benefit over other therapies.

Potential future indications may include:
Regenerative medicine therapies of the heart or other indications, intracranial stent/therapies, other targeted therapies.
## Competitor Landscape

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>OATH NUSTENT</th>
<th>Boston Scientific + REVA ReZolve</th>
<th>Magnamarus Biotronik</th>
<th>OrbusNeich COMBO Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stent Design</strong></td>
<td>Open cell FrameWork®</td>
<td>Slide and spiral lock</td>
<td>6-crown 2-link zig-zag</td>
<td>Dual helix</td>
</tr>
<tr>
<td><strong>Strut Design / Materials</strong></td>
<td>Mg Core PLLA enclosure + FePt</td>
<td>p-tyrosine derived polycarbonate</td>
<td>Mg PLLA coating</td>
<td>Stainless steel 316L Sirolimus + CD34 Antibody Coating</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>1 month</td>
<td>3 – 6 months</td>
<td>~ 3 months</td>
<td>Infinite</td>
</tr>
<tr>
<td><strong>Radial Support</strong></td>
<td>3 months</td>
<td>24 – 48 months</td>
<td>12 months+</td>
<td>None</td>
</tr>
<tr>
<td><strong>Resorption Time</strong></td>
<td>FIM planned in 2021</td>
<td>Coronary target; FIM in 2013; Positive results presented in 2018</td>
<td>In Clinical Trials: 30K of 55K patients enrolled; CE in process</td>
<td>Multiple clinical trials CE Mark approved</td>
</tr>
<tr>
<td><strong>Current Status</strong></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td><strong>Biodegradable</strong></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td><strong>Imageable</strong></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Magnetized / Targetable</strong></td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td><strong>Regenerative Properties</strong></td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
</tr>
</tbody>
</table>
Timeline

IDE-Enabling Work in PAD
1) In vivo degradation: $100K
2) Stem cell retention & repair: $200k

- Pre-IND Meeting

Build OATH Core Team

Phase I Clinical Trial - PAD

IDE

Phase I Clinical Trial - CAD

$300K Blavantik

$10M Series A
Oath Endovascular

Al Sinusas
MD, FACC, FAHA
Physician Scientist

Tarek Fahmy
PhD
Scientist

Carlos Mena
MD
Physician

Anthony Mathur
MA, MB, BChir, MRCP, PhD
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John Martin
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Business Development