# Coath endovascular

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

### 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

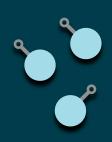
PCT/US2016/025328 Title: FERROMAGNETIC PARTICLES BOUND TO POLYMERIC IMPLANTS PCT/US2015/023880 Title: IRON PLATNIUM PARTICLES FOR ADHERENCE OF BIOLOGICS ON MEDICAL

**IMPLANTS** 

1



2

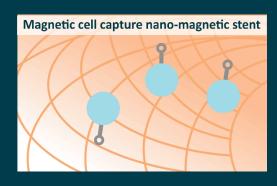


Magnetic cell capture nano-magnetic stent

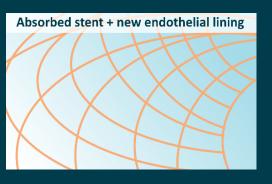
Adult progenitor cells from the patient's own bone marrow are tagged with an ultra-small iron-oxide nanoparticle using a commercially available cell selection system. Our team has successfully practiced this technique across 1,000 patients.

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



4



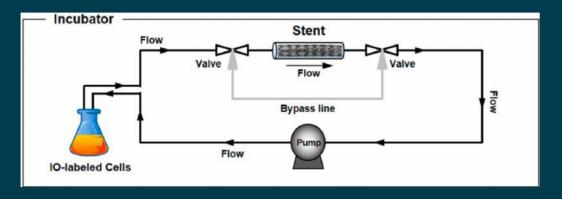
The iron tagged progenitor cells are attracted to the magnetised stent where they promote rapid endothelialisation. Cells that are not captured pass to the distal vascular bed where they promote an increase in blood supply.

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 down stream.

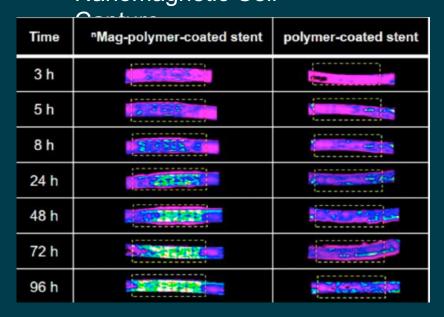


### **Completed Bioreactor Studies**

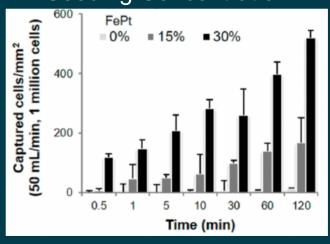
#### **Experimental Setup**



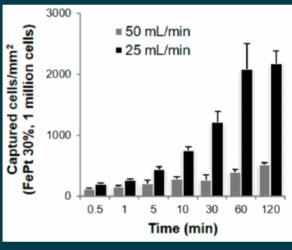
#### Nanomagnetic Cell



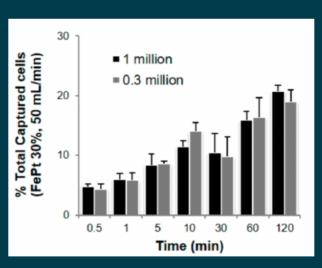
#### Seeding Concentration



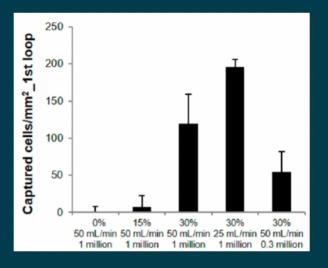
### Flow Rate



#### Number of Cells Infused



#### **Retained Cells on First Pass**



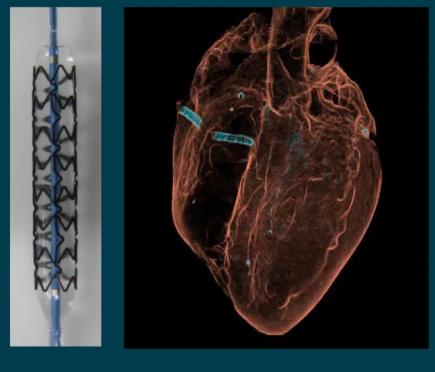


### **Completed Preclinical Studies**

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



ex vivo CT



ex vivo SPECT/CT



### Global Market Size by 2023

## FIRST INDICATION Critical Limb Ischemia

Cardiac Stent Market

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.

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**

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



### Timeline



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

IDE

Phase I Clinical Trial - PAD

**Build OATH Core Team** 

IDE

Phase I Clinical Trial - CAD

\$300K Blavantik

\$10M Series A

### Oath Endovascular



Al Sinusas MD, FACC, FAHA Physician Scientist



Anthony Mathur MA, MB, BChir, MRCP, PhD Physician Scientist



Tarek Fahmy
PhD
Scientist



**John Martin** *MD, F MED SCI, FRCP*Physician Scientist



Carlos Mena MD Physician



Jamison Langguth MPH, MSED Business Development