



## Positive Initial Results for *Fantom* Released at TCT

**San Diego, California and Sydney, Australia (Friday, 16 October 2015, AEST)** – REVA Medical, Inc. (ASX: RVA) (“REVA” or the “Company”) is pleased to announce that Dr. J. Ribamar Costa from the Institute Dante Pazzanese of Cardiology, in Sao Paulo, Brazil, presented results from REVA’s clinical trial program for its *Fantom*<sup>®</sup> sirolimus-eluting bioresorbable scaffold at the Transcatheter Cardiovascular Therapeutics (“TCT”) Conference, which is being held October 11<sup>th</sup> through 15<sup>th</sup> in San Francisco, California.

Dr. Costa presented data from both the FANTOM I pilot study and the FANTOM II CE Mark clinical trial during the *Bioresorbable Vascular Scaffolds, Part 2* session, which was held on Thursday, October 15<sup>th</sup>.

The FANTOM I pilot study enrolled seven patients, all of whom have now completed their follow-up evaluations through the six-month time point, including the primary imaging assessment at four months. The FANTOM II CE Mark clinical trial has completed enrollment of 110 patients who will have their primary follow-up evaluations during the next six months. Results released on both sets of patients showed excellent acute procedural outcomes and safety results for *Fantom*. Additionally, the initial results confirm sustained restoration of blood flow and very low reported Major Adverse Cardiac Events (“MACE”) to date.

Data from the FANTOM II six-month primary endpoint is scheduled to be presented at EuroPCR, which will be held next May in Paris, France. This data will be the basis of REVA’s CE Mark application, which is planned for mid-2016.

The presentation materials delivered at the Bioresorbable Vascular Scaffolds session are attached hereto. The presentation materials are also available in the *Investor Relations* section of REVA’s website at [www.revamedical.com](http://www.revamedical.com) and are being filed with the U.S. Securities and Exchange Commission.

### About REVA

REVA is a clinical stage medical device company located in San Diego, California, USA, that is working to commercialize its proprietary bioresorbable stents, which are called “scaffolds” because of their temporary nature. The Company’s scaffolds have been developed as an alternative to metal stents, which are small tube-like devices permanently implanted into an artery to treat coronary artery disease. Scaffolds provide restoration of blood flow, support the artery through the healing process, then disappear (or “resorb”) from the body over a period of time. This resorption allows the return of natural movement and function of the artery, a result not

attainable with permanent metal stents. The Company's initial product, the *Fantom*® scaffold, has been designed to offer an ideal balance of thinness and strength and distinct ease-of-use features including complete scaffold visibility under x-ray, expansion with one continuous inflation, and no procedural time limitations. REVA will require successful clinical trial results and regulatory approval before it can commercialize *Fantom* or any other products.

### Forward-Looking Statements

*This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that are not statements of historical fact, including those statements that address future operating performance and events or developments that we expect or anticipate will occur in the future, are forward-looking statements, such as those statements regarding our ability to obtain regulatory approvals, timely and successfully complete our clinical trials, protect our intellectual property position, commercialize our products if and when approved, develop and commercialize new products, recruit and retain our key personnel, and estimates regarding our capital requirements and financial performance. You should not place undue reliance on forward-looking statements. Although management believes forward-looking statements are reasonable as and when made, forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to vary materially from those expressed in forward-looking statements, including the risks and uncertainties that are described in the "Risk Factors" section of our Annual Report on Form 10-K filed with the US Securities and Exchange Commission (the "SEC") on March 30, 2015, and as may be updated in our periodic reports thereafter. Any forward-looking statements in this announcement speak only as of the date when made. REVA does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.*

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# ***Fantom<sup>TM</sup>***

## **Differentiating Features and Clinical Trial Insights**

**Jose de Ribamar Costa Jr, MD, PhD, FACC**

**Instituto Dante Pazzanese de Cardiologia**

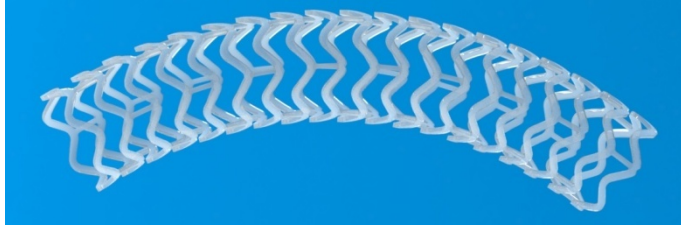
**HCOR**

**São Paulo - Brazil**

# Disclosure Statement of Financial Interest

**I, J Ribamar Costa Jr, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.**

# Fantom Bioresorbable Scaffold



**Fantom™**

***Sirolimus-Eluting Bioresorbable Scaffold  
Desaminotyrosine Polycarbonate***

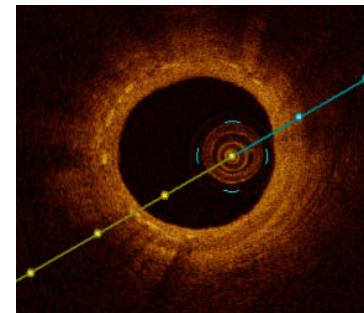
- Key Scaffold Features
  - Complete scaffold visibility under x-ray
  - Single-step continuous inflation
  - Clinically significant expansion range
  - Radial strength at 125 µm strut thickness
  - Vasomotion restoration < 1 year
  - No special storage or handling



***Visibility***



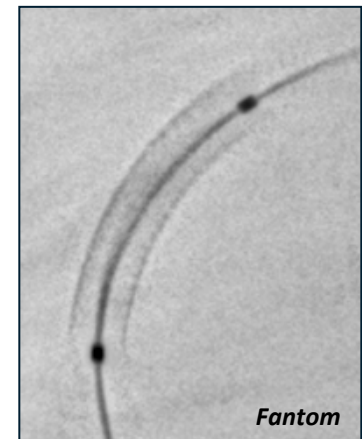
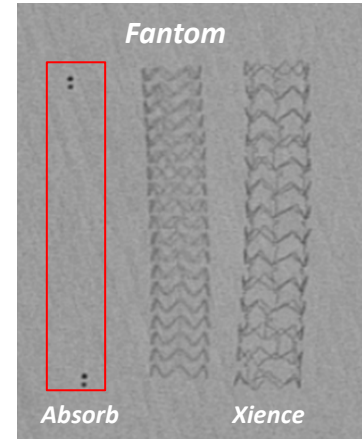
***Deliverability***



***Vessel Patency***

# *Fantom* Bioresorbable Scaffold

- *Fantom*'s complete (x-ray) visibility
  - Precise scaffold placement
  - Accurate lesion coverage
  - Reduces need for IVUS/OCT
- Single-step inflation to intended diameter
  - No need for intermediate inflation steps



# *Fantom Bioresorbable Scaffold*

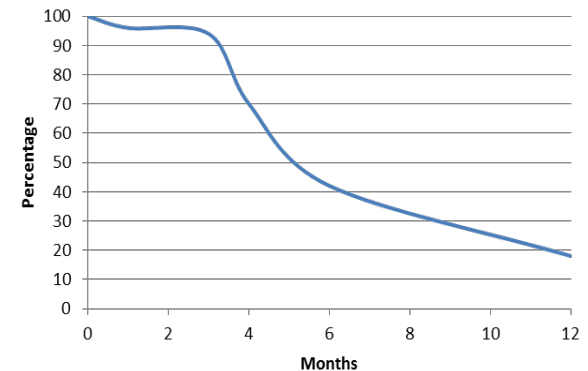
- Post-dilation without compromise
  - Substantial expansion safety margin
  - Able to adjust for vessel taper
- Greater than 80% degradation within one year
  - Restoration of natural vasomotion
  - Eliminates undesirable shear stress induced by a permanent implant

3.0mm Nominal Device



*Polymer enables expansion to 4.0mm without fracture*

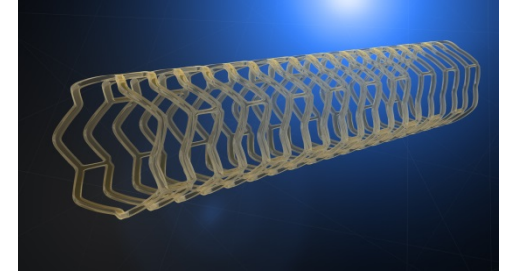
**Degradation Profile**  
Molecular Weight Loss



# ***Fantom Bioresorbable Scaffold***

## Clinical Program Overview

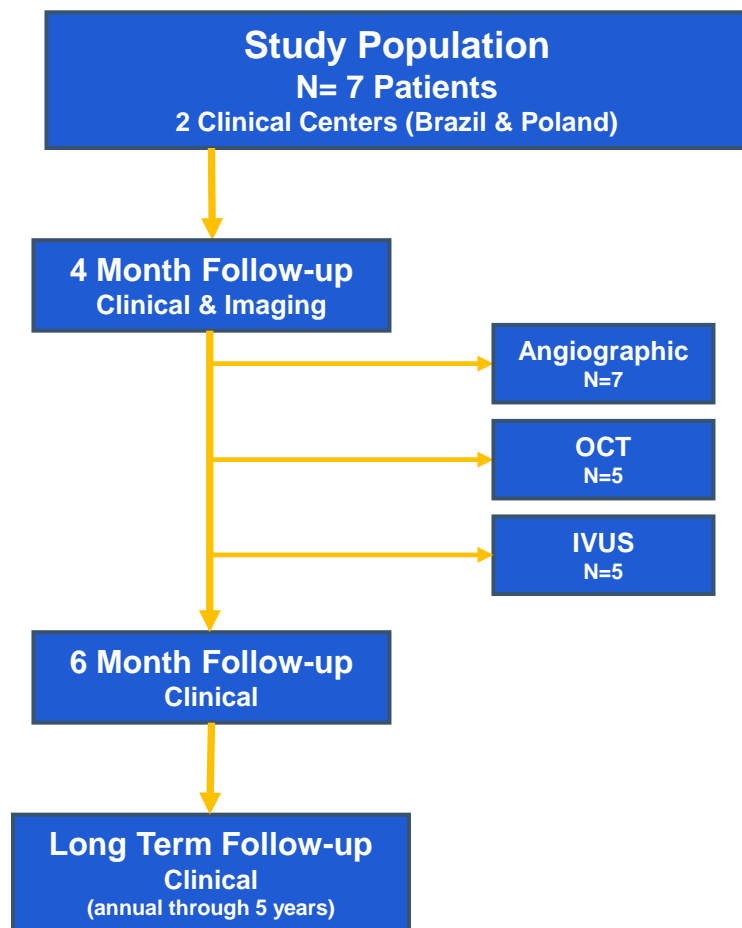
- FANTOM I (*Pilot Trial*)
  - 7 patients; 2 clinical sites
  - Goal: verification of acute performance
- FANTOM II
  - 220 patients; up to 30 clinical sites
    - Cohort A - 110 patients for CE Mark application data set
    - Cohort B - 110 patients for additional data to support product use
  - Goal: safety & performance evaluation to support CE Mark





# FANTOM I

## Study Design and Baseline Characteristics



### Patient Characteristics

Patient Age (average years)	55.9±7.7
Male	100%
Diabetes	42.9%
Current/Former Smoker	100%
Hypertension (requiring medication)	85.7%
Hyperlipidemia (requiring medication)	71.4%
Prior PCI	57.1%
Prior CABG	0%
Prior MI	57.1%
LVEF	50.7±12.2% (n=6)

# FANTOM I

## Lesion Characteristics and Procedural Outcomes

### Lesion Characteristics

Target Lesion Location (n=7)	
LAD	14.3% (1)
LCX	42.9% (3)
RCA	42.9% (3)
ACC/AHA Lesion Class (n=7)	
Type A	14.3% (1)
Type B1	71.4% (5)
Type B2	14.3% (1)
Type C	0.0% (0)

### Initial Outcomes

Acute Procedural Outcomes		
Delivery Success <sup>(1)</sup>	100%	n=7
Acute Procedural Success <sup>(2)</sup>	100%	n=7
Clinical Procedural Success <sup>(3)</sup>	100%	n=7

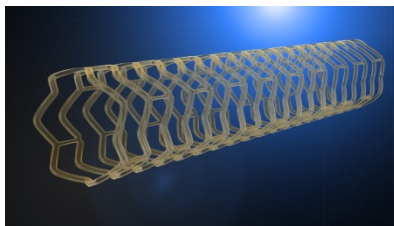
(1) Defined as successful delivery and deployment of the device.

(2) Defined as delivery success with residual stenosis <50% with no immediate (in-hospital) MACE.

(3) Defined as acute procedure success without the occurrence of MACE through 30 days.

# FANTOM I

## MACE Results\*



### MACE Results for all 7 patients

Timeframe	Events
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In-Hospital	0
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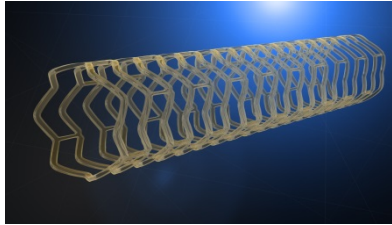
30-Day Follow-up	0
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4-Month Angiographic Follow-up	0
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6-Month Follow-up	0
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# FANTOM I

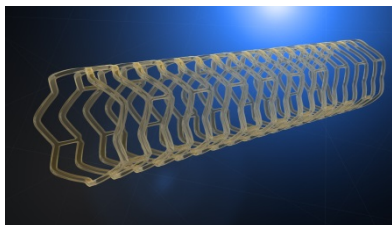
## Angiographic – QCA Results\*



In-Scaffold Analysis	Baseline (n=7)	Post Procedure (n=7)	4 Months (n=7)
RVD (mm)	$2.75 \pm 0.18$	$2.78 \pm 0.19$	$2.51 \pm 0.29$
MLD (mm)	$0.91 \pm 0.32$	$2.69 \pm 0.18$	$2.32 \pm 0.37$
Acute Gain (mm)	$1.62 \pm 0.30$		
Diameter Stenosis (%)	$67.31 \pm 9.82$	$2.84 \pm 7.11$	$7.55 \pm 11.92$
Acute Recoil (%)	4.82%		
Median Late Lumen Loss (mm)	0.21 (-0.06,0.88)		

# FANTOM I

## IVUS Results\*



In-Scaffold Analysis	Post Procedure (n=5)	4 Months (n=7)
Mean vessel area, mm <sup>2</sup>	12.82 ± 1.85	14.19 ± 2.90
Mean scaffold area, mm <sup>2</sup>	6.15 ± 0.69	6.00 ± 1.10
Mean scaffold diameter, mm <sup>2</sup>	2.81 ± 0.16	2.77 ± 0.25
Mean lumen area, mm <sup>2</sup>	6.15 ± 0.68	5.60 ± 0.67
Mean lumen diameter, mm	2.69 ± 0.18	2.32 ± 0.37
Malapposed Volume, mm <sup>3</sup>	0.15 ± 0.37	0.06 ± 0.05
NIH area, mm <sup>2</sup>	0.41 ± 0.64	
% of NIH obstruction	3.14 ± 2.04	

# Fantom

## Optical Properties Comparison\*

### Differences and Similarities

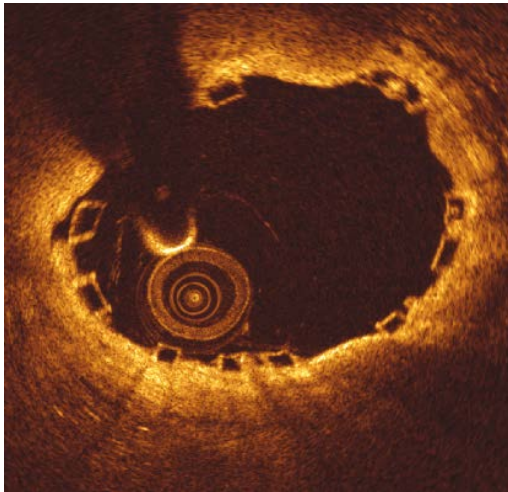
Absorb

ABBOTT

Poly-L-lactic acid

157 $\mu$ m

Crossing profile ~1.5mm



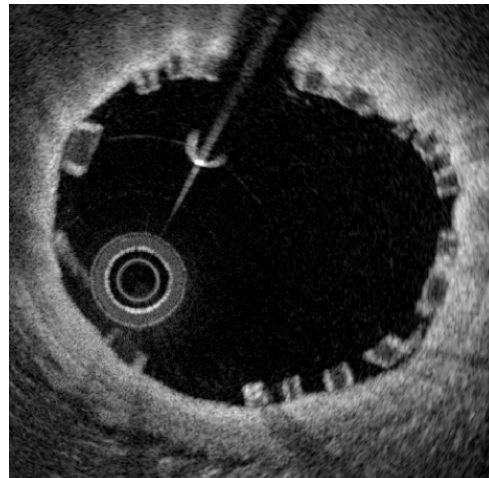
DESolve NX

ELIXIR

Poly-L-lactic acid

150 $\mu$ m

Crossing profile ~1.5mm



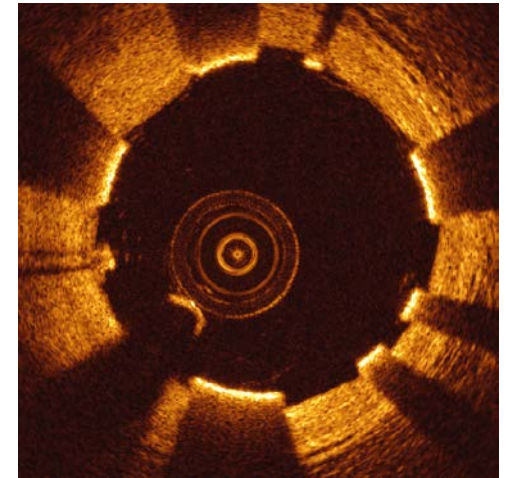
Fantom

REVA MEDICAL

poly(I<sub>2</sub>DAT-co-lactic acid)

125  $\mu$ m

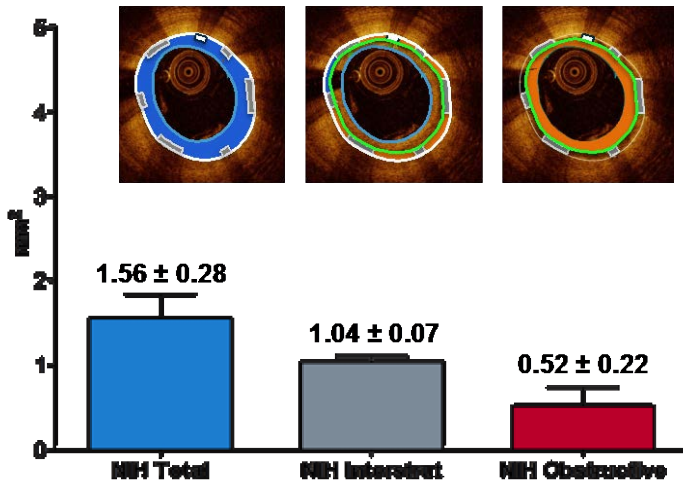
Crossing profile ~1.3mm



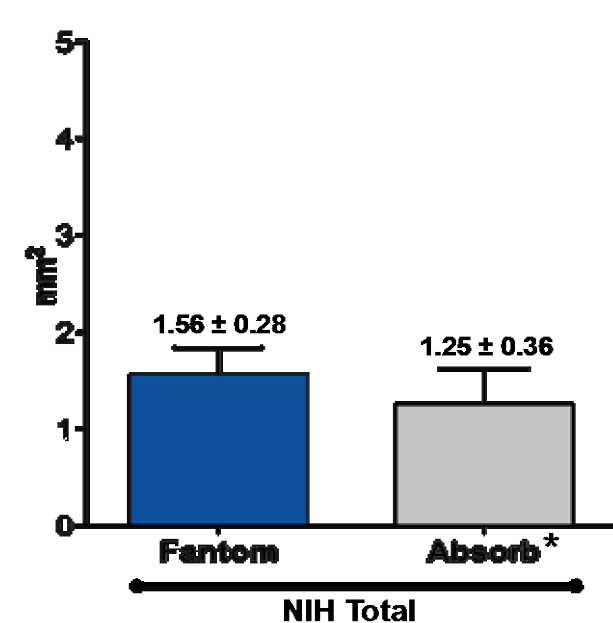
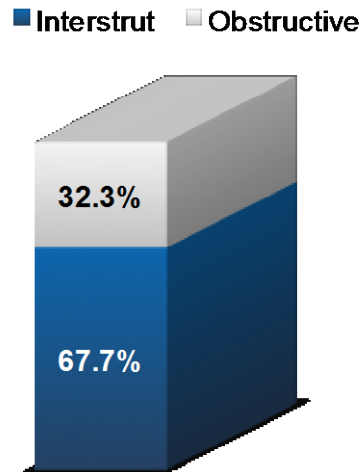
# FANTOM I Main OCT Results

## NIH QUANTIFICATION

NIH Area



NIH Area: % from Total



\* Serruys PW, et al. Circulation 2010;122:2301-2312

\* Serruys PW, et al. Circulation 2010;122:2301-2312

# FANTOM I OCT Results\*

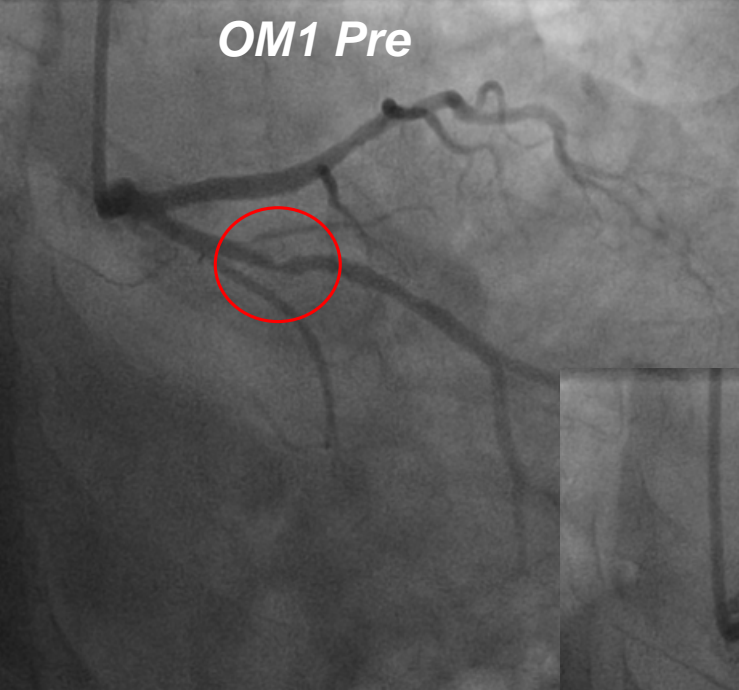
## CROSS-SECTION LEVEL ANALYSIS

	Post-Procedure N=6	4-Month FU N=6	Difference (95% CI)	P
Analyzed Scaffold Length, mm	17.63 ± 2.09	18.45 ± 1.47	-0.81 (-3.68 to 2.05)	0.916
Analyzed cross-sections per lesion	30.0 ± 3.57	31.16 ± 2.31	-1.16 (-5.63 to 3.30)	0.684
Mean Scaffold Area, mm <sup>2</sup>	7.05 ± 0.78	6.55 ± 0.76	0.49 (-0.14 to 1.12)	0.116
Min. Scaffold Area, mm <sup>2</sup>	6.03 ± 0.86	5.49 ± 0.67	0.53 (-0.09 to 1.16)	0.080
Strut Core Area, mm <sup>2</sup>	0.04 ± 0.00	0.03 ± 0.00	0.00 (-0.002 to 0.005)	0.317
Mean Scaffold Expansion, %	125.66 ± 27.96	126.02 ± 19.36	-0.35 (-23.48 to 22.76)	0.893
Mean Lumen Area, mm <sup>2</sup>	6.89 ± 0.68	5.08 ± 0.83	1.80 (1.18 to 2.43)	0.028
Min. Lumen Area, mm <sup>2</sup>	5.63 ± 0.91	3.87 ± 0.82	1.76 (0.62 to 2.90)	0.028
Flow Area, mm <sup>2</sup>	6.51 ± 0.62	5.08 ± 0.83	1.42 (0.75 to 2.10)	0.028
Analyzed struts per scaffolds	251.83 ± 32.65	255.50 ± 19.39	-3.66 (-34.21 to 26.88)	0.917
Freq. of covered struts per lesion, %	N/A	99.14 ± 1.01	...	...
Freq. malapposed struts per lesion, %	2.07 ± 3.69	0.00		
Mean NIH thickness over cov. struts, mm	N/A	0.09 ± 0.03	...	...

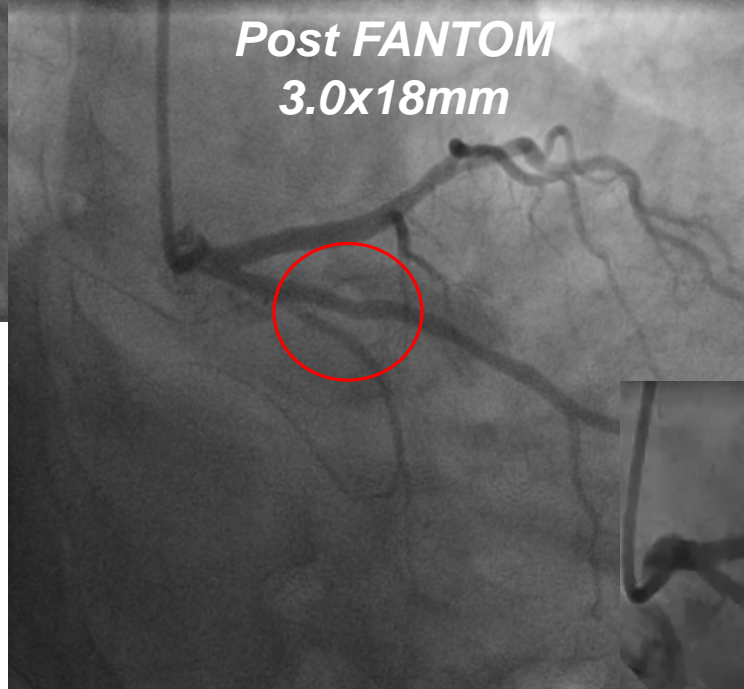


# Example from FANTOM I Trial

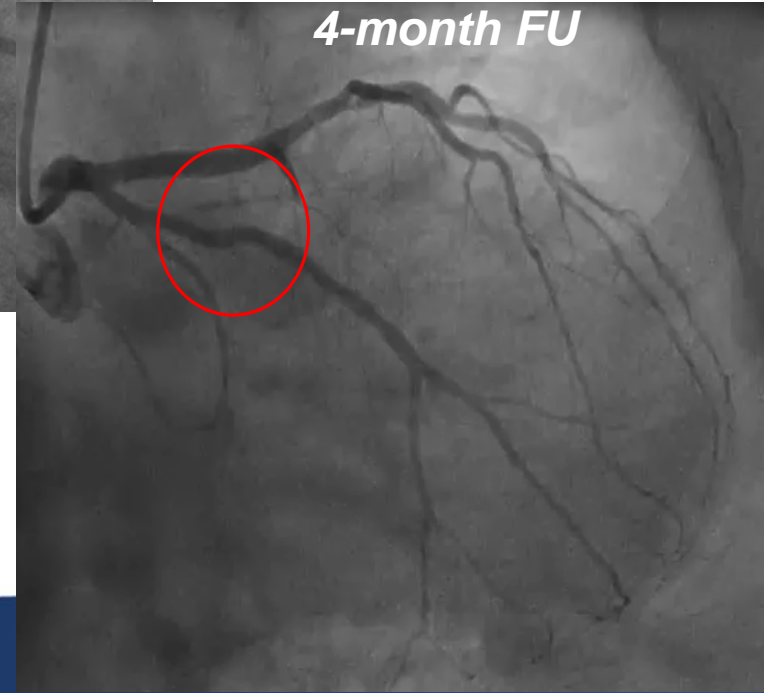
*OM1 Pre*



*Post FANTOM  
3.0x18mm*



*4-month FU*

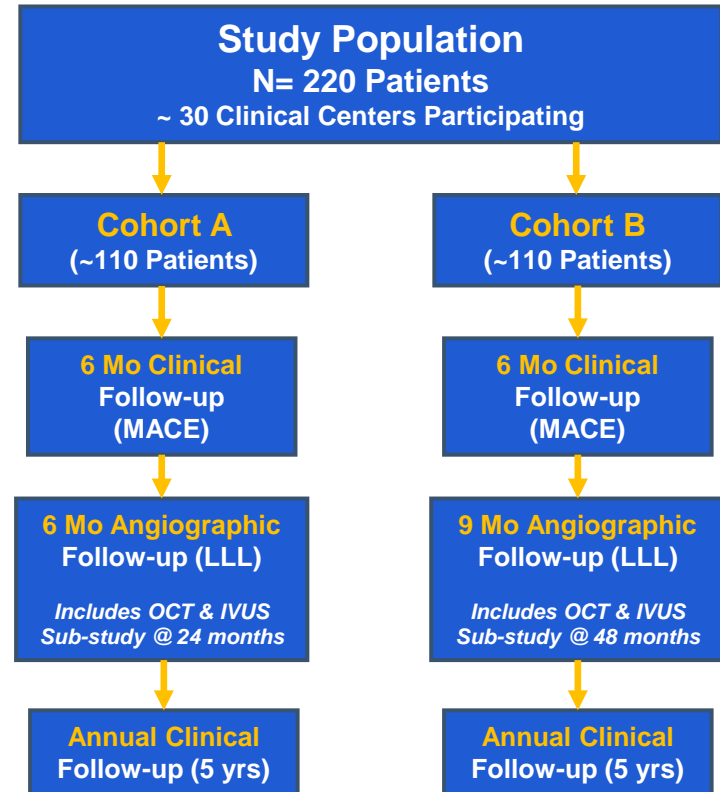


# FANTOM II

## Study Design and Endpoints

- **Study Design**

- Safety and Performance Trial
- Up to 220 patients in 2 cohorts
- 2.5mm to 3.5mm vessels
- Lesion length  $\leq$  20mm
- Angiographic Follow-up
  - Cohort A: 6 Months 110 Pts.
  - Cohort B: 9 Months 110 Pts.
- Serial imaging sub-studies
  - Cohort A: 24 months
  - Cohort B: 48 months



# FANTOM II

## Current Status

- **Cohort A**
  - Enrollment complete September 2015
    - Follow-up ongoing
  - Presentation of primary endpoint targeted for EuroPCR
- **Cohort B**
  - Enrollment ongoing

# FANTOM II

## Interim Results\*

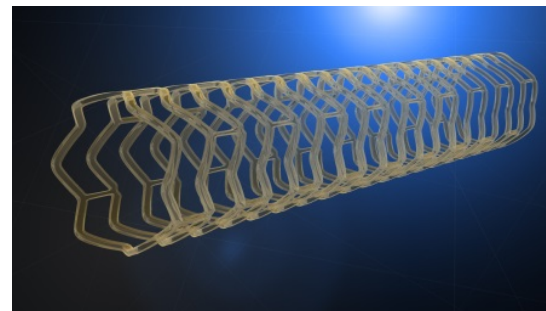
### Acute Procedural Outcomes

Delivery Success <sup>(1)</sup>	96.19%	n=105
Acute Procedural Success <sup>(2)</sup>	99.01%	n=101
Clinical Procedural Success <sup>(3)</sup>	98.00%	n=100

(1) Defined as successful delivery and deployment of the device.

(2) Defined as delivery success with residual stenosis <50% with no immediate (in-hospital) MACE.

(3) Defined as acute procedure success without the occurrence of MACE through 30 days.



### Preliminary MACE Results

Timeframe	Events	N
In-Hospital	0	105
30-Day Follow-up	1 (post-procedure MI)	72
90-Day Follow-up	0	21

# FANTOM Program

## Summary

- **New and interesting features:**
  - Radiopacity
  - Lower crossing profile
  - Faster resorption
  - Direct inflation to intended diameter
- **Initial clinical data suggest:**
  - Good acute performance
    - High rate of device deliverability
    - Minimal residual stenosis and acute recoil
    - Encouraging imaging performance at 4 months (minimal NIH formation, all struts covered and apposed)
    - Low MACE rate
  - More clinical data: EuroPCR 2016!