

## **REVA Medical**

Corporate Presentation November 2018

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## REVA Medical is a leader in bioresorbable polymer technologies for vascular applications

Commercializing proprietary products for Coronary Artery Disease and Peripheral Artery Disease and pursuing Embolization Therapies

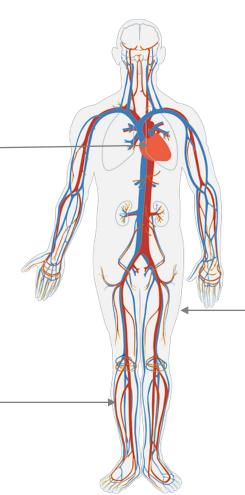
# ~\$9 Billion Market Opportunity in Vascular Applications

#### **Coronary Artery Disease**

- ~\$4 billion global stent market
- CAD is the most common type of heart disease
- Occurs when a build-up of plaque blocks blood flow to the heart

## Peripheral Artery Disease: Below-the-Knee

- \$1.5 billion global market potential
- Common in diabetic patients
- Occurs when a build-up of plaque blocks blood flow to the foot



#### **Embolization Therapy**

- \$1.3 billion global market potential
- Used to treat cancerous and non-cancerous tumors
- Purpose is to block blood supply to tumors to cause them to shrink

## Peripheral Artery Disease: Above-the-Knee

- \$2.1 billion global market potential
- Symptomatic of advanced cardiovascular disease
- Occurs when a build-up of plaque blocks blood flow to the leg

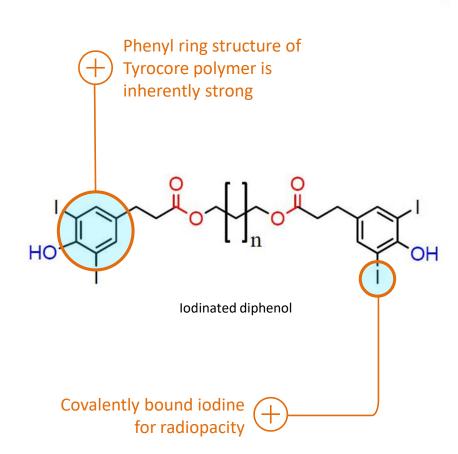
Sources: CAD Market: JP Morgan Equity Research Interventional Cardiology Market Model Feb. 2018. PAD Markets: REVA estimates based on BTK: Nehler M, et al. Epidemiology of peripheral arterial disease and critical limb ischemia in an insured national population. J Vasc Surg 2014;60:686-95. ATK: Murabito J, et al. Temporal trends in the incidence of intermittent claudication from 1950-99. Am J Epidemiol 2005;162:430-37. Population data from United Nations online database. Accessed Dec. 2017. Embolics: Market Research Engine, 2017.

## **REVA's Disruptive Technology: Tyrocore™**

## The World's Only Radiopaque, Bioresorbable Polymer Approved for Use<sup>1</sup> in Medical Devices

#### **Tyrocore Properties**

- Proprietary bioresorbable polymer
- Strong for excellent mechanical properties
- X-ray visible, ideal for vascular procedures
- Naturally biocompatible: derived from the tyrosine amino acid
- Polymer properties are tailorable to meet a clinical application by modifying:
  - Strength
  - Flexibility
  - Degradation time
  - Drug delivery profile



### **REVA's Product Portfolio**

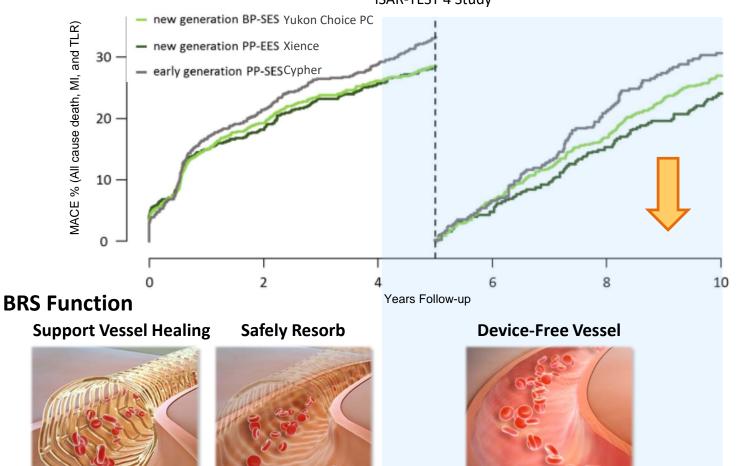
### **Built from Tyrocore**

Disease	Product	Regulatory Status	Commercial Stage
Coronary Artery Disease	Fantom® and Fantom Encore™ Bioresorbable Scaffolds	CE Mark	Available in Europe and Middle East
Peripheral Artery Disease: Below-the- Knee	MOTIV™ Bioresorbable Scaffolds	CE Mark	Limited Launch in Europe
Peripheral Artery Disease: Above-the- Knee	Bioresorbable scaffold	Pre-approval	R&D
Embolization Therapy	Bioresorbable microbeads	Pre-approval	Prototype and Pre- clinical Feasibility



# BRS are Designed to Improve Long-Term Outcomes Compared to Metal DES

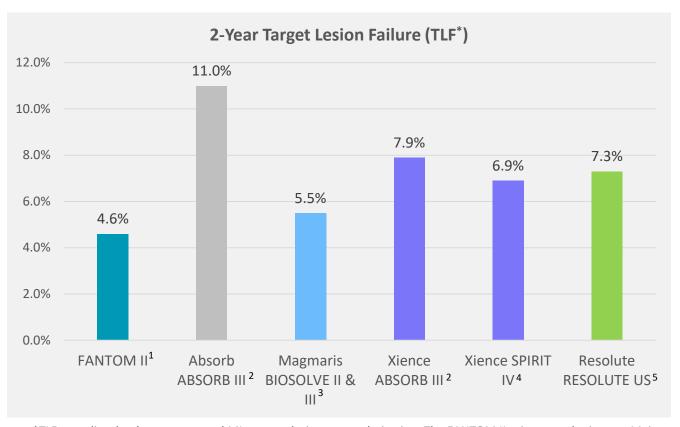
New-Generation DES Continue to Accrue Adverse Events through 10-Year Follow-up
ISAR-TEST 4 Study<sup>1</sup>



3.3% per year increase in MACE with DES<sup>2</sup>

BRS are designed to resorb and eliminate risk of device-related adverse events

# REVA Has Demonstrated Excellent Clinical Performance with Fantom



\*TLF = cardiac death + target vessel MI + target lesion revascularization. The FANTOM II primary endpoint was Major Adverse Cardiac Events (MACE) = cardiac death + all MI + target lesion revascularization. The 24-month MACE rate was 5.0%.

<sup>1)</sup> Data on file at REVA Medical. MACE rates presented: Abizaid, A. New 24-month data from the FANTOM II clinical trial. EuroPCR 2018. 2) Ellis S, Kereiakes, D. A bioresorbable everolimus-eluting scaffold versus a metallic everolimus-eluting stent: ABSORB III. Presented ACC 2017. 3) Haude M, et al Safety and clinical performance of the drug-eluting absorbable metal scaffold in the treatment of subjects with de novo lesions in native coronary arteries at 24-month follow-up: BIOSOLVE-III and BIOSOLVE-III. TCT 2018. 4) Stone G, et al. Randomized Comparison of Everolimus- and Paclitaxel-Eluting Stents 2-Year Follow-Up From the SPIRIT IV Trial. JACC 2011;58(1):19-25. 5) Mauri L. 2-year clinical outcomes from the pivotal RESOLUTE US study. Presented ACC 2012.

## **Fantom Has Also Demonstrated Low Scaffold Thrombosis**

### **Strong Performance through 2 Years**

	Fantom (n=240)	<b>Absorb</b> (n=1,322)	Xience DES (n=686)
Study	FANTOM II <sup>1</sup>	ABSORB III	ABSORB III
Scaffold Thrombosis			
Acute (0 to 1 day)	0%	0.15%²	0.58%²
Subacute (2 to 30 days)	0.4%	0.91%²	0.15%²
Late/Very Late (>31 days)	0.4%	0.76% <sup>2,3</sup>	0% <sup>2,3</sup>

<sup>1)</sup> Abizaid, A. New 24-month data from the FANTOM II clinical trial. EuroPCR 2018. 2) Ellis S, et al. Everolimus-eluting bioresorbable scaffolds for coronary artery disease. NEJM 2015;373:1905-15. 3) Ellis S, Kereiakes, D. A bioresorbable everolimus-eluting scaffold versus a metallic everolimus-eluting stent: ABSORB III. Presented ACC 2017.

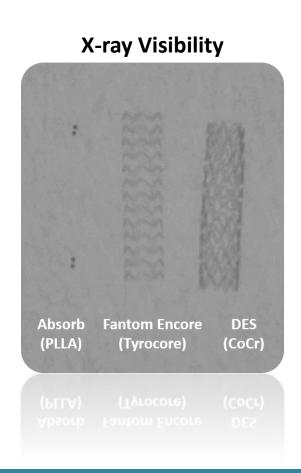
# **REVA Has Launched Its 3<sup>rd</sup> Generation: Fantom Encore**

## Our Tyrocore Polymer Makes Fantom Encore the Most Advanced BRS

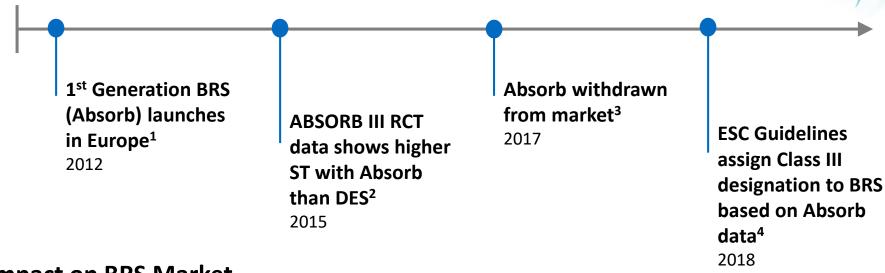
▼ Thinnest strut profile of any commercial, CE Mark BRS for deliverability and vessel healing

95 μm	2.5 mm diameter
105 μm	3.0 mm diameter
115 μm	3.5 mm diameter

- ✓ X-ray visible for treatment accuracy
- ✓ Key ease-of-use features like single-step inflation and higher expansion range
- ✓ Biocompatible for safety
- ✓ Stable for room temperature shipping and storage



## **But Absorb Has Created Significant Headwinds** and Changed The Competitive Landscape

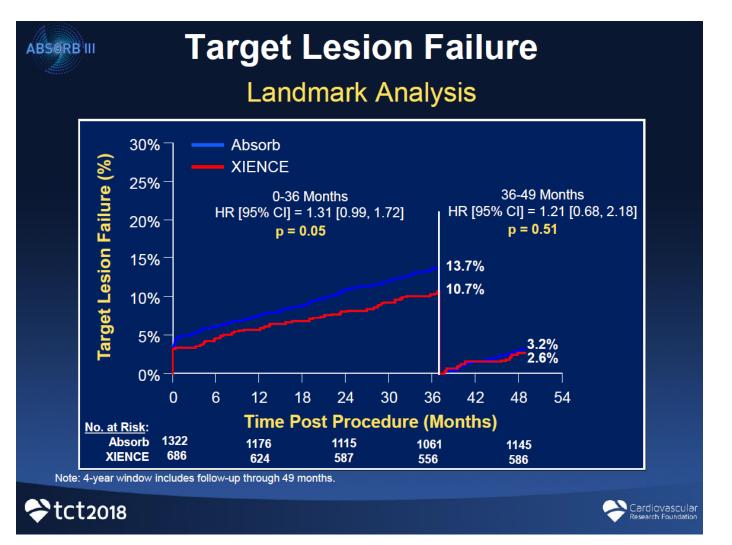


#### Impact on BRS Market

- Competitors with PLLA scaffolds like Absorb gone from European market
- Chinese and Indian competitors with PLLA scaffolds focused on Chinese market with no plans to enter Europe
- Single remaining European competitor with magnesium-based scaffold is redesigning their product and postponing investment in randomized clinical trials

<sup>1)</sup> Abbott press release, Sept. 2012. 2) Ellis S, et al. Everolimus-eluting bioresorbable scaffolds for coronary artery disease. NEJM 2015;373:1905-15. 3) Cox, C. No more Absorb BVS: Abbott puts a stop to sales. tctmd.com 2017. 4) Neumann FJ, et al. 2018 ESC/EACTS guidelines on myocardial revascularization. EHJ 2018;00:1-96.

## Fortunately, Absorb is Beginning to **Demonstrate the Value of Bioresorption**



Absorb and **Xience Show Equivalent Performance** between 3 & 4 **Years** 

## **REVA's Coronary Program Status**

#### **Commercial Results: Progress Every Quarter**

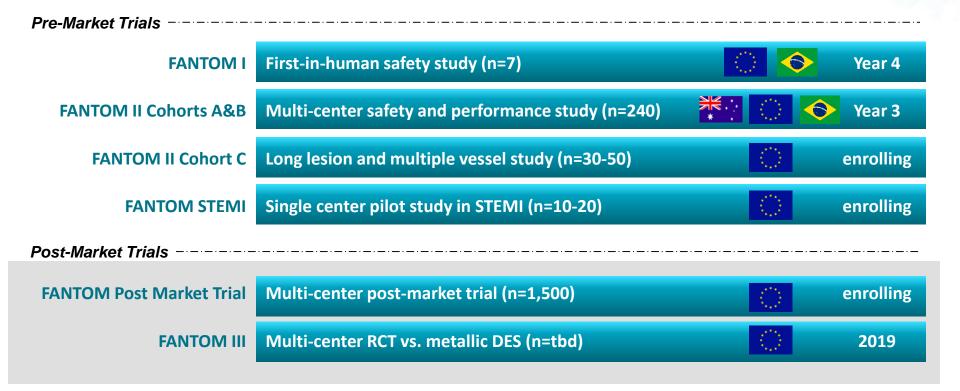
	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018
Targeted Launch	<b>Direct Sales</b> in	n Germany, Switzerland	d, and Austria	<b>Distributor</b> : Turkey	<b>Direct:</b> Belgium and Netherlands <b>Distributor:</b> Italy
Customers		125% increase	78% increase	38% increase	18% increase
Billings <sup>1</sup>	\$105,000	\$98,000	\$128,000	\$149,000	\$185,000
Revenue <sup>2</sup>	\$17,000	\$28,000	\$53,000	\$91,000	\$93,000

With very few competitors remaining in BRS and an advanced 3<sup>rd</sup> generation product, REVA is positioned to win in coronary; however, we now need to drive a change to the ESC Guidelines. Next steps:

- Conduct our 1,500 patient post-market trial\*
- Launch our post-market randomized clinical trial in early 2019\*
- Continue to publish clinical data (3-year results in May 2019 at EuroPCR)

<sup>\*</sup> Product to be purchased commercially for the trial.

# **Building Clinical Evidence to Change the ESC Guidelines and Drive Commercial Use**



## **REVA's Shift in Business Strategy**

- In coronary we will focus in Europe on commercial growth and driving change to the ESC Guidelines
- Our broader business strategy has shifted to:
  - Right-sized operations for slower projected coronary growth
  - Increased focus on peripheral and embolization therapy programs with nearer term value creation opportunities



## **Peripheral Program**

## Peripheral Artery Disease of the Lower Limbs

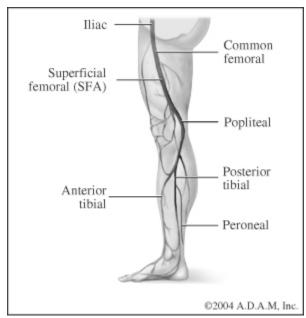
#### Below-the-Knee (BTK)

- Common indications are claudication and critical limb ischemia
- Patients have reduced blood flow leading to wounds, infections, and amputation
- Critical limb ischemia (CLI) is a heart attack for the leg
  - 25% of CLI patients have amputation within one year<sup>1</sup>
  - 25% of CLI patients die within one year¹

#### Above-the-Knee (ATK)

- Common indication is intermittent claudication
- Patients have reduced blood flow causing severe pain and reduced function
- PAD patients have advanced disease which often requires retreatment





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## **Current Treatment Options**

### Revascularization Improves Outcomes but there are Limitations with Current Treatment Options

Treatment	Benefit	Challenge
Balloon angioplasty (POBA)	<ul> <li>Restores blood flow to the vessel</li> </ul>	High rates of restenosis
Drug-coated balloons (DCB)	<ul> <li>Restores blood flow to the vessel</li> <li>Delivers drug to reduce tissue growth during initial vessel healing</li> </ul>	<ul> <li>Lacks mechanical support and sustained drug delivery during vessel healing</li> </ul>
Drug-eluting stents (DES)	<ul> <li>Restores blood flow to the vessel</li> <li>Mechanical support to vessel</li> <li>Sustained drug delivery during vessel healing</li> </ul>	<ul> <li>Challenges with stent fracture</li> <li>Interferes with retreatment</li> </ul>

## Bioresorbable Scaffolds May Improve Treatment for Patients with PAD

#### Value of BRS:

- Provide mechanical support and sustained drug delivery during vessel healing
- Eliminate issues associated with metal fracture
- Preserve retreatment options



## **BRS Shown to Help Patients with PAD**

#### **Below-the-Knee**

- Abbott's Absorb scaffold in BTK¹:
  - 33 patients with critical limb ischemia treated with Absorb
  - 100% of critical limb ischemia patients avoided amputation at 1 year
- Meril's Credence scaffold in BTK<sup>2</sup>:
  - 30 patients with critical limb ischemia treated with Credence
  - 97% of patients avoided amputation at 6 months
- Results compare favorably to 25% 1-year limb amputation rate with conventional treatment<sup>3</sup>

#### **Above-the-Knee**

- Abbott's Esprit scaffold in ATK<sup>4</sup>:
  - 35 patients intermittent claudication patients treated with Esprit
  - 2-Year target lesion revascularization rage of 11.8% compares favorably to
    - DES: 19.5% with paclitaxel-eluting Zilver stent
    - DCB: 30% with paclitaxel-eluting Lutonix DCB

1) Varcoe R, et al. Experience with the Absorb Everolimus-Eluting Vascular Scaffold in Arteries Below the Knee. *JACC CI* 2016;9(16)1721-8. 2) Warwadedar, G. 30-days clinical outcomes of novel thin strut (100 μm) bioresorbable peripheral vascular scaffold system in the treatment of critical limb ischemia of below-the-knee arteries. Presented EuroPCR 2018. 3) Olin, JW. Peripheral arterial disease: current insight into the disease and its management. Mayo Clin Proc 2010;85(7):678-692.4) Lammer J, et al. Bioresorbable Everolimus-Eluting Vascular Scaffold for Patients With Peripheral Artery Disease (ESPRIT I) 2-Year Clinical and Imaging Results. *JACC CI* 2016:9(11)1178-87.

### **REVA's MOTIV BTK Bioresorbable Scaffold**

## 1<sup>st</sup> & Only BRS Approved for Below-the-Knee Revascularization Therapy

- ✓ CE Mark secured in July 2018
- Made with Tyrocore
- ✓ Thin strut profile for deliverability and vessel healing
- ✓ X-ray visible for treatment accuracy
- Strong for vessel support
- Sustained drug delivery to maintain vessel patency



## **Peripheral Milestones**

- Limited launch of MOTIV in Europe, Q1 2019
- Evaluating pathways for geographic expansion
- Polymer R&D for optimal characteristics of scaffolds for ATK applications
- Development of tailored bioresorbable scaffolds for peripheral artery disease applications



# **Embolization Therapy is an Established Procedure with Large Market Opportunity**

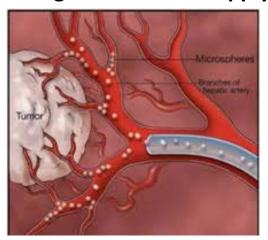
#### **Embolization Overview**

- Purpose to occlude blood vessels to restrict the supply of blood to a tumor in order to shrink the tumor
- Minimally invasive procedures
  - Performed by Interventional Radiologists
  - Particles are delivered through catheters guided by x-ray in a cath lab

#### **Common Indications**

- Cancerous tumors (oncology)
  - Hepatocellular carcinoma (liver cancer)
- Non-cancerous tumors (gynecology and proctology)
  - Uterine fibroids in women
  - Benign prostatic hyperplasia in men

#### **Blocking Tumor Blood Supply**



#### **Large Market Opportunity**

- 500,000 new cases of hepatocellular carcinoma are diagnosed every year<sup>1</sup>
- 75% of women will develop uterine fibroids in their lifetime<sup>2</sup>
- 50% of men will develop BPH by age
   60³

## **REVA's Technology Fills an Unmet Need**

#### **REVA Has the Only X-ray Visible and Bioresorbable Embolic Microbead**



Permanent

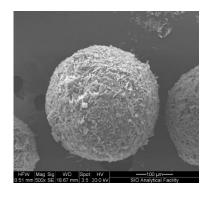
Absorbable

### **REVA's Bioresorbable Embolic Microbeads**

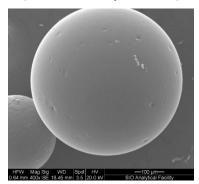
## REVA's Polymer Technology Meets All Requirements of the Ideal Embolization Particle

- ✓ X-ray visible for treatment accuracy
- Compressible and buoyant for easeof-use and injectability
- ✓ Biocompatible for safety
- ✓ Loadable for drug delivery
- Resorbable to avoid chronic inflammation and allow retreatment

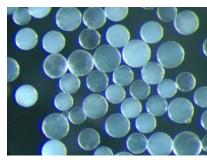
**Dry microbeads** 



Hydrated microbeads (~ 2 min rehydration)

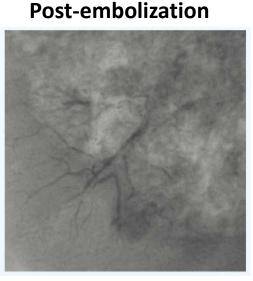


Various sizes achieved

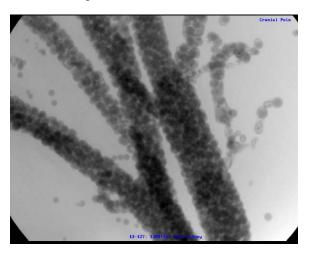


## Safety and Efficacy Demonstrated in Pre-Clinical Study

- Renal embolization in swine model
- Size reduction of treated tissue observed in all animals
- No evidence of thrombosis, hemorrhage, or inflammation



**Densely Packed Microbeads** 



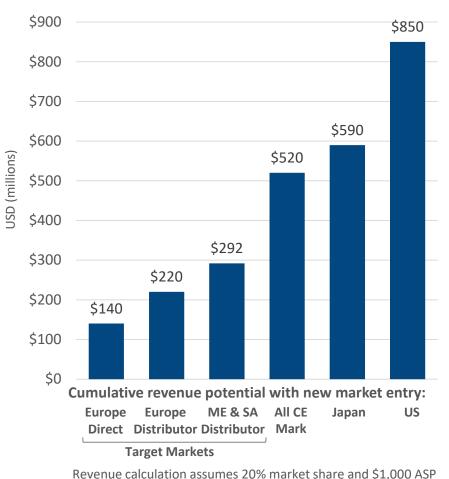
## **Embolization Therapy Milestones**

- Finalize product design
- Complete bench and pre-clinical testing
- Evaluate 510k as path to US clearance
- Conduct early feasibility studies of small molecule and large molecule drug-loaded microbeads targeting oncology

## **Innovating to Build a \$1+ Billion Company**

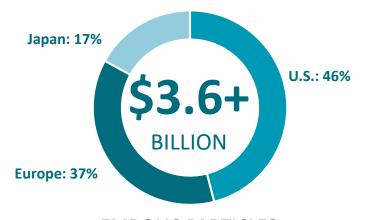
#### **Coronary Revenue Potential**



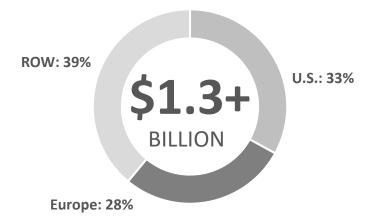


## Peripheral and Embolics Market Opportunities

#### **BELOW AND ABOVE-THE-KNEE**



#### **EMBOLIC PARTICLES**



Sources: Coronary estimate: DRG MedTech 360 Market Report IC Devices Europe, June 2015; . PAD Markets: REVA estimates based on BTK: Nehler M, et al. Epidemiology of peripheral arterial disease and critical limb ischemia in an insured national population. J Vasc Surg 2014;60:686-95. ATK: Murabito J, et al. Temporal trends in the incidence of intermittent claudication from 1950-99. Am J Epidemiol 2005;162:430-37. Population data from United Nations online database. Accessed Dec. 2017. Embolics: Market Research Engine, 2017.

## **Experienced Management Team**

#### **Reggie Groves**

CHIEF EXECUTIVE OFFICER







#### **Brandi Roberts**

CHIEF FINANCIAL OFFICER







#### **Jeffrey Anderson**

SVP, CLINICAL AND REGULATORY AFFAIRS







#### **Carmelo Mastrandrea**

VP, EUROPE







#### Joann Yao

SR. DIR., GLOBAL MARKETING







### **Board of Directors**

**Ray Larkin**, Chairman (2017– ) Eunoe Inc, Bentley Labs, Nellcor Puritan Bennett

**Reggie Groves**, CEO (2017– ) Medtronic, McKinsey

**Bob Stockman**, Co-Founder (1999– ) loptex, "A" Company, Critikon

**Brian Dovey** (2001– ) Domain Associates, Rorer Group

**Robert Thomas** (2010– ) Citigroup Australia, multiple boards

**Ross Breckenridge**, MA FRCP PhD (2015– ) Silver Creek Pharmaceuticals, University College London Hospital

**Steve Oesterle** (2018– ) Medtronic, NEA, Temasek, Harvard & Stanford















## **REVA Investment Highlights**

DISRUPTIVE TECHNOLOGY	<ul> <li>Proprietary x-ray visible, bioresorbable polymer technologies for vascular applications</li> <li>Strong IP patent protection extending 2029-2034</li> </ul>	
LARGE, PROFITABLE MARKETS	<ul> <li>\$4 billion coronary stent market ripe for innovation</li> <li>\$3.6 billion market opportunity for BRS to treat below- and above-the-knee peripheral artery disease</li> <li>\$1.3 billion market opportunity for embolization therapy in oncology and other tumors</li> </ul>	
COMMERCIALIZING FANTOM	<ul> <li>Commercial: Germany, Switzerland, Austria, Turkey, Italy</li> <li>In progress: Additional countries in Europe, Middle East, and Asia</li> </ul>	
LAUNCHING IN PERIPHERAL MARKET	<ul> <li>Limited launch of MOTIV in 2019 in select centers         <ul> <li>Initial focus on short lesions and dissections</li> </ul> </li> <li>Evaluating pathways for expansion in Asia and US</li> <li>Developing crush recoverable polymer for above-the-knee peripartery disease</li> </ul>	
CORPORATE FACTS	<ul> <li>Listed on Australian securities exchange in 2010 (ASX: RVA.AX)</li> <li>Cash: \$7.1 million<sup>1</sup></li> <li>Mkt Cap: \$73 million<sup>2</sup></li> </ul>	

• Potential US stock market listing 2019; SEC registered



