

# Corporate Overview

November 2019

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Shockwave Medical peripheral products are Rx only. Please reference the Instructions for Use (www.shockwavemedical.com) for more information on indications, contraindications, warnings, precautions and adverse events.

In the United States, Shockwave C<sup>2</sup> Coronary IVL catheters are investigational devices, limited by United States law to investigational use.

Shockwave C<sup>2</sup> Coronary IVL catheters are commercially available in certain countries outside the U.S. Please contact the local Shockwave representative for specific country availability. The Shockwave C<sup>2</sup> Coronary IVL catheters are indicated for lithotripsy-enhanced, low-pressure balloon dilatation of calcified, stenotic de novo coronary arteries prior to stenting. For the full IFU containing important safety information please visit: https://shockwavemedical.com/clinicians/international/coronary/shockwave-c2/



Seeking to transform the treatment of calcified cardiovascular disease

Seeking to establish a new standard of care through intravascular lithotripsy (IVL)

Differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque

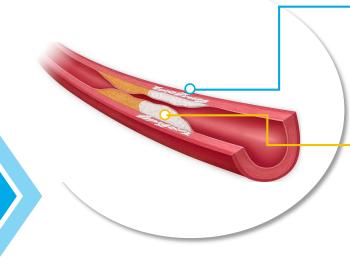


#### Goal of Vascular Intervention: Restore Vessel Size and Blood Flow

#### Atherosclerosis

Disease of aging in which arteries become narrowed ("stenotic") by the progressive growth of plaque.

Calcium in atherosclerotic plaque can prevent therapies from opening the stenotic artery.

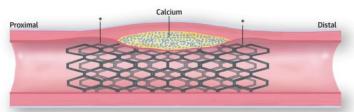


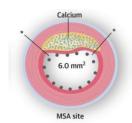
#### Medial ("Deep") Calcium

Calcification in middle layer (associated with stiffening)

#### Intimal ("Superficial") Calcium

Calcification close to the inner surface of the artery (associated with obstruction and embolization)





\* Stent struts

Calcified Arteries Resist Expansion Resulting in More Complications and Vessel Damage

# Common Risks with Traditional Methods to Treat Calcified Atherosclerosis

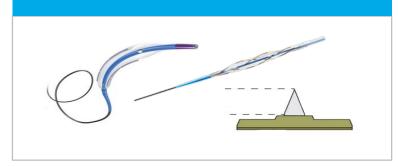
Standard Balloons (> 15 atm)



**Atherectomy** 



Specialty Balloons (cutting & scoring)



#### Risks

- Dissection
- Perforation
- Restenosis (from tissue damage)

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- Embolism
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- Dissection
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There is a Need for Devices to Safely and Easily Prepare Calcified Arteries

# Lithotripsy Has a History of Safely Cracking Calcium

#### Lithotripsy

Method has 30 years of success for safe elimination of kidney stones

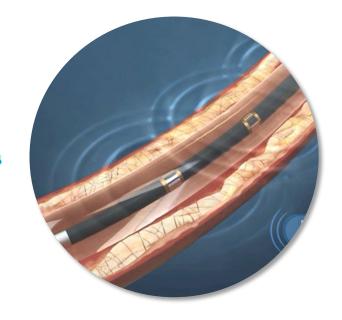
Sonic pressure waves preferentially crack calcium without harming soft tissue

Shockwave's Cardiovascular Lithotripsy

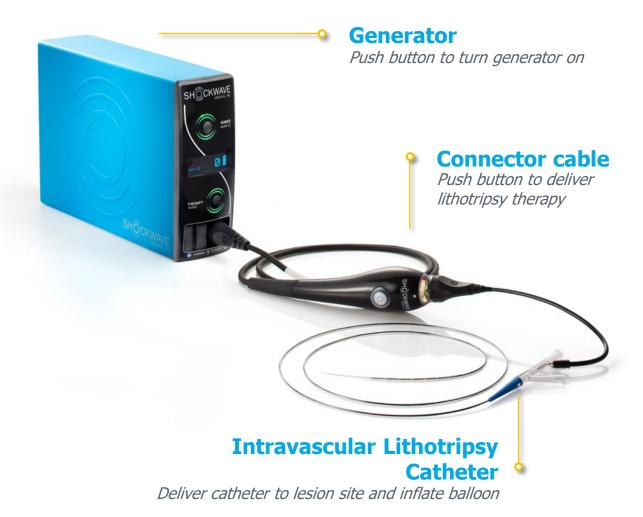
Miniaturized, localized treatment

Sound waves pass through soft tissue to crack calcium

Vessel expands under low pressure



# Our Solution: Intravascular Lithotripsy



Miniaturized local treatment

Expands vessel under low pressure

Treats both superficial and deep calcium

Improves safety; no harm to soft tissue

Improves stent expansion

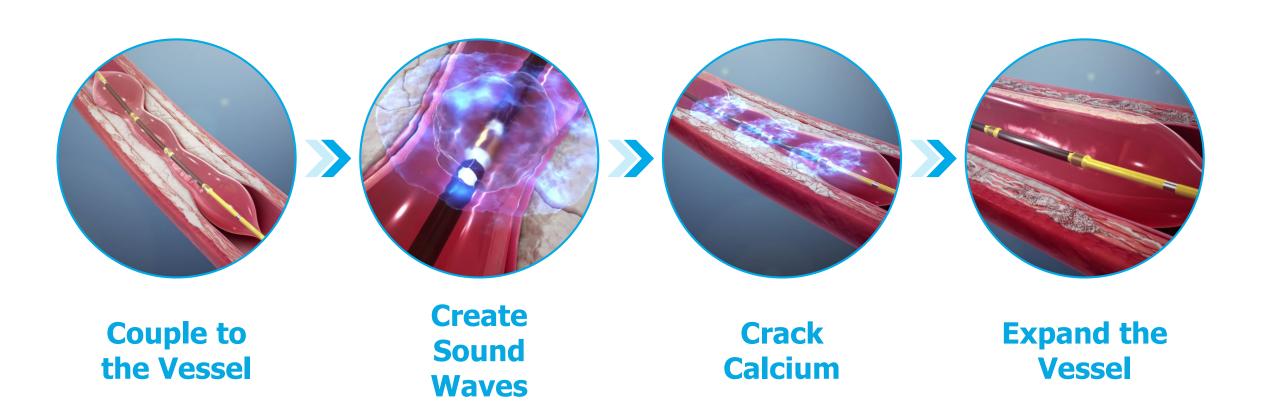
Easily integrates into interventional practice

Expands access to interventional techniques

Meaningful cost-saving potential

# IVL is Uniquely Able to Address Superficial and Deep Calcium

Low pressure inflation reduces dissection risk

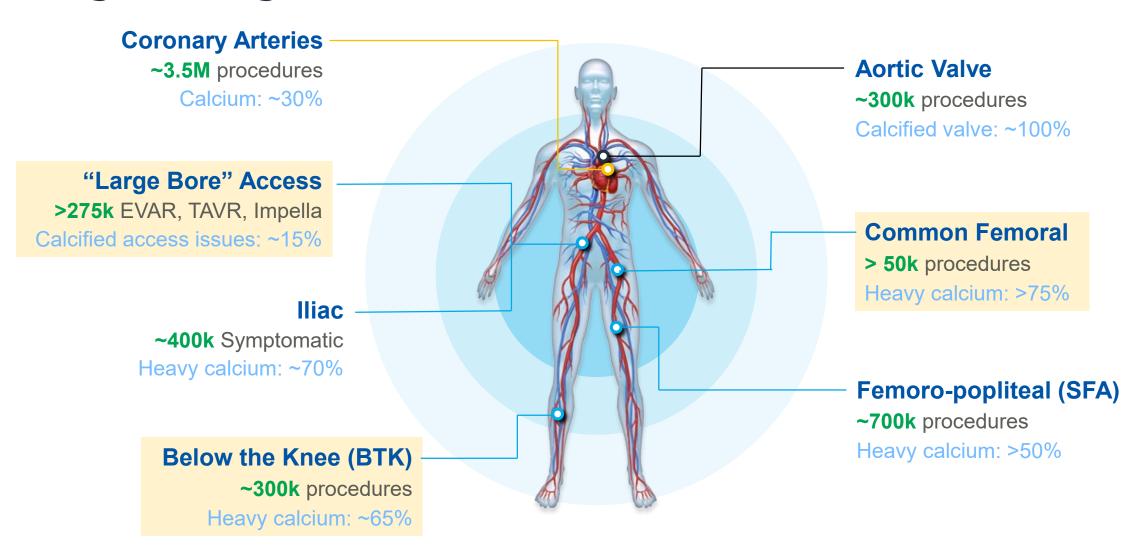


Standard Interventional Techniques Encourage Adoption

# Why Shockwave

Safe	Treating most complex calcified anatomies while minimizing complications
Simple	An interventional operator can use IVL (OR: No learning curve)
Effective	Unique mechanism of action that cracks both medial and intimal calcium

# Targeted Segments Have a TAM of >\$6 Billion<sup>1</sup>



<sup>1.</sup> Annual procedures in the United States and internationally (nine European countries, five Asian countries), according to DRG and Company estimates; Proportion of annual procedures associated with calcified disease, according to Yost, M. L., Prevalence and Significance of Calcium, Vulnerable Plaque and Plaque Morphology in Peripheral Artery Disease (PAD). Beaufort, SC: THE SAGE GROUP; 2016 (for femoropopliteal, BTK, TAVR and common femoral) and Company estimates based on multiple occlusive disease studies (for iliac and EVAR). Aortic Valve annual procedures in 2025 according to the Journal of Thoracic Disease, 2017;9(6):1432 1436.

#### IVL has Potential to Grow Markets and Take Share

Below-the-Knee

#### **Peripheral Artery Disease (PAD) Coronary Artery Disease (CAD) Aortic Stenosis (AS)** Market Growth Market Growth Market Growth Iliac Left Main Very Old/Frail Common Femoral Ostial Lesions Contraindicated for TAVR High-Risk PCI "Large Bore" Access Co-Morbidities Below-the-Knee "Standard" Cardiologists Young Patients Potential Shockwave Share Gain Potential Shockwave Share Gain Potential Shockwave Share Gain All cross-able lesions TAVR Procedures Femoropopliteal (SFA)

# IVL's Platform Technology

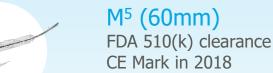
Multi-Year pipeline of vascular & structural heart products







### **Peripheral**



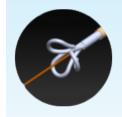






Ongoing global studies to support U.S. and Japan approval<sup>1</sup>

Valve<sup>2</sup>

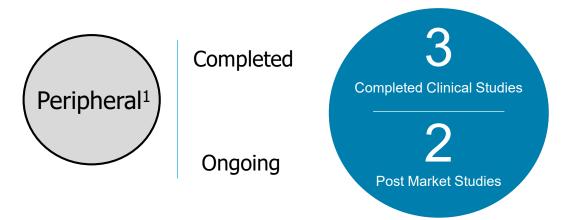


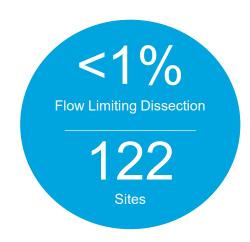
TAVL
Treat calcific leaflets,
delay replacement

<sup>1.</sup> Enrollment initiated in Q1 2019 for CAD III and Q4 2019 for CAD IV

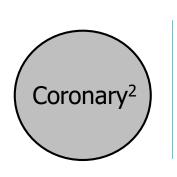
<sup>2.</sup> Clinical development stage

### **Shockwave Clinical Study Highlights**









Completed

Ongoing







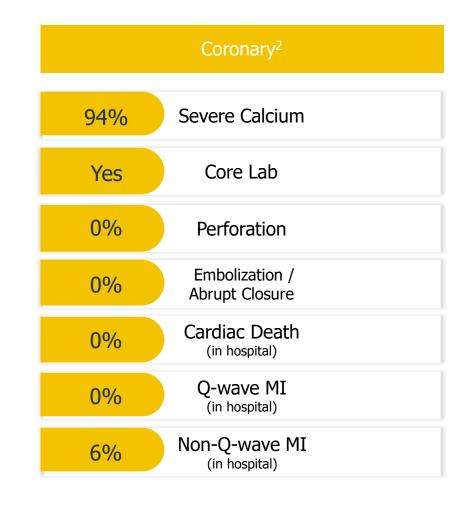
2. Disrupt CAD I - IV Studies; Data on file at company. Data as of November 11, 2019

<sup>1.</sup> Disrupt PAD I - III and BTK Studies Data on file at company. Data as of November 11, 2019

### Key Advantage of Shockwave IVL: Safety

Demonstrated Safety Profile of IVL Delivered Via a Low-Pressure Balloon

Peripheral <sup>1</sup>		
85%	Severe Calcium	
Yes	Core Lab	
0%	Perforation	
0%	Embolization	
0%	Abrupt Closure/ Slow Flow	
1.7%	Bail-out Stenting	



<sup>1.</sup> Disrupt PAD II Study, data on file at company.

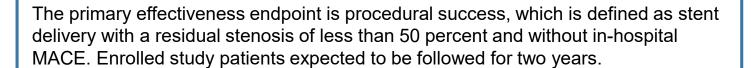
<sup>2.</sup> Disrupt CAD II Study, data on file at company.

# Disrupt CAD III Trial — Enrollment Ongoing

Multicenter, prospective, non-randomized trial (50 clinical sites in U.S. and Europe)

392 Pivotal Patients

Assessed Post Procedure and at 30 Days



FDA Approval of C<sup>2\*</sup>

**Anticipated Commercialization** H1 2021 U.S.

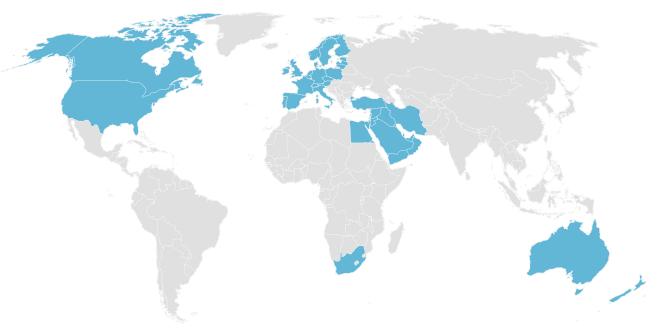
## Commercialization Strategy

Two paths for growth: procedure share and expansion into new indications

#### **United States**

Mix of direct sales reps and clinical specialists

Low service burden enables cost efficient sales model



#### **International**

Commercial sales in over 35 countries

Direct sales Germany, Austria and Switzerland

Distributors cover other European countries as well as Africa, ANZ, Asia, Canada and the Middle East

>80 sales and marketing professionals worldwide1

Similar Call Points for Vascular IVL Catheters Allowing Further Leverage of Field Sales Team

## Multiple Catalysts for Growth

Near Term Catalysts (2020)

Medium Term Catalysts (2021) Long Term Catalysts (2022+)



#### Peripheral

- S<sup>4</sup> launch
- International large bore
- International BTK

- LX launch
- PAD III clinical data
- ► M<sup>5+</sup> Launch
- ► S<sup>4+</sup> Launch

- BTK clinical data
- NG PAD System



#### Coronary

- CAD III data
- New countries

- U.S. launch
- C<sup>2+</sup> launch

- Japan launch
- China launch
- Broader / RCT data (new trial)
- Health economic studies

### IVL Drives Economic Value for Hospitals



**Time Savings** 



**Procedure Savings** 



**Hospital Savings** 

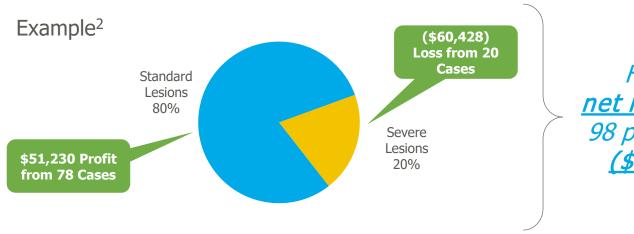
Severe lesions represent

20% of interventions, but
are very expensive to
treat...resulting in a net
loss

Reduced time required by physicians to understand and adopt our system

Reduced need for complex, risky and expensive procedures for additional devices and potential complications

Reduced costs associated with complications that lead to high supply costs and lower profitability



Hospital

net loss for the

98 procedures:
(\$9,198)1



Dartmouth-Hitchcock, "Lesion complexity drives the cost of superficial femoral artery endovascular interventions," J Vasc Surg. 2015 October; 62(4): 998–1002. 10.10.16/j.jvs.2015.04.450 and VIVA 2017 Presentation by Richard Powell "How Does Tracking Quality, Training, Experience and Outcomes Lower Procedural Costs Across Vascular Specialties?", Slides 15 & 17

 Information on loss is for illustrative purposes only; actual results & data may differ

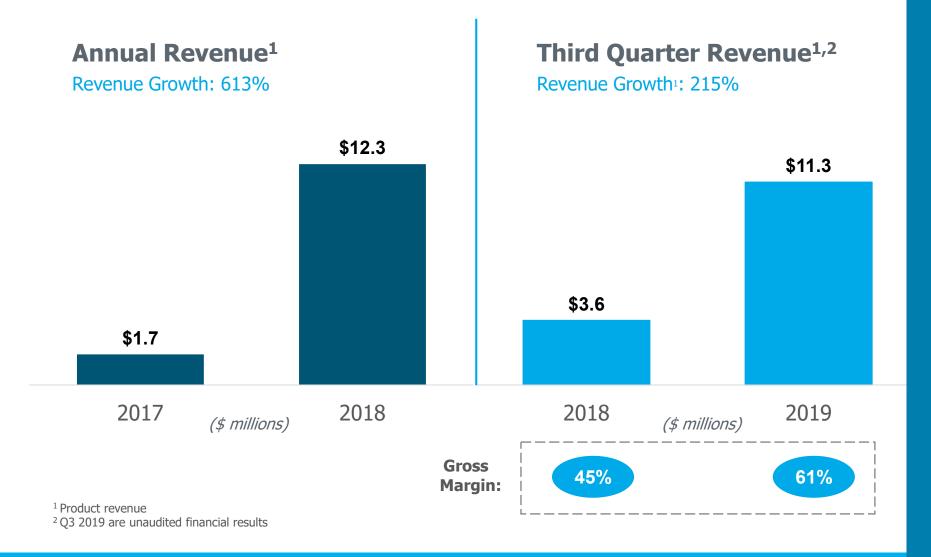
<sup>2.</sup> Example may not be representative of all hospitals

## Operational Excellence

- Headquarters located in Santa Clara, CA
- European subsidiary in Germany
- Third party logistics provider based in the Netherlands
- 260 employees<sup>1</sup>
- Lean manufacturing expected to drive margin expansion
- 85 manufacturing employees<sup>1</sup>
- Specialized sales force fosters deep relationships
- Marketed products in more than 35 countries and growing
- Robust IP portfolio of 81 issued and 40 pending patents<sup>1</sup>



# Strong Financial Profile



- Revenue growth of 215% year over year
- U.S. revenue grew by 204% to \$6.2MM
- International revenue grew by 229% to \$5.1MM
- Balance Sheet (as of September 30, 2019):
  - Cash, cash equiv. and short-term investments: \$114.1MM
  - Debt: \$15.4MM

Q3 2019 Performance<sup>1</sup>

#### **Growth Drivers**

#### Advance Clinical Evidence

- Demonstrate that IVL is standard of care for calcified arteries
- Expand indications
- Improve economic story

# **Expand Commercial Capabilities**

- Increase direct and distributor field sales organization
- Grow across indications and geographies
- Initiate broader Medical Affairs initiatives

# **Scale Business**

- New products
- Increase interventional procedures by addressing unmet clinical needs
- Partnerships for mutually beneficial outcomes
- Scale efficiencies



## **Investment Highlights**

# ADDRESSES LARGE UNMET CLINICAL NEED

Advancing proprietary IVL System for multiple large **addressable markets totaling \$6B+** 

**Optimizes existing treatment** with improved outcomes and **expands market** with superior, effective products

# DIFFERENTIATED AND COST EFFECTIVE PLATFORM

Unique mechanism of action that cracks both medial and intimal calcium

**Cost saving potential** through reduced complications and minimal required time and training for physicians

#### **STRONG PIPELINE**

Ongoing clinical programs to **expand geographies and indications** and build a robust body of clinical evidence

Platform IVL **Technology leverageable** for new products to satisfy additional significant unmet clinical needs



# We Crack Calcium