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# **Ischemic Heart Disease**

#### Prevalence: 250 million people worldwide

- Leading cause of death for women and men
- Includes heart attacks and conditions that reduce blood flow to the heart
- > \$80 billion of US healthcare costs / year

# Misdiagnosis

### Major problem for women

- Less likely to get an accurate diagnosis
- Less likely to get appropriate testing
- More likely to die from a heart attack

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# Bio

#### Samit Shah MD, PhD

Dr. Shah is an Interventional Cardiologist who specializes in the invasive evaluation of coronary artery disease, coronary physiology, and complex coronary interventions.

His scholarly work has focused on the outcomes of cardiovascular interventions and the invasive assessment of coronary physiology. He is the national principal investigator of the <u>DISCOVER INOCA multi-center registry</u> and the <u>Vahaticor</u> <u>SERRA-I A-Flux Coronary Sinus Reducer Early Feasibility Study</u> for coronary microvascular disease.

His research is supported by:





0 3 FALL 2024 Samit Shah samit.shah@yale.edu Women's Health Research at Yale

# Every year > 10 million people in the United States seek medical attention for chest pain





Stents **1M** 



Heart Surgery **400K** 

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# 2004 to 2024

# Ischemia with Nonobstructive Coronary Arteries (INOCA)

- At least 3-4 million people in the United States
- More common in women (> 70%)
- Cannot be diagnosed with routine testing



**Coronary Microvascular Disease (CMD)** 



# **Coronary Vasospasm**

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A 38-year-old woman goes to the ER with chest pain

#### Urgent heart catheterization due to suspected heart attack



AngioView

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#### No blockages O<mark>ngoing chest pain</mark>



#### Coronary Vasospasm Complete relief with medication





**Our Method:** Coronary Function Testing



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Reference: Cigarroa et al., J Am Heart Assoc 2024 Oct;13(19):e035852 Jeronimo et al., Cardiovasc Revasc Med 2023 Aug:53:45-50 Ahmad et al., Circ Cardiovasc Interv 2023 Jul;16(7):e012387

# No Diagnosis

- Repeat testing
- Ongoing symptoms
- Spend \$45,625 / patient
- Higher mortality

# Diagnosis

- Targeted therapy
- Improved symptoms
- Save \$23,793 / patient
- Better prognosis
- Class I Guideline Rec

# angiomedix **Our Solution: AngioView**



# Drug: Acetylcholine Chloride

- Stable for 28 days at room temperature

**Device: Slow Inject Syringe** 2



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• Used to test the endothelium (or lining) of coronary arteries • No formulation available for cardiovascular use (off label) • Solves a major bottleneck that limits coronary function testing

 Rapid injection of acetylcholine chloride can cause arrhythmias • Slow injection is safe and can be performed routinely • Injected through standard coronary artery catheters

# Market Opportunity (United States)

> 10 MM people in the U.S. are evaluated for chest pain each year ~40% of patients with unexplained symptoms may have INOCA



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\$600 ASP **\$1.9B Market** 

**Global Market** is 6x

# Go to Market Strategy



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#### Licensing & **Field Support**

**Secondary Market** 

**Slow inject syringe for** other medications

Protamine, Furosemide, Amiodarone, etc

# Key Advantages



- SAFE: Tested in > 13,000 patients
- Shelf stable for 28 days
- Apply for new procedure reimbursement



# **IP Strategy**

Patents Filed/Pending
Acetylcholine chloride formulation and use

Slow Injection Syringe
(2 Designs)

#### **Market Exclusivity**

- FDA New Chemical Entity (NCE)
  - Up to 5 years

Reference: Takahashi et al., J Am Coll Cardiol, 2022 Jun 21;79(24):2367-23787

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# Competition







## Miochol Eye Drops

Off label

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- Time / labor for compounding
- No reimbursement

#### Non-invasive Tests

- Detect ischemia
- Complimentary test (needs AngioView for diagnosis)

#### **Invasive Tests**

- Pairs with AngioView
- Complimentary technology (microvascular test)



• 2023 Q4 Provisional Patent filed for Acetylcholine formulation

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• 2025 Q1

**Prototype and** file provisional patent for **AngioView** Syringe

• 2025 Q1 Formulation & • Regulatory Filing Stability testing for

acetylcholine chloride

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• 2025 Q3 • Fee waiver eligible • 2025 Q2 FDA 505(b)(2) New **Drug Application** (new indication of an existing drug)

#### • 2026 Q1

 Market launch for AngioView