# Transforming the Management of Critical Bleeding

Introductory Investor Deck







## **Clinical Need**



**Uncontrolled bleeding** is a major cause of morbidity and mortality in surgery, trauma, intensive care, childbirth, etc.

Systemic bleeding is caused by **defects in the blood itself**.

Targeted transfusion applies **one of four treatments** to control systemic bleeding.

Targeted transfusion requires understanding the specific blood defect to determine the appropriate treatment.



Existing diagnostic tests are slow, incomplete, complicated, and expensive.



## **Our Solution**

The Quantra<sup>TM</sup> System helps to diagnose the cause of bleeding and thereby enables targeted transfusion.

Quick

Results in < 15 minutes

Near the patient

Clear

Outputs tied to therapy Simple dial display



Measures all four causes of bleeding

**Easy** 

3 Steps
Plug and Play Operation
Automated Quality Control

**Economical** 

No dedicated personnel

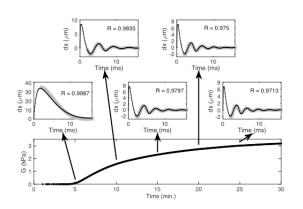


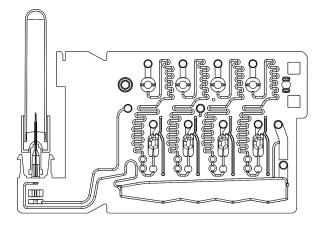


## **Enabling Technologies**

### Ultrasonic Stiffness Measurement

Patented technology measures evolving clot stiffness by ringing the clot like a bell.





## Differential Cartridge

Single use, four channel cartridge uses different reagents to measure four different clotting components.

## **Dial Display**

Intuitive display provides comprehensive, actionable results at a single glance.





## Targeted transfusion improves outcomes & lowers cost

#### **Better Outcomes**

Scientifically managed transfusion of blood products **reduces**:

- Mortality by 2.5x
- Myocardial infarction by 3.0x
- Renal failure by 13.0x
- Stroke by 3.6x<sup>1,2</sup>

#### **Lower Cost**

- Targeted transfusion of blood products saves hospitals \$50k to \$100k per month, while improving patient care<sup>4,5</sup>
- Hospital stay reduced by 0.8 days for every unit of unnecessary transfusion eliminated<sup>3</sup>



<sup>&</sup>lt;sup>1</sup> Relationship of blood transfusion and clinical outcomes in patients with acute coronary syndromes. JAMA, 2004

<sup>&</sup>lt;sup>2</sup> Effect of peri-operative red blood cell transfusion on ... mortality following CABG surgery. Eur. J. Cardiothorac. Surg., 2005

<sup>&</sup>lt;sup>3</sup> Blood Transfusion is Associated with Increased Resource Utilization. Annals of Cardiac Anesthesia 2008

<sup>&</sup>lt;sup>4</sup> Cost reduction of perioperative coag. management in cardiac surgery: value of bedside TEG. Eur J Cardiothorac Surg, 2007

<sup>&</sup>lt;sup>5</sup> The clinical and cost effectiveness of TEG/TEM. Health Technology Assessment Report 11, 2008

## Quantra Addresses \$1.0B Global Market

#### **Instrument Sales Model**

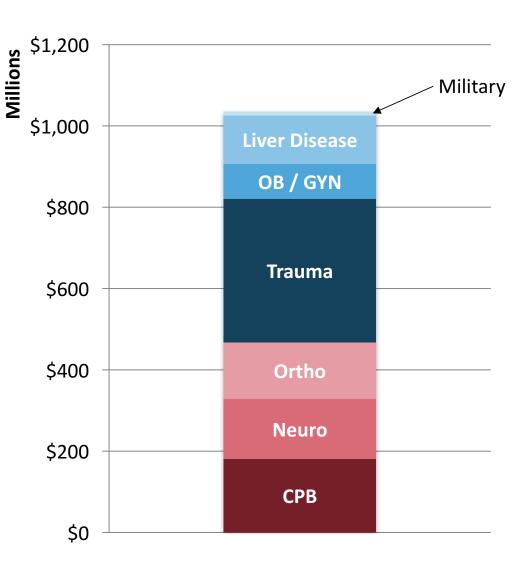
- \$20,000 for Quantra
- \$75 per cartridge

#### **Reagent Rental Model**

- Quantra loaned at no cost
- \$93 per cartridge

#### **Key Points:**

- US and EU are initial markets
- Targeting 85% gross margin on cartridges
- Reimbursed via existing DRGs (Diagnostic Related Groups)





## **Market Penetration Strategy**

#### **Initial Targets**

- Large medical centers (over 300 beds)
- Centers performing complex cardiac, spine, and trauma surgeries

#### **Approach**

- Sales calls to both surgeons and anesthesiologists
- Sales specialists will expand usage to additional applications

#### **United States:**

- Direct sales force
- Targeted rollout
- Initial 12 person sales force, growing to 50 in five years
- Buyer chooses instrument purchase or reagent rental
- Cost reimbursed by existing DRG and offset by transfusion reduction

#### **European Union:**

- Distributor sales model
- Distributors purchase inventory at 30-40% discount
- Targeted rollout by country



## **Competition**

	Existing Products	Next Gen Products	HEMOSONICS  Quick, Clear, Complete.
Results in 15 min.?	X	×	<b>✓</b>
Comprehensive?	X	×	✓
Efficient workflow?	X	×	✓
Intuitive display?	X	×	✓
Meets lab reqs.?	X	Unknown	<b>✓</b>
Publications?	1	×	In Process
Available?	✓	EU Only	Launch 2017
	TEG 5000 ROTEM δ  Limited Adoption	TEG 6s ROTEM σ  Still Miss the Mark	Quantra  The Solution!

## **Proven Leadership Team With Deep Domain Expertise**



Tim Fischer\*













i-STAT

Bill

Moffitt\*

the Board

Chairman of

**AHSC Baxter** 



Mark Wheeler, MD\* Director

**WT Investment Advisors LP** 





Josep Manent\* Director









Bill Walker\* CTO & Founder









Francesco Viola\* CSO & Founder

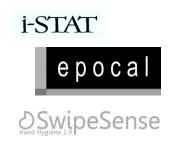
JNIVERSITY

SCHOOL OF ENGINEERING

ONCOLOGY



Jeff Baker Commercial





**Thomas** Givens VΡ **Engineering** 







Megan **Shaw VP Business** Development









**David Bryant VP Quality Systems** 















## **Recent and Upcoming Milestones**

Completed and published clinical studies

FDA agrees with direct de novo 510(k) pathway and clinical study design

Quantitative market research confirms \$1B market and customer need

Clinical Registration Study initiated in July, 2016

Commenced cGMP manufacturing of instrument and cartridge

Initiated pre-launch commercial activities with positive customer feedback

Targeting EU launch in early 2017

Targeting US launch in mid 2017 (contingent upon FDA clearance)

Raising \$15MM to support launch and commercialization

## **Investment Highlights**

## Quantra<sup>™</sup>: Next generation product to guide the management of critical bleeding

Clinically Proven
Patented Technology

Advanced technology for surgery, trauma, OB, and critical care Extensive patent portfolio covers core functionality

**Low Regulatory Risk** 

Direct de novo 510(k) Pathway
CE Mark planned late 2016, FDA clearance planned in 2017

Saves Lives and Reduces Cost of Care

Existing products are slow, confusing, incomplete, complex & costly Quantra is quick, clear, complete, easy, and economical Saves cost by eliminating unnecessary transfusions

Rapidly Expanding Market

Reducing transfusions is a priority because of their cost and risk Aging population and surgical advances drive market growth

Large, Profitable Market

>\$1 B market

High gross margin cartridge

