Platform Monitoring Company: Real Time ICU Diagnostics At the Bedside
Investor Highlights

- **Multi Billion $ Market**
- Clinically validated product, preparing for US, EU commercialization
- **Competition: None**
- **Corporate Validation**
- Experienced management team
ICU Care

- Expensive: 1% of US GDP (~$150 B)
  - 25% of US hospital costs
- Morbid: 10% death rate (>700k/yr)
- Large population: >6 M US patients per year
- Growing market: 5% per year
Lead Indication: Automated Glucose

~$3 B WW*

*Similar to public estimates of major device companies and wall street analysts, both diabetes and “stress hyperglycemia”
ICU Glucose Background

- Worldwide
- All ICU’s have a target glucose range
- Placing 60-70% of patients on IV insulin
- Obtaining 8-10 glucose values/d.
  - US: hand held meters
    - Inaccurate
    - Labor Intensive
- Better centers: patients in range 60% of time
2015 Studies: > 80% of glucose values in Range needed (Time in Range, TIR)

• Cardiac Surgery Study: lower wound infection rate, ventilation duration, stay in the ICU
• Large, Multi Center Surgical + Medical ICU Study: increased odds ratio for living
• Large, Single Center Surgical + Medical ICU Study: increased odds ratio for living
Low TIR: increased risk of death and expense from

**Hypoglycemia:** one value < 70 mg/dl increases risk of death

Hyperglycemia: average glucose >140 mg/dl increases risk of death

Adding $2700/ event

Adding $1500/ event
Achieving high TIR requires more frequent measurement

• “Optimal glycemic control required a measurement interval no longer than 1h, with further benefit obtained using measurement interval of 15’. “

– JDST, 2015
The OptiScanner: Automated Glucose Monitoring for the ICU

- 15”, Automated Measurement
- Green: In Range, Red: Out of Range
- Alarms to assist staying in range
- No calibration, for years
- Published to obtain >90% Time in Range
How the OptiScanner Works

1. Connects to patient’s Standard Venous Line (CVC, MAC, PICC, Peripheral IV)

2. Fluidics System Extracts ~0.1 ml

3. Automatically Measures Hemoglobin, Oxygen (NIR spectroscopy)

4. Centrifuges Sample (true plasma reading)

5. Measures Glucose, Lactate (Mid-infrared Spectroscopy)

6. Glucose, Lactate, Hemoglobin, Oxygen Displayed With Alarms (Glu shown)
FDA Approval Pathway for automated ICU glucose

- 2008 Safety Animal Study
- 2009: Control I
- 2010: Control II
- 2011: Manage I
- 2012: Manage II
- 2013: Multi Center US Trial Approved (November)

Healthy Diabetic Studies. 78 patients, >2000 paired measurements
Intended use safety studies, 155 patients, 1271 paired measurements
Diabetic Studies: Best accuracy ever shown using automated glucose monitoring

Control I: 8 hours, 15” paired measurements

Control II: Up to 72 hrs., minimum of 8 paired measurements/d.

Each study: > 1000 paired data points, 99% of values in CEG A
EU ICU Single Center Studies

MANAGE I: Amsterdam, NL

Manage I, Algorithm 6

- 71 subjects
- 451 predictions
- 13 No Calls

- A: 91.8%
- B: 8.2%
- C: 0%
- D: 0%
- E: 0%
- PCV: 9.11%

MANAGE II: Brussels, BE

Manage II, algorithm revision 3.1.3.1

- 85 subjects
- 863 predictions
- 21 No Calls

- A: 95.1%
- B: 4.75%
- C: 0%
- D: 0.116%
- E: 0%
- PCV: 10.3%
- MARD: 8%

van Hooijdonk et al. *Annals of Intensive Care* 2014, 4:8
US Approval Trial: 4 site study

- Title: MANUAL VS. AUTOMATED MONITORING ACCURACY OF GLUCOSE
- ClinicalTrials.gov ID: NCT #02211300
- Primary endpoint: Mean Absolute Relative Deviation (MARD) of 10% or less
  - MARD: Commonly used metric to gauge accuracy in outpatient market, where best in class has a 12% MARD
  - Comparing Paired OptiScanner glucose measurements to YSI 2300 reference analyzer
US Approval Trial

- **Phase I (roll in phase):**
  - 61 patients completed

- **Phase II (General Enrollment) Goal:** 200 patients
  - >140 patients, or > 70%, enrolled
  - Trial completion: Q3 2015
  - Submission: Q4 2015
Phase One Data is Excellent!

MARD : Far below 10% primary endpoint!
Competition?

- 8 followers, spending >$500M, failed in their attempts to automate glucose in the ICU, either:
  - Failing to overcome interferents from pharmaceuticals commonly administered in the ICU environment, and/or
  - Had major limitations, rendering them not useful in the ICU
Platform Increases rate of Adoption: Stable Pricing with Higher Value

2\textsuperscript{nd} Indication: Automated Lactate

- Sepsis Management: + 1 M US ICU patients (daily labs)

3\textsuperscript{rd} Indication: Automated Hemoglobin

- Bleeding Detection, Transfusion Mgt.: + 0.5M US ICU patients (stat labs)

CE Mark: Q1 2016
Persistent, Elevated Lactate increases probability of death

All interventions start at 4 mmol or sooner

Figure 5. Probability of survival compared with initial arterial blood lactate concentration in ICU patients. Severity of perfusion failure and probability of survival are identified by the magnitude of hyperlactatemia. Reproduced with permission from Weil and Afifi (38).
Need Proven in a Randomized Trial

• Patients entering ICU with lactate of 4 mmol +
• Serial lactate measurement arm:
  – Prompted faster change from failed intervention
  – Lowering Mortality
  – Reducing Length of Stay
• ~20% of ICU patients (+1M in US)
Patient who needed OptiScanner continuous Lactate in US Trial

OptiScan (Green) v. YSI (Black dot)
Hemoglobin

• Needed to detect spontaneous bleeding
  – Trauma
  – Certain post surgical populations

• Needed to titrate expensive and risky blood transfusion:
  – 1 unit of packed cells: $341
  – Blood transfusion increases risk of death
  – Morbidity: Bacterial contamination, ALI
Intellectual Property

• 29 allowed patents in US alone
• Defensive for spectroscopy: 10
• Offensive: 19
  – Non dilute, small sample withdrawn
  – Automated Plasma Generation
  – Multiple Analytes
  – Closed Loop Insulin Delivery
Corporate Validation

• One of largest healthcare companies in the world, expert in assessment of glucose monitoring technologies, invested in last round of financing

• Extensive Diligence Process Completed:
  – Intellectual Property Review, Clinical Need, Clinical Data, Field Visits, Regulatory Review
  – Finance Review (detailed review of market opportunity and revenue projections)
  – Operations Review (Product, Supplier, Documentation, Capacity, Capital, Vendor Reviews on site, R&D pipeline)

• 5 additional major corporations have signed CDA’s
Experienced Management Team

- Peter Rule, CEO
- Jim Causey, VP, R and D
- Dana Deyette, VP, CR
- Patrick Nugent, VP, CFO
- Don Webber, VP, COO