

Detect Sepsis Early, Non-Invasively to Save Lives

Sepsis

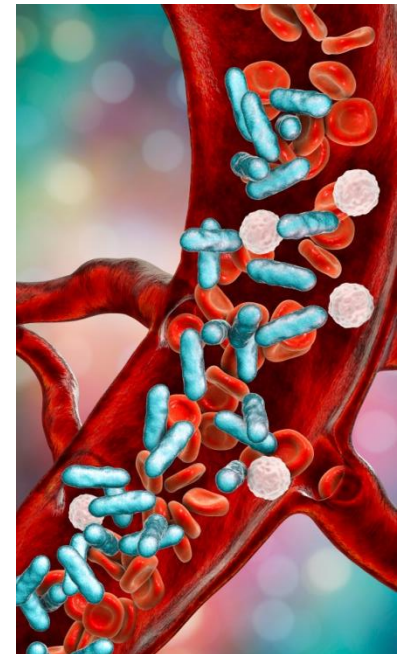
- Condition caused by various unchecked infections.
- Can lead to tissue damage, organ failure, and death.
- Develops mostly in frail, aging, or otherwise immune-compromised patients.
- Affects +49m people/year worldwide.
- #1 cost hospitalization/skilled nursing U.S. \$62 B/yr.
- In US alone, Sepsis affects 1.7m people.
- #3 US cause of death – 350,000 /year.

Need

- Current rapid screening methods are deficient.
- Reliable diagnoses can take days for confirmation.
- Mortality increases ~8% every hour treatment is delayed.
- 80% of sepsis deaths are preventable with rapid diagnosis and treatment.
- Effective screening would save typical 300-bed hospitals ~\$1.2m/yr. in unreimbursed expenses vs. current methods.

Solution

- **Early, Quick, Noninvasive, Highly Predictive**
- Proprietary (IP Protected) algorithm leveraging measurement of Exhaled Breath coupled with other non-invasive biomarkers.
- Near-instant Results (~1 min) for immediate decision.
- Non-invasive, no blood sampling.
- Portable, usable in variety of locations (ER, ambulance, bedside, nursing home).
- Small capital with proprietary consumables.
- Filed patents with follow-ons anticipated in '24.



Founded: 2015 LLC (MN)

Q3 '21 Post – Cap.
5.1 M Fully Diluted Units

Management Team:

CEO - Tom Burke
CTO - Carter Anderson
CSO - Russ Morris
CFO - Clayton Anderson
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Clinical

Completed IRB Confirmatory Study 2023

- HealthPartners (Regions, Methodist Hospitals)
- Enrollment: (104 Patients plus 40 Healthy Subjects)

Completed IRB Pilot Study 2020 – University of Minnesota

- Included equal parts of healthy volunteers and patients presenting with suspected Sepsis to the Emergency Department. (total N = 32)

Exhaled Breath readings coupled other non-invasive measurements:

- USE in TRIAGE -- risk scores on a 5-point scale:
 - High scores with high sepsis risk (high positive predictive value).
 - Low scores with low sepsis risk (high negative predictive value).
- Provides physicians actionable data to decide whether to immediately administer antibiotics or withhold them pending further analysis.
- Sensitivity to confirmed infection that exceeds existing tests.
 - Allowing ability to find sepsis in patients that other tests miss.

Further Confidential data/detail available.

Regulatory Strategy

- 510(k) Class II device approval process – Confirmed by Regulatory Consultant.

Commercialization/Exit Strategy

- Strategy of near-term exit via established diagnostic company - acquisition prior to product launch.
- In-place advocacy and key opinion leader network.
- Commercial product release estimated within 3-4 years.
- Razor/Razorblades flexible revenue model – worldwide ~\$4.0 B market.