

Executive Summary

CardiacSense is an innovative Israeli start-up on track to revolutionize the Wearable Health Industry by providing an affordable, comfortable Medical FDA/CE certified Medical Watch capable of continuous 24/7/365 monitoring of Vital Signs including Heart Rate and Blood Pressure and making accurate real time diagnostics of a slew of medical conditions such as Heart Arrhythmias and High Blood Pressure (Hypertension).

Mission Statement and Goals

- Providing one device with all the requisite sensors to accurately (FDA level) measure Vital Signs.
- Wrist worn device must be comfortable and able to provide continuous 24/7/265 bio sense monitoring.
- Device must integrate into hospital environment for monitoring in-house patients, as well as provide ambulatory capabilities.
- Cloud based data collection enabling future Big Data Analysis of data in order to enable preemptive medical occurrence prediction and warning.

The Pain

Heart Disease is currently the **number one cause** of major medical conditions and deaths in the United States. Arrhythmias, or irregularities in Heart Rhythm, often cause Heart Disease and are difficult to diagnose as they may be asymptomatic and may not occur during a limited time ECG monitoring by a physician. 2 major Arrhythmias: **Atrial Fibrillation (A-Fib) & Cardiac Arrest (CA)**.

- **A-fib** - the most common Arrhythmias and a major cause for **strokes** increasing the probability by **X5**. US Annual cost is estimated at **23B US\$**.
- **CA** occurs at home in 70% of cases, has a **fatality rate of 90%** with about 400,000 out of hospital cases per year in the US. Treatment with an Automatic External Defibrillator within 3 minutes multiplies **survival rates by X7**.

Hypertension (HTN), is known as the "silent killer" as 29% (75 million) Americans suffer from it and its consequences with another 29% (75 million) in a pre HTN phase. 20% of US adults are unaware they have HTN, and of those who are aware only 50% have it under control. It is associated with strokes and is difficult to diagnose due to many false positives.

Our Solution – Hospital System and Ambulatory System

- **CardiacSense Commercial Medical Watch** combining PPG and ECG technologies and an advanced Artifact sensor, monitors vital signs including BP, HR, HRV, Breathing Rate, SPO2 with on-watch medical diagnostics.
- **CardiacSense Ambulatory Mobile App** (Android & IOS) receives data from watch through BLE protocol and provides extended algorithmic diagnostic capabilities and GUI.
- **CardiacSense Cloud** concentrates data acquired to central cloud based DB.
- **CardiacSense Concentrating Application** interfaces between Watch and EMR in hospitals / health service providers.

Core competencies

Our market leading solution is based on **advanced PPG optics**, patented **mechanical artifact sensor**, **advanced algorithms** and low **energy consuming electronics** – all developed in house.

Intellectual Property

- Strong suit of patents, in various stages, protecting key components of our technology. Major patents: **cancellation of motion artifacts & optical configuration for PPG**.
- **Proprietary** leading-edge **algorithms** for diagnosing blood pressure, arrhythmias, breathing rate and more vital signs.

Info:

- Name: CardiacSense
- Location: Caesarea, IL
- Industry: Medical Devices
- www.cardiacsense.com

Current Status:

- started 2013
- Solid & Growing IP portfolio
- POC 1st Gen product
- Successful initial clinical trial of limited scope
- Starting clinical trials in 4Q18 geared towards CE & FDA approval for A-fib in 2019
- Self & Seed funded, now towards series A

Key Investment Metrics:

- First-to-market, next generation solution
- Patented technology
- Proprietary algorithms
- High entry barrier
- Strong team of high-tech and bio-med veterans
- Disruptive solution to a concrete problem, aimed at multiple colossal markets!

Clinical Verification and Certification Roadmap

- **Successful A-fib initial clinical trial** (20 subjects) at Tel Aviv Medical Center (9/16) – key results for A-fib detection: sensitivity 100%, specificity 93% completed.
- **Ambulatory A-fib clinical trial** (120 subjects in total) in 5 hospitals – Tel Aviv Medical Center, Kaplan Medical Center, Sheba Medical Center, Rambam Medical Center & Cleveland Clinic will begin in **Nov/Dec 2018** – expected to take **up to 6 months**.
- **CE and FDA** pre-submissions for A-fib done. Full submission subsequent to completion of medical trials, around **mid-2019**.
- Medical trials for SPO2 (finger), Blood Pressure & Cardiac Arrest – planned for 2019 with CE & FDA submission in 2020.
- Medical trials for Breathing Rate, SPO2 (wrist) & Heart Failure – planned for 2021/2022 with CE & FDA submission in 2022/2023.

The Market

- About 2% of people <65 have **A-fib**, rising to **9% for people over 65**. About **400K** cases of **CA** annually result in **90% fatalities**, with a median age of **65**, but cases also occur in the 30's and 40's. AED's can save lives if CA is identified and treated within minutes.
- Almost **60%** of the population suffering from **Hypertension** or **pre-Hypertension** and requiring close monitoring of Blood Pressure.
- Initial target market, can be segmented to higher risk patients with comprehensive insurance coverage, while using **existing CPT codes**.

Competitive Landscape

Existing solutions: intrusive HR 1-lead ECG, non-intrusive 1-14 day ECG HR capturing with external device/sticker, Apple "medical" watch with "FDA certified" HR measurement with limited functionality and only viable in Hospital controlled environment (poor results in Ambulatory setting).

FDA certified accurate Vital Sign monitoring and diagnostics – no existing solutions.

Continuous, 24/7/365, unlimited data non-intrusive HR monitoring – no existing solutions.

Continuous, 24/7/365, unlimited data BP monitoring without an inflating sleeve – no existing solutions.

Comprehensive Vital Signs capturing, uploading, diagnostic solution for Hospital Environment (EMR) and for Ambulatory use – no existing solutions.

The hype created by the Apple Watch 4 of offering an FDA approved HR monitoring device is promoting the potential technology and systems which will soon be offered by CardiacSense – some exclusively and others with substantial lead on the market.

The Team

The Company's team consists of the top professionals including:

- ✓ **Eldad Shemesh** (founder & CEO), veteran of the Israeli Air Force, and VP Engineering of Israeli Space Agency
- ✓ **Prof. Sami Viskin** (Chief Medical Officer), Senior cardiologist Tel Aviv Medical Center & Associate Professor at the Tel Aviv University,
- ✓ **Prof. Boris Spektor** (Head of Optical team), senior researcher at the Technion, Prof. Giris Jacob (Head of Blood Pressure team), Head of the Autonomic Research Center at the Tel Aviv Medical Center & Professor of Medicine and Physiology at Tel Aviv University
- ✓ **Mr. Israel Makov** (Board member), Former CEO of TEVA & current chairman of BioLight, MicroMedic and Indian Sun,
- ✓ **Dr. Jon Hunt** (active Chairman), who recently joined the Board bringing over 30 years of top level managerial experience of medical devices companies, several of which were acquired by Boston Scientific, including executive positions at Bardy Diagnostics, Cameron Health, Cardiac Pathways, St. Jude Medical, and Cardiac Pacemakers.