

CardiacSense Ltd – March 21 report

1. The watch

our watch is produced at mass production line! 😊

- a. These watches are being used for development and clinical trials.
- b. As these are the first series of watches there are still fine-tuning tasks (such as plastics updates etc.) needed.
- c. Mass production of final watches will start in April
- d. Shipments of units (1st batch includes 3,000 units) to distributors is expected starting in April.

2. Regulation:

- a. Atrial Fibrillation
 - i. **CE Mark:** We got our CE approval 😊.
 - ii. **FDA:** in order to get this approval, we need to conduct a wider (wider than the one already finished) trial in the USA. This trial is planned to start in the coming months.
 - iii. We are in communication with the FDA (called pre-sub) to better prepare our future trials.

3. Clinical trials:

a. Respiratory Rate

This clinical trial was finished successfully a week ago.

We are preparing the data for submission to CE and FDA.

b. Early deterioration of COPD and heart failure

Data was collected from 30 inpatients. We are continuing with this data collection to improve our algorithm.

We are planning a very wide (hundreds) and long (years) trial together with a strategic partner.

c. Arrhythmias detection

We want to add the capability of detecting 3 additional heart arrhythmias on top of Atrial Fibrillation.

The 3 arrhythmias are: Bradycardia (very low heart rate), Tachycardia (very high heart rate) and Pause (stop of the heart activity during few tens of seconds).

The algorithms were developed and embedded in the watch and are being checked during a clinical trial for data collection at Rambam hospital.

d. Blood Pressure

We hope the trial that was stopped due to corona situation will be resumed this month at Ichilov hospital.

Following this trial, we will start a trial in the US that will be submitted to CE and FDA

e. Oxygen saturation - SpO2

This trial is going to be conducted in USA. We estimate it will start in April-May timeframe.

4. R&D:

- a. Our R&D team efforts revolve around the commercial version watch (V12.1). It is clear to us that it will take approximately 6 months until software will be stabilized on efficient operating time and performance.
- b. Optical performance of this watch is excellent!
- c. There is a big improvement in new optical concept that will improve system performance. This development is still in the prototype phase.

5. Commercial:

- a. Distributors backlog orders has reached \$100M
There are near term contracts of additional \$15M
- b. We are communicating with 2 international leading companies that are potential partners for strategic cooperation. We hope that one of these channels will mature in the coming quarter.

6. Finance and commercial

- a. The round of \$70M pre-money was completed last month. \$2.4M were raised.
- b. A new round has started and will be closed this month. Valuation is \$90M. In this round we anticipate raising \$3-6M
- c. Unfortunately, we cannot disclose here the status of going public. We hope to update you in next status report.