CancerPredict

Rapid and reliable test, for improved breast cancer prediction

CancerPredict is <u>transforming breast cancer diagnostics</u> offering an investment opportunity to bring this game-changing technology to \$5 billion growing market









INNOVATION AT SHEBA MEDICAL CENTER

The Problem

We can reliably diagnose breast cancer, not <u>predict</u> it

- Breast cancer accounts for about 1 in 3 of all new female cancers each year
- Early detection significantly increases effectiveness of treatment
- The current breast cancer screening program is useful only in cancer detection, not prediction
- Currently, cancer prediction is based on results of routine screening program and the evaluation of risk factors (i.e Tyrer-Cuzick model)
- <u>Current prediction tools are far from being accurate or reliable</u>:
 - Most of the "high-risk" women would not develop cancer, eventually
 - Many "low-risk" women would develop cancer



The Problem

Current models fail to accurately predict cancer

- Large population, retrospective study* reveals limitations of Tyrer-Cuzick model (132,139 women in screening test, spanning over 19 years):
 - 4645 predicted as "high risk" according risk factors evaluation
 - At the end of the study:
 - Total 2,699 were diagnosed with invasive breast cancer
 - Only 273 of the "High Risk" developed cancer -> 10% accuracy
 - False positive rate: 94%
 - The model missed 2426 women (classified as low risk, eventually developed cancer)
- Risk models fail to reliably identify high-risk individuals



In the study, Tyrer-Cuzick model displayed a 10% accuracy rate and 94% false positive rate, while missing out on 2426 women who were classified as low risk but eventually developed cancer

Overview

Hyperplasia stage linked to future cancer development

 Large population retrospective study indicated that 30% of hyperplasia stage women developed breast cancer within 25 years regardless of other risk factors*.



Shown is the cumulative incidence of breast cancer (invasive and ductal carcinoma in situ) after a diagnosis of atypical hyperplasia. The dashed lines in Panel A denote 95% confidence intervals.

*Lynn C. Hartmann, M.D., et al., .- Atypical Hyperplasia of the Breast — Risk Assessment and Management Options

<u>Overview</u>

Biomarker levels at hyperplasia stage

Biomarker expression level in biopsy samples indicates:

- Normal cells: 100% samples show high biomarker level
- Hyperplasia: 67% samples show high biomarker level,
 33% samples show low (or no) biomarker
- Cancer: 22% samples show high biomarker level 78% samples show low (or no) biomarker



*Biomarker level was measured in biopsy samples at different disease stages. In each stage the ratio between high and low biomarker expression was calculated.

The Product

CancerPredict kit & software

- Product is based on:
 - Proprietary immunohistochemistry kit for CancerPredict's specific biomarker
 - Proprietary AI software
- Software will give a more accurate and reliable breast cancer prediction based on biomarker data and other relevant background data
- Breast cancer prediction will become more accurate over time, as more data will enter the database



*Illustration

The Solution

CancerPredict

- CancerPredict utilizes biopsy sample taken as part of the routine screening program (no need for extra sampling)
- The biomarker's expression level is measured in biopsy samples that were staged as hyperplasia by the screening's pathology test
- The biomarker's level in the hyperplasia staged biopsy sample indicates the probability of breast cancer development in future



Layout of routine breast cancer screening program and CancerPredict's test integrated

CancerPredict received grant from the Israel Innovation Authority

רשות החדשנות
L > Israel Innovation
Authority 7

- License for using the software and kit to authorized labs and clinics in global reach at global or regional basis
- Each lab/clinic will be responsible for the regulatory activities and registration in its region
- Data from all labs and clinics will be streamlined to CancerPredict's data center routinely, and will be used to improve test reliability and accuracy

The Market

Breast cancer diagnostic market

- The global breast cancer diagnostics market size is estimated to be worth USD 4.82 billion in 2024 and is projected to reach from USD 5.16 billion in 2025 to USD
 9 billion by 2033, growing at a CAGR of 7.62% during the forecast period (2025-2033)
- <u>CancerPredict's Edge:</u>
 - More reliable than current models
 - Potential expansion to other cancer types
 - Strategic fit alongside existing screening methods



Finance

- <u>CancerPredict's target of the current fundraising round is (to be disclosed)</u>
- The funds will enable reaching an inflection point:
 - Completion of:
 - Validation study
 - Kit prototype
 - Software prototype
 - Pre-IDE meeting with health authorities (e.g. FDA)
 - Initiate pilot(s) with major medical centers
- At that point, the engagement of large companies is anticipated as well as better access to large funding opportunities