NANOSTICS
PRECISION HEALTH

Contact: Colin Coros
Email: colin.coros@nanosticsdx.com

MANAGEMENT TEAM
John Lewis - CEO
Catalina Vasquez – COO
Colin Coros - CCO
Robert Paproski - CTO
Desmond Pink - CSO
Adrian Fairey – CMO
Eric Hyndman - CMO

BOARD OF DIRECTORS
John Lewis
Mike Schoenberger
Melina Cimler
Armen Aprikian
Aubrey Rankin

INDUSTRY
Category: Life Sciences
Sub-category: Diagnostics

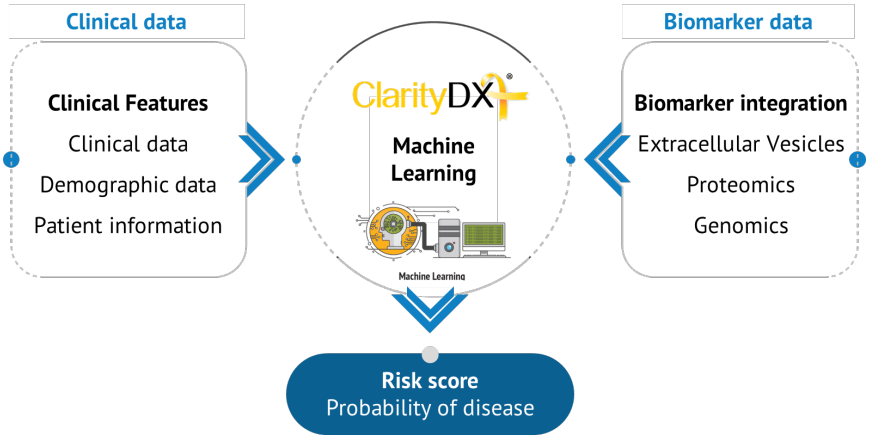
INTELLECTUAL PROPERTY:
- PCT patent filed for the use of machine learning and biomarker detection
- Patent filed for the use of machine learning for the detection of Prostate Cancer
- Patent-focused use of propriety biomarkers for detection of Bladder Cancer

KEY MILESTONES
- Initial prostate cancer study: Complete
- Pivotal 3,448-patient prostate validation study: Complete
- Bladder cancer validation study: In progress
- CPSA accreditation: Complete
- FDA regulatory approval: In progress
- Canadian Distribution partner: Established
- US Distribution partner: Established

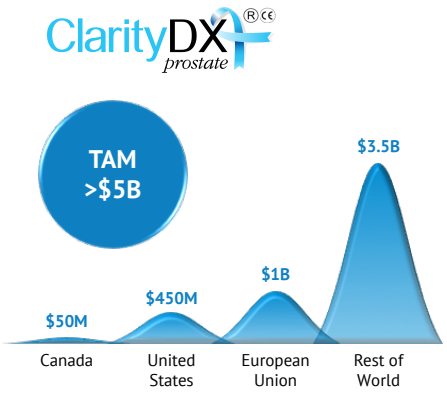
OVERVIEW:
Nanostics is a commercial precision health company with a leading approach to machine learning and biomarker-driven improvements to patient care. Our mission is to help bring clarity to healthcare decisions. Nanostics' detection platform is applicable to a wide range of cancers and other diseases and our lead product, ClarityDX Prostate®, is a highly accurate test designed to assist in the diagnosis of clinically significant prostate cancer and aid in the decision to proceed to a biopsy.

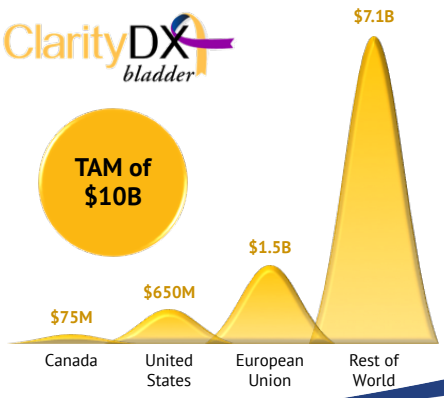
NEED:
The upcoming paradigm shift brought by genetic screening will worsen the problem of overdiagnosis without providing clear guidance on the need for intervention. This will dramatically increase over-treatment, reduce patient quality of life, and increase healthcare costs. There is an immediate need for more informative early-detection tests to improve health outcomes for patients.

SOLUTION:
Our platform technology, ClarityDX, uses machine learning along with biological and clinical biomarkers to generate disease risk scores that can be used to make healthcare decisions.



MARKET OPPORTUNITY:
The ClarityDX platform has the potential to impact all of the major healthcare sectors and can be leveraged to improve outcomes for all of the major diseases. Our lead product, ClarityDX Prostate, is targeted to improve prostate cancer care and as the second most deadly cancer among North American men, prostate cancer is a major public health concern. Our follow-up product, ClarityDX Bladder, is positioned to be the most accurate molecular test for bladder cancer detection.





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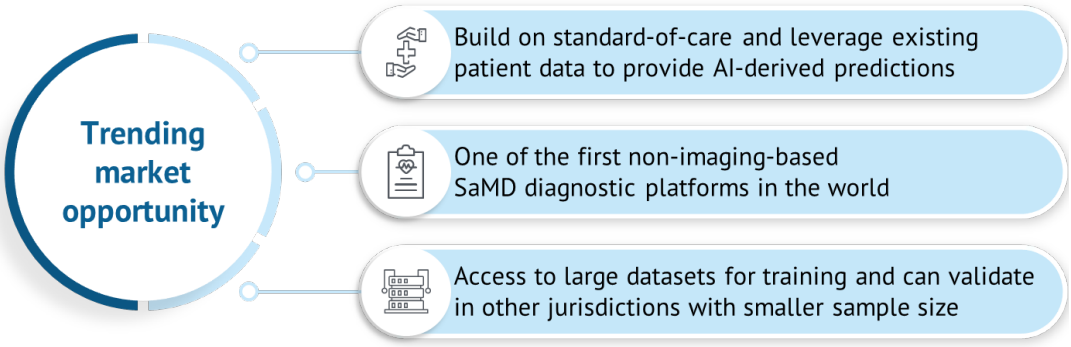
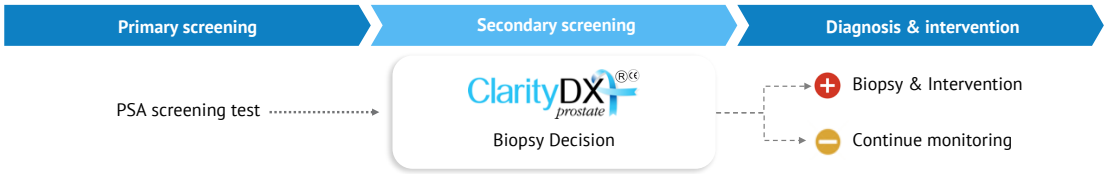
CLARITYDX ADVANTAGE:



CLARITYDX PROSTATE:

ClarityDX Prostate® is a test that combines the lab results of total and free PSA along with well-defined clinical features to calculate the risk of having clinically significant prostate cancer, defined as Gleason grade group 2 or higher, on prostate biopsy. Our test is easily incorporated into the standard of care and executed by any standard clinical diagnostic laboratory.



CLINICAL EVIDENCE:

A validation study involving five independent cohorts totaling 3,448 men, including 1,409 men from Alberta, demonstrates that ClarityDX Prostate is 3X more specific than PSA at detecting clinically significant prostate cancer. This improved specificity can be used to better inform clinical decision-making on whether to proceed to prostate biopsy.

REGULATORY APPROVAL:

In September 2023, Nanostics received accreditation from the College of Physicians and Surgeons of Alberta to sell the ClarityDX Prostate test through its clinical testing lab in Edmonton, Alberta. Nanositcs is preparing further approvals through the Food and Drug Administration to enable sales in the United States.

IMPACT:

A recent health economic study found that adding ClarityDX Prostate to the standard care pathway for the diagnosis of prostate cancer yielded significant savings. For every 1,000 men who had elevated PSA test results, adding ClarityDX Prostate to their clinical care resulted in the avoidance of 146 biopsies on prostate cancer negative patients, resulting in $280,740 of cost savings. With an average of 16,000 patients receiving the results of an elevated PSA test every year in Alberta, incorporating the ClarityDX Prostate test will provide up to $4.5 million in savings to the healthcare system annually.

FUNDING TO DATE

$6.8 million in equity and $4.7 in non-dilutive funding

FINANCING SOUGHT

Series A funding

USE OF PROCEEDS

- Establish global sales force for ClarityDX Prostate
- Complete global regulatory approvals and secure test reimbursement
- Completion of validation studies for ClarityDX Bladder
- Expand test platform

CURRENT PARTNERS

APL (formerly DynaLIFE Medical Labs)
- Third part collection provider in Alberta

Alberta Innovates
- Funding through the AICE- Market Access program

Government of Canada
- Funding through NRC-IRAP program

Alberta Cancer Foundation and Cure Cancer Foundation
- Philanthropic Funding support

Motorcycle Ride For Dad
- Philanthropic Funding support

Prostate Cancer Centre
- Clinical recruitment

Kipnes Urology Centre
- Clinical recruitment