



Pioneering Mitochondrial DNA Technology

Corporate Presentation
June 2017



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Investment Highlights

Commercial stage molecular diagnostic company

- Launched blood-based “liquid biopsy” prostate cancer test in late 2016
- Prevents or delays risky and costly surgical biopsy procedures
- Only company known to be developing tests based on market-disruptive mitochondrial DNA technology
- Previously launched tissue-based prostate cancer test provides technology validation and fits within diagnostic continuum

Best-in-Class test performance and simplicity

- Reliable, actionable results from minimal sample material
- Highly sensitive, proprietary biomarkers for early detection of disease
- “Plug and play” for commercial lab partners

Proprietary mitochondrial DNA platform for product development

- Enables “bench-to-marketed” diagnostic product in 12-14 months
- Pipeline diagnostic in endometriosis expected to launch in Q3 2017
- Established proof-of-concept in 11 oncology categories
- Additional applications in CVD, CNS, endocrinology, dermatology

Commercially-Focused Executive Leadership

Chris Mitton, Chief Executive Officer

- ▶ 15+ years medical device and diagnostics experience at leading molecular diagnostics companies
- ▶ Experience includes international product launches, sales/marketing, BD, and licensing
- ▶ Senior commercial operations at Ipsogen, Qiagen, and Cancer Genetics; Sales roles at Abbott and Bayer Healthcare

Jennifer Creed, Chief Development Officer

- ▶ World leader in identifying non-invasive molecular approaches to previously invasive tests
- ▶ 100+ global patents and applications covering commercial/clinical aspects of mitochondrial genomics
- ▶ Instrumental in translating Mitomic technology from ancient DNA investigations to clinical science

Andrew Harbottle, Ph.D., Chief Science Officer

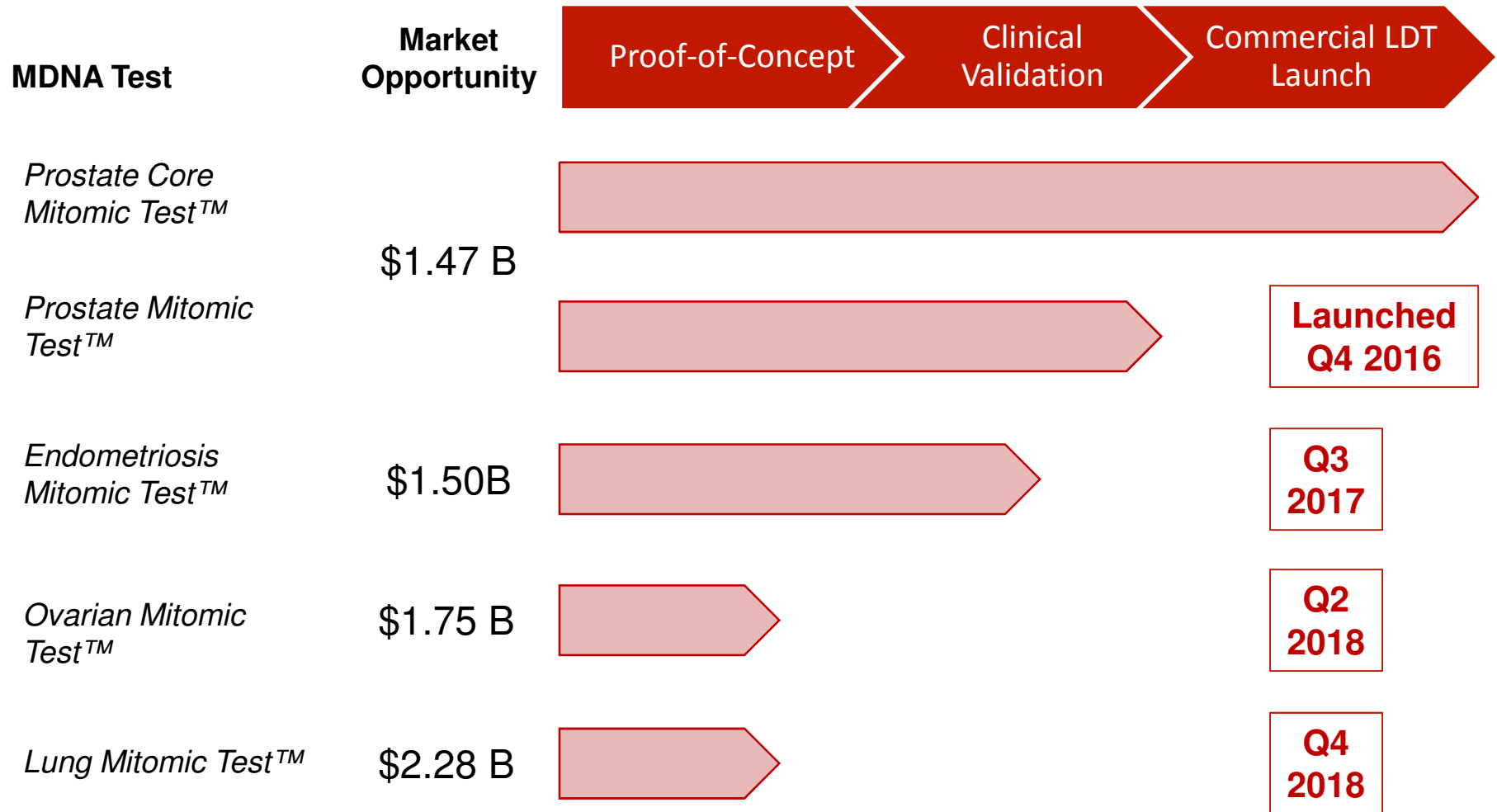
- ▶ Expert in applying molecular technologies to mtDNA and its translation from benchtop to clinic
- ▶ PhD from the University of Newcastle Upon Tyne in the Departments of Pharmacology and Surgery;
- ▶ Specialized in cancer research, the protection of genes vs DNA damage, and tumor cell drug resistance

Robert Poulter, VP Corporate Development

- ▶ 25+ years of experience in finance, sales, and marketing
- ▶ 10 years of experience in biotechnology, cancer diagnostics, and international licensing
- ▶ Former practice leader at IBM and Accenture



Anticipated Near-Term Product Launches



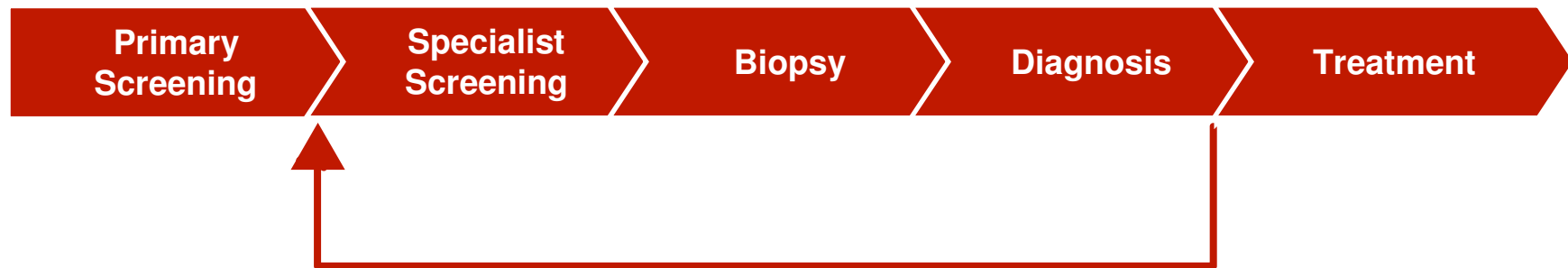
Source: Trimark Publications. April 2008. Biomarker Technology Platforms for Cancer Diagnoses and Therapies. Rogers PA, et al. Priorities for endometriosis research: recommendations from an international consensus workshop. *Reprod Sci* 2009;16(4):335-46)
 U.S. Preventive Services Task Force (USPSTF) recommends annual screening for (a) heavy smokers (i.e. 1 pack / day for 30 years) who still smoke or have smoked within the last 15 years and are between 55



The Problem: High Incidence of Prostate Cancer False Negatives



First generation mitochondrial DNA-based product, PCMT™, is revenue-generating product that addresses “gap” in early diagnosis



Negative Biopsy Initiates Continual and Costly Diagnostic Loop

Treatment is delayed due to misdiagnosis resulting from false negatives

PCMT is Proven to Reduce the Uncertainty of a Negative Prostate Biopsy

PCMT™ Enables More Accurate, Actionable Results

Negative Biopsy



Negative

Identifies men who can safely forego/delay follow-up biopsy

- Increased confidence in diagnosis
- **Avoid or delay** repeat biopsies

Positive

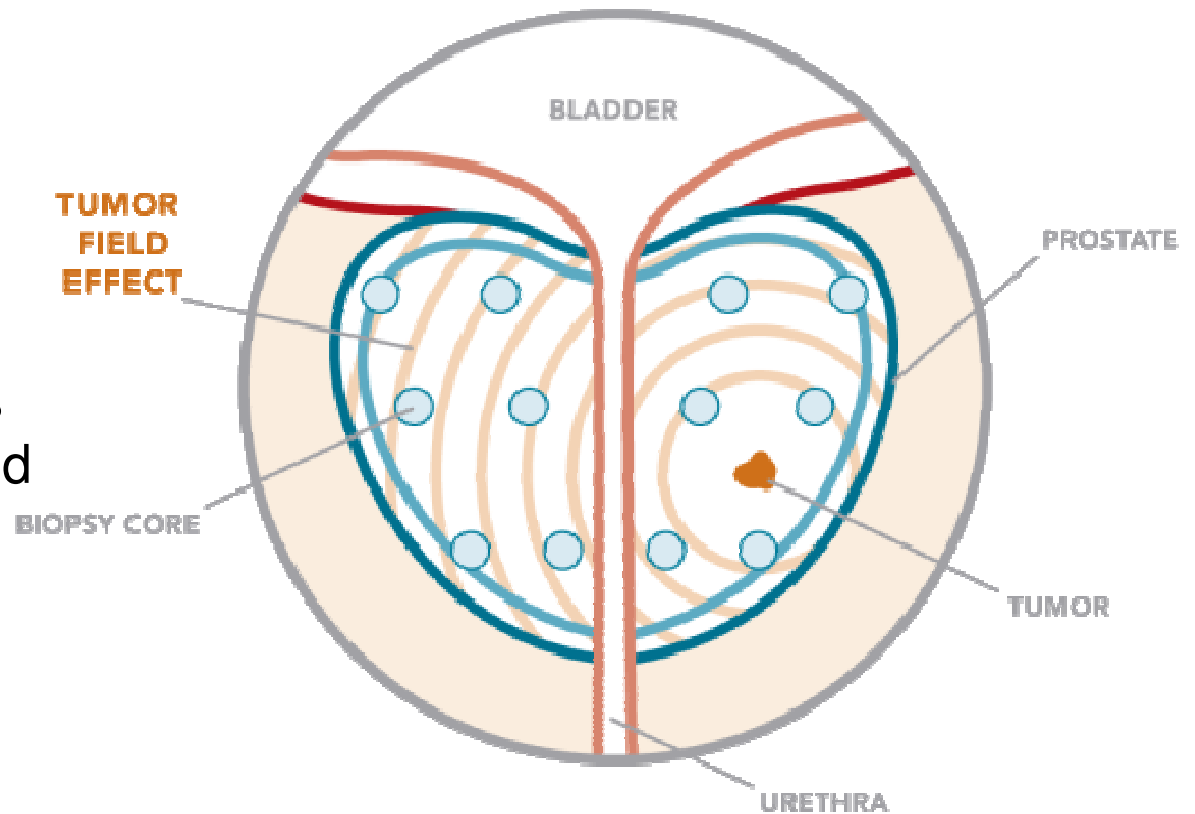
Detects *undiagnosed* prostate cancer

- Advance decision to repeat biopsy
- **Earlier diagnosis** and treatment

PCMT Leverages the Tumor “Field Effect”



- ▶ Tumor “field effect” is significantly enhanced for PCMT’s mtDNA biomarkers



PCMT™ Saves Costs by Reducing Uncertainty



Cost Drivers

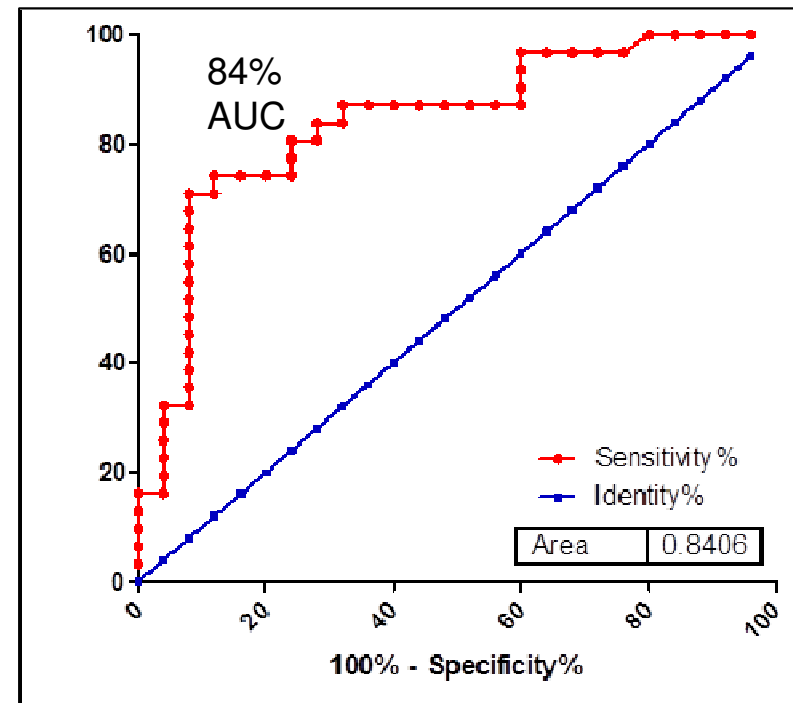
- 1. Ineffective Screening** – An abnormal PSA can often be caused by factors other than cancer, including infection, inflammation, or other benign conditions, such as benign prostatic hyperplasia (BPH)
- 2. Biopsy Complications** – Painful surgical procedure can lead to infection, bleeding, incontinence, dysfunction, and death
- 3. Repeat Biopsy/Late Detection** - Many tumors are missed because only 1/2500th of the prostate is sampled with each needle

Finding Prostate Cancer in Blood



MDNA's best independent predictor of prostate cancer – now in a non-invasive test

- ▶ **Market-disruptive** blood-based prostate cancer test **launched Q4 2016**
- ▶ Early presence of mtDNA biomarkers enables more accurate and timely biopsy decisions
 - **Save 100,000's of men annually from unwarranted biopsy**
 - Reduce healthcare costs
- ▶ Clinical validation completed with University of Cambridge
 - **Market leading performance**



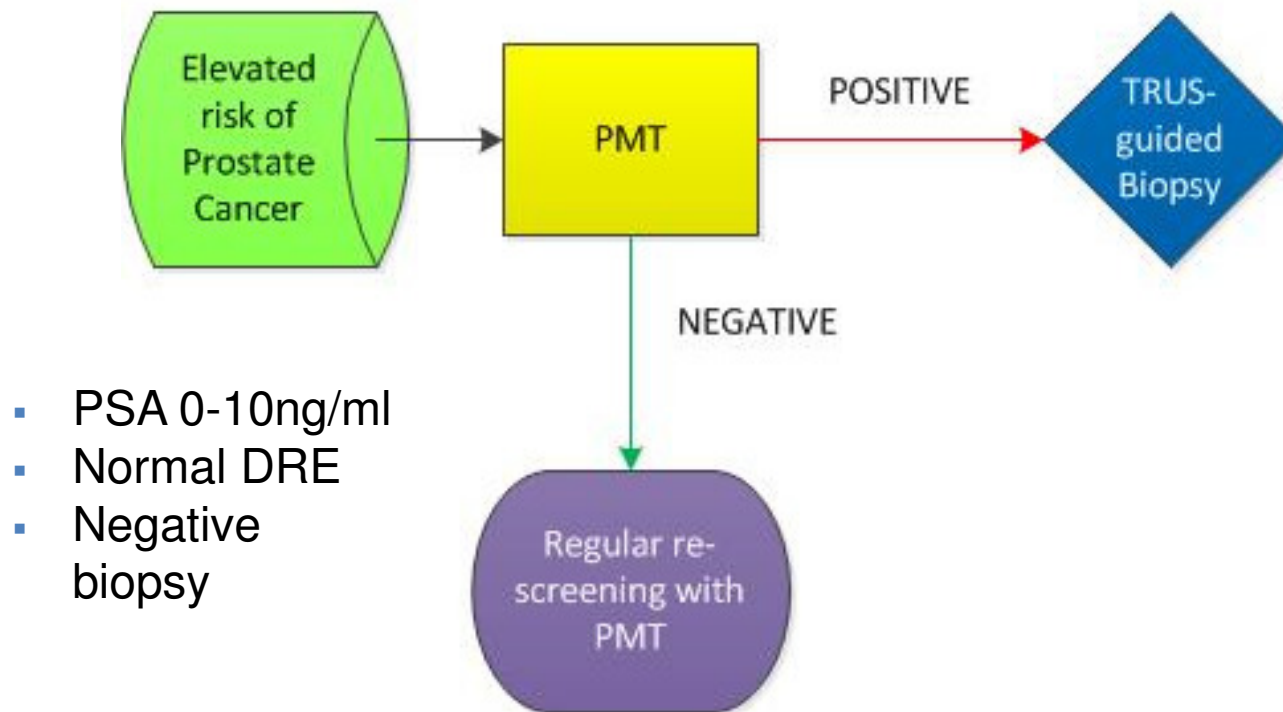
Derived from internal company validation data.

PMT detects the 3.4kb deletion, an *independent* predictor of prostate cancer

- Blood-based test that provides biological information distinct from PSA; the only test on the market not reliant on PSA
- For patients with equivocal indication (PSA 0-10ng/ml), PMT can assist in identifying the best candidates for biopsy by safely identifying those men who are unlikely to have significant prostate cancer detected on biopsy.
- PMT is not indicated for patients with clear indication for biopsy (irregular DRE, PSA>10ng/ml, bone pain).

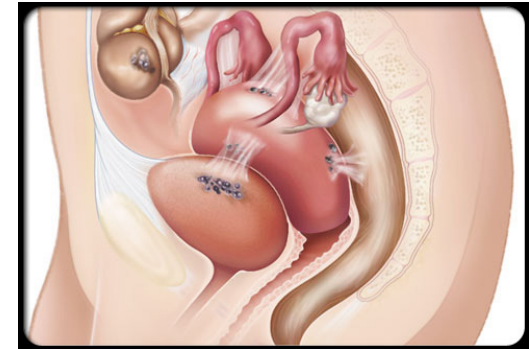
Derived from internal company data

Blood- based Test for Prostate Cancer when Biopsy is Considered



Endometriosis: Near-Term Growth Opportunity

- ▶ Abnormal growth of endometrial cells outside of the uterus
 - Causes pelvic pain and often leads to laparoscopic surgery and hysterectomy



- ▶ Large, underserved market with significant diagnostic challenge
 - Affects est. ~10% of women of childbearing age
 - 175 million women worldwide; 5 million in the U.S.⁴
 - Varying, intermittent symptoms hinder accurate diagnosis

Currently No Reliably Accurate Non-Invasive Blood-based Diagnostic Option Exists

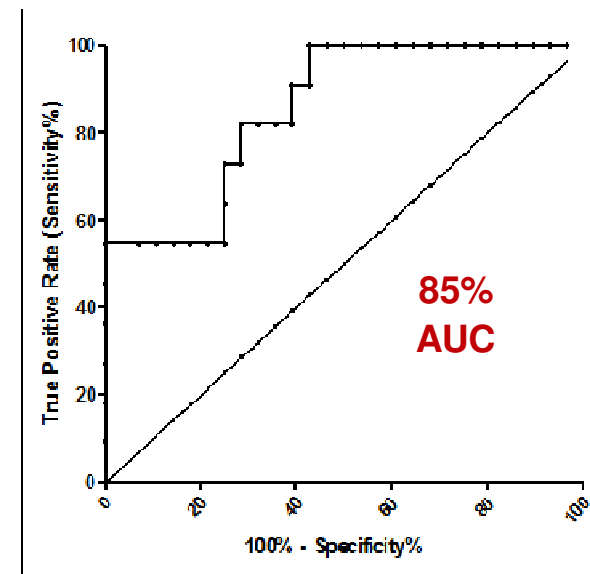
Fulfilling the Need for a Non-Invasive Diagnostic

- ▶ Physical exams are unreliable due to symptom inconsistency
- ▶ **Surgery and biopsy** are the only conclusive means of diagnosing endometriosis today
- ▶ Many patients are misdiagnosed, leading to years of unnecessary/inappropriate treatment

Significant need exists for a reliable non-invasive test for diagnosing and monitoring for reoccurrence of endometriosis

Groundbreaking MDNA Test for Endometriosis

- ▶ First **blood-based test** for endometriosis
 - Non-invasive: disruptive to current standard for screening, diagnosis and monitoring – surgery
- ▶ Projected **Q3 2017 launch** in partnership with CLIA labs
- ▶ Established proof-of-concept:
 - EMT accurately discriminates between women with endometriosis and those without ($p < 0.001$)
- ▶ Collaboration with University of Oxford
- ▶ **Significant expansion opportunity** as a disease monitoring tool



Derived from internal company data

Business Model



- ▶ Biomarker discovery
- ▶ Translate to clinical test format
- ▶ Maintain Proprietary LIMS
- ▶ Develop Marketing Materials & Messaging
- ▶ Develop Regulatory strategy & support filings



Commercial Lab Partner

- ▶ Validation of LDT in CLIA lab
- ▶ Sales and Marketing
- ▶ Sample Processing
- ▶ Billing and Reimbursement
- ▶ Logistics

Revenue Share

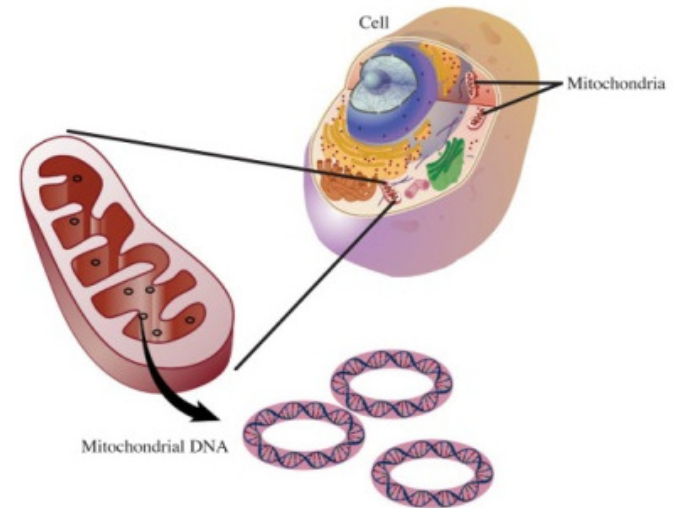


Key Initiatives Driving Commercial Success



The Power of Mitochondrial DNA (mtDNA)

- ▶ Mitochondria exist in very **high copy number** per cell
 - mtDNA is abundant and easily extracted
- ▶ Mutations/deletions occur **frequently** in response to cellular stress
 - Are **not repaired** and generally **do not cause cell death**
- ▶ **Disease-specific biomarkers** are detectable:
 - **Before** typical clinical evidence of disease
 - In tissue surrounding a malignancy or pre-malignancy (“**Field Effect**”)
 - In body fluids and in **blood**
- ▶ Once identified, **mtDNA biomarkers** are easily quantified using standard laboratory techniques



Mitochondrial DNA: An Optimal Biosensor

Biological Feature

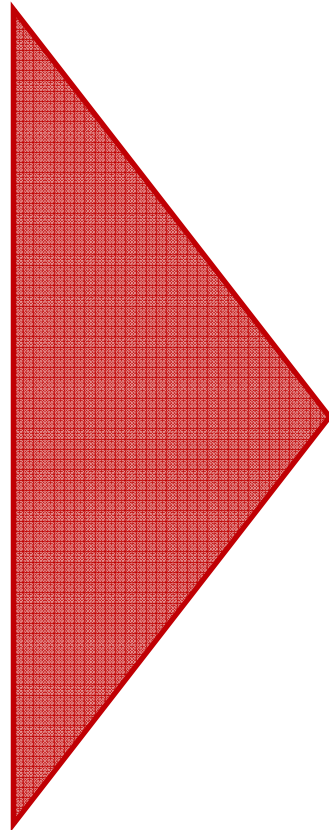
High Copy
Number

Mutation at
High Frequency

Lack of Repair/
Cell Death

Occur in
"Healthy" Cells

Disease-Specific



Clinical Benefit

Enables much earlier detection

Tests are highly sensitive / specific

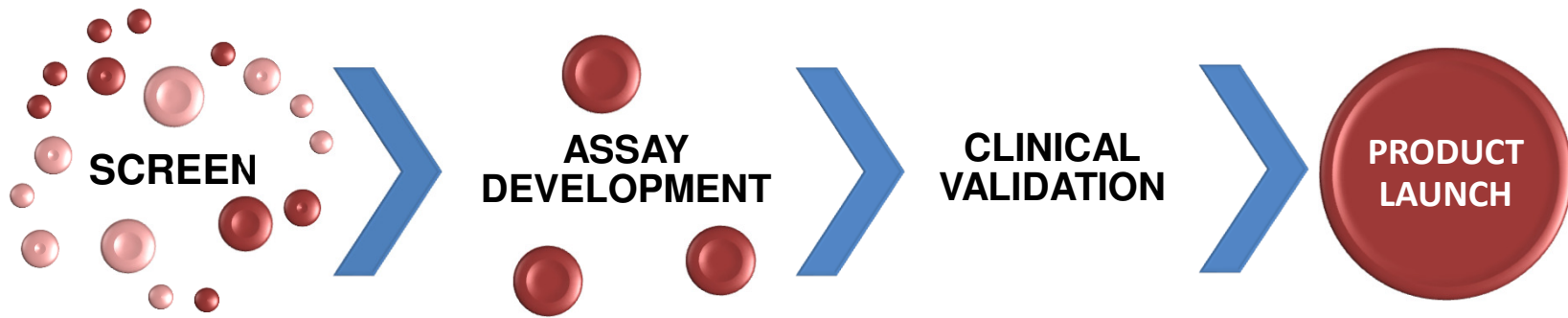
Mutations persist/accumulate
in detectable state

Actionable:
Detects real-time disease, not hereditary risk

Multiple Biomarkers per disease state

Highly quantitative –
Even with low sample material

Discovery to Product Launch in 12-14 months for All Products in the Pipeline



- Identify unique independent biomarkers (next-generation sequencing)

- Develop QPCR assay(s)
- Test against control blood samples (blinded)

- Establish clinical performance statistics

- Regulatory submission and market launch

Multiple Opportunities for Rapid Test Expansion

Opportunity
Prostate Cancer
Endometriosis
Ovarian Cancer
Lung Cancer
Testicular Cancer
Breast Cancer
Uterine Cancer
Cervical Cancer
Melanoma
Bladder Cancer
Colorectal Cancer

- Successful proof-of-concept studies highlight exceptional test performance in 11 different disease states
- Targeting diseases that are:
 - Underserved with significant testing need
 - Established at-risk population
 - Reliant on invasive diagnostic procedures
 - Opportunity to reduce costs
- Potential for unmatched performance at every stage of disease
 - Identified multiple, independent disease-specific biomarkers in each category
- Reveals the depth of the MDNA opportunity and future product launches

Protected by Strong and Growing IP Portfolio

A Leader in the Use of Mitochondrial DNA-Based Biomarkers to Detect Disease

- ▶ Robust intellectual property portfolio
 - 91 granted patents; 35 applications pending
 - \$2.8M invested in IP portfolio
- ▶ 15 years of research dedicated to revealing the unique role of mtDNA in disease pathways
 - Proprietary trade secrets, algorithms and databases
 - \$25M invested in R&D to date

Highlights

- ▶ Completion of University of Cambridge clinical validation of Prostate Mitomic Test
- ▶ Clinical Utility Study published in December and Medicare appeals process commenced
- ▶ 1st Commercial Lab Partners
- ▶ Commercial launch of PMT December 2016
- ▶ Collaboration Agreement with University of Oxford for Endometriosis
- ▶ Active discussions with strategic lab partners in China, Korea, Australia, EU, and UK

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