



MutantDx

THE LIQUID BIOPSY COMPANY™

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Overview

- **Best-In-Class Molecular Diagnostics Newco**, focusing on **Companion Diagnostics** and the **Liquid Biopsy** for **oncology applications**
- Proven **superiority to all competing methods** in **sensitivity, specificity and cost**
- Filling **unmet clinical needs** and **the technology vacuum** in a **\$40B market**
- **Disruptive patented portfolio** of **platform** technologies
 - **Multiplexed** novel modifications of '**Gold Standard**' Sanger Sequencing (**not NGS**)
- **100% subsidiary** of MultiGEN Diagnostics Inc, a **California registered company**
- **Early stage**, but only **9 months to IPO** and **rapid cash flow** from operations
- **Financing required pre-IPO: \$5M as a convertible debenture.** No encumbrances.
- **Business model post-IPO:**
 - **Retailing reimbursable multiplexed** mutation panels to oncology centers coast-to-coast through a **MutantDx CLIA/CAP laboratory**
 - Development of **Companion Diagnostics for Big Pharma**
- **Exit:** Licensing/royalty deals. **Acquisition by a multinational in 3-5 years**



The Future of Oncology

- **Cancer will soon be screened** for annually in **totally well** people with a single blood sample searching for circulating cancer-specific DNA mutations in a **multiplexed mutation panel**
- **People diagnosed** with asymptomatic cancer will be treated with mutation-specific companion therapeutics **and cured** before they ever develop symptoms!
- **Screening Market size:** \$40Billion USD (estimated/annual)

MutantDx will dominate this massive market due to Best-in-Class performance characteristics



Performance Characteristics

Best-in-Class in all 4 Categories:

1 Sensitivity

2 Specificity

- Identification **AND**
- Confirmation

3 Multiplexing ability – Currently up to 8 targets (higher number in development)

4 Patented Quality Control: I-C Code

- True internal control with every test – avoids false negatives
- Cross-contamination elimination
- Positive sample ID



Sensitivity

- **Liquid Biopsy**

- Detects **femtogram** concentrations of circulating cancer associated DNA mutations in plasma (not circulating cancer cells)

There are 1,000 trillion femtograms in one gram!

- Not limited by DNA fragment size – detects 100 nucleotide fragments
- **1,000 times better LLOD** (Lower Limit of Detection) than competitors

- **Cancer Biopsies** (FFPE – Formalin Fixed/Paraffin Embedded) **and Fine Needle Aspiration Biopsies**

- **1,000 times better sensitivity** than competitors -- published
- **Picogram detection level** (vs. competitors nanogram level)
- Expensive manual cancer 'enrichment' not required



MutantDx

Specificity and Verifiability

'Gold Standard' Sanger Sequencing allows incontrovertible:

**Target Identification
+
Target Confirmation**

All multiplexed simultaneously!



Multiplexed Mutation Panels

Only MutantDx can Multiplex mutation panels with the unmatched accuracy and dependability of Sanger sequencing

Advantages

- Multiple results in a single test from a single sample
- Lower cost per reported result than any competitor
- Ability to add additional cancer mutations when discovered and treatable with companion therapeutics

NOTE: *MutantDx is NOT in the target discovery business
We shall commercialize the discoveries of others*



Quality Control

- **True Wild Type Internal Control** — not offered by most competitors – avoids false negatives
- **Prevention of Cross-Contamination** by IC code patent – avoids false positives
- **Positive Sample ID** with bar-coded short oligonucleotide



Patented Portfolio of Platform Technologies

Patent protected modifications of Sanger Sequencing

- **MultiGEN**
- **PrimaCap**
- **TumorPlex™** – proprietary combination of MultiGEN + PrimaCap
- **Seq-Var**
- **Oligo-Pur**
- **IC Code**



Comparison Studies for BRAF V600E using DNA from FFPE cancer biopsies

IonTorrent (Mt Sinai Hospital, NY, NY) vs MutantDx

- **69% false negatives ****
- 100% concordance for positives
- No wild type control

SNaPshot (Cross Cancer Center, Alberta, Canada) vs. MutantDx

- **50% false negatives ****
- 100% concordance for positives

THxID Bio-Merieux (LabCorp, Burlington, NC) vs. MutantDx

- **36% false negatives**
- 100% concordance for positives
- No wild type control

** Published: Journal of Solid Tumors 2017 Vol 7, No.2. <http://dx.doi.org/10.5430/jst.v7n2p14>



Investment required

\$5 million convertible debenture

Use of funds for 9 months (see *pro forma*):

- Hire CEO/CFO/VP Business Development/Sales Manager/Lab staff
- Lease lab space – San Diego, CA, or Research Triangle, NC
- Capital equipment
- Patent maintenance/new patent applications
- Clinical trials
- Obtain FDA approval for one assay
- Retain legal/accounting for IPO
- IPO road show – likely reverse merger

NOTE: No actual retail testing until post-IPO



Business Model | Post-IPO

- **Reimbursable retail testing of referred-in samples from major U.S. oncology centers:**
 - **Phase 1** – Testing for mutations from FFPE sections of cancer biopsies
 - **Phase 2** – Liquid Biopsy monitoring for cancer recurrence after initial treatment (surgery/chemo/radiotherapy)
 - **Phase 3** – Liquid Biopsy screening of cancer in asymptomatic people
- **Co-Development of Companion Diagnostics with Big Pharma**
- **Exit Strategy:**
 - **License/Royalty deals**
 - **Acquisition by Big Pharma**



KEY PERSONNEL | 1

Dr. Roger Hodkinson, Interim CEO

- **General Pathologist** (FCAP and FRCPC)
- **Medical Degrees** Cambridge University, UK
- **Chairman** Bio-ID Diagnostic Inc. (Parent company)
- **Previously:**
 - CEO for a large retail diagnostic medical laboratory in Alberta, Canada
 - Assistant Professor, Faculty of Medicine, University of Alberta, Canada
 - President of the Alberta Society of Laboratory Physicians
 - Key player in restructuring the \$250million laboratory industry in Alberta
 - Laboratory accreditation inspector
 - Chairman of the Examination Committee in General Pathology for the Royal College of Physicians and Surgeons of Canada
- **Co-author** of publications based on MultiGEN technology



KEY PERSONNEL | 2

Dr. Thurai Vinayagamorthy, CSO

- **Ph.D.** in microbiology
- **35 years experience** in molecular diagnostics
- **President:**
 - Bio-ID Diagnostic Inc.
 - MultiGEN Diagnostics Inc.
- **Principal discoverer** of patented platforms in molecular diagnostics
- **Senior author** of over 60 papers published in various professional journals
- **Principal discoverer** of the melanoma-associated gene Calnexin



Corporate Chart

Bio-ID Diagnostic Inc.

- Canadian Holding Company for MultiGEN Patents



MultiGEN Diagnostics Inc.

- 100 percent Subsidiary
- California-Registered Company



MutantDx (Newco)

- 100 percent Subsidiary
- Liquid Biopsy Company using MultiGEN Patents

