Better Cancer Monitoring with Circulating Tumor DNA

May 2016
Forward-Looking Statements

Statements in this presentation about the Company's expectations, applications of its technology, markets, launch of tests and other statements that are not historical facts constitute “forward-looking statements” for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and are based on management's current beliefs, assumptions, estimates and projections.

Actual results may differ materially from those projected in the forward-looking statements for various reasons, including, without limitation, risks associated with product and test development, test transfer to contracting labs, government regulation, market acceptance, limited commercial experience, dependence on key personnel, obtaining financing and other factors discussed in the Company's periodic reports filed with the Securities and Exchange Commission, and the Company anticipates that subsequent events and developments will cause its views to change. While the Company may elect to update these forward-looking statements in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this presentation.
Our Goal

Improve Patient Outcomes Through Noninvasive Cancer Monitoring

Trovgene’s technology noninvasively detects and quantitates circulating tumor DNA in urine and plasma for improved disease management
Trofagene’s noninvasive liquid biopsy assays are used to detect and monitor oncogene mutation status, response to therapy, disease progression, minimal residual disease and recurrence.

Proprietary methods of extracting, purifying, detecting and quantifying oncogene mutations in cell-free DNA.

Clinical collaborations with leading cancer centers and pharmaceutical partners.

CLIA certified, CAP accredited, high complexity lab to offer diagnostic services.

NASDAQ listing in 2012
Foundation IP: Detection of Cancer in Urine
Cash: $67.5M as of Dec 31, 2015
Liquid Biopsies are Transforming Cancer Diagnostics

Detection & Quantitation of Circulating Tumor DNA (ctDNA)\(^1\)

\[\text{Tumor cells shed DNA}^2\]

\[\text{ctDNA enters blood stream and kidneys}\]

\[\text{Liquid Biopsies}\]

1 Bardelli and Diaz. JCO. 2014

2 Tumor growth causes an increase in tumor cell turnover
Liquid Biopsies Enable Detection & Quantitation of ctDNA\(^1\)

*Provides information before treatment, after treatment and at disease progression*

- Systemic understanding of tumor dynamics
- Captures intra- and inter-tumor heterogeneity
- Clinically actionable data in real time
- Flexibility of more frequent testing

\(^1\) Bardelli and Diaz. JCO. 2014
Monitoring is the Largest Liquid Biopsy Opportunity

**Liquid Biopsy Market – $13.6B est.**

- Therapy Selection: $1.7B
- Treatment Monitoring: $5.0B
- Recurrence Monitoring: $6.9B

**Estimated Late-Stage/Metastatic Cancer Incidence/yr**

- Lung: 72,160 (26%)
- Breast: 40,450 (14%)
- Colorectal: 23,170 (8%)
- Pancreatic: 20,330 (7%)
- Ovarian: 14,240 (5%)
- Melanoma: 4,320 (2%)

- Lung: 85,920 (27%)
- Prostate: 26,120 (8%)
- Colorectal: 26,020 (8%)
- Pancreatic: 21,450 (7%)
- Liver: 18,280 (6%)
- Melanoma: 9,330 (3%)

Source: Piper Jaffray 2015 Liquid Biopsy Report

Source: 2016 American Cancer Society, Inc., Surveillance Research
Proprietary mutant allele enrichment method enables ultra-sensitive detection and quantitative monitoring of clinically actionable mutations.

Collection, Extraction and Isolation of ctDNA

Extracted sample contains a small number of mutant DNA fragments in a sea of wild-type.

Mutant Allele Enrichment

Proprietary blocking technology selectively inhibits amplification of wild-type fragments while enabling amplification of mutant fragments.

Detection and Quantitation

Results in a much higher mutant to wild-type ratio, enabling ultra-sensitive detection and quantitation.
Trovagene Value Proposition

- Ultra-Sensitive
- Quantitative
- Noninvasive
- Actionable Mutations
The Trovagene Difference

Where has the MolDx Industry Missed?

- Multi-gene panels with relatively few actionable mutations
- One and done test model
- High cost, low clinical utility, limited impact on outcomes

Trovagene Difference

- Tests are designed to focus only on clinically relevant biomarkers, with clear clinical utilities
- Create value for physicians by quantitatively monitoring disease over time
- Greater clinical utility enables clinicians to optimize treatment and save costs to the healthcare system
Trovagene Precisions Cancer Monitoring® (PCM) Allows Physicians to Make Clinically Actionable Decisions in Real-Time

Current Approach

Diagnosis + Scan at 3 Month

Trovagene PCM

Treatment Starts

Respond?

Respond?

Respond?

Baseline Whole Body Molecular Scan

KRAS BRAF EGFR

Regular Noninvasive Monitoring of Molecular Activity
The Trovagene Advantage

Convenient  Informative  Actionable
## Backed by Robust Intellectual Property

<table>
<thead>
<tr>
<th>Patent Families</th>
<th>Patent Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentrating Urine Family</td>
<td>2035 US app filed</td>
</tr>
<tr>
<td>51-110 bp TrNA Family</td>
<td>2034 US app filed</td>
</tr>
<tr>
<td>Small Footprint Family</td>
<td>2034 US app filed</td>
</tr>
<tr>
<td>Monitoring Disease Family</td>
<td>2034 US app filed</td>
</tr>
<tr>
<td>20-50 bp TrNA Family</td>
<td>2029 US &amp; EU</td>
</tr>
<tr>
<td>Anion Exchange Purification Family</td>
<td>2027 US, EU, Canada</td>
</tr>
<tr>
<td>Viral and Pathogen TrNA Families</td>
<td>2026 US, EU, JP, China, Australia, Canada, India</td>
</tr>
<tr>
<td>TrNA Patent Family</td>
<td>2018 US &amp; EU</td>
</tr>
</tbody>
</table>
29 Clinical Studies Utilizing our PCM Platform

<table>
<thead>
<tr>
<th>Disease</th>
<th>Ongoing</th>
<th>Pending Protocol in Dev/Approval</th>
<th>Market Size U.S. (# of pts)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung Cancer (NSCLC)</td>
<td>7</td>
<td>_</td>
<td>399,000</td>
</tr>
<tr>
<td>Colorectal Cancer</td>
<td>4</td>
<td>2</td>
<td>1,154,000</td>
</tr>
<tr>
<td>Pancreatic Cancer</td>
<td>4</td>
<td>2</td>
<td>42,000</td>
</tr>
<tr>
<td>Melanoma</td>
<td>3</td>
<td>2</td>
<td>922,000</td>
</tr>
<tr>
<td>ECD/LCH</td>
<td>2</td>
<td>2</td>
<td>5,000</td>
</tr>
<tr>
<td>All-Comers, Metastatic Cancers</td>
<td>1</td>
<td>_</td>
<td>525,000</td>
</tr>
<tr>
<td>Total # of Studies</td>
<td>21</td>
<td>8</td>
<td></td>
</tr>
</tbody>
</table>
## Demonstrating the Analytical & Clinical Value of Our Assays

<table>
<thead>
<tr>
<th>Expected in Q1 2016</th>
<th>Expected in Q2 2016</th>
<th>Expected in Q3 2016</th>
<th>Expected in Q4 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Personalized Medicine World Congress</strong>&lt;br&gt;Oral Presentation Revolutionizing Cancer Care with ctDNA</td>
<td><strong>Noninvasive Urine Testing of EGFR Activating Mutation and T790M Resistance Mutation in NSCLC: A Case Report</strong> – David Benz, MD</td>
<td><strong>Detection and monitoring of EGFR mutations in matched urine and plasma ctDNA of NSCLC patients treated with Rociletinib (CO-1686)</strong> – Karen Reckamp, MD</td>
<td><strong>ESMO 2016 Abstract</strong>&lt;br&gt;<strong>EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Abstract</strong>&lt;br&gt;<strong>World Conference on Lung Abstract</strong>&lt;br&gt;<strong>AMP (Pathology) Oral Presentation</strong></td>
</tr>
<tr>
<td><strong>Research Brief: Complete Response to BRAF-MEK Combination in Colorectal Neuroendocrine Tumors Harboring Oncogenic BRAF(^{V600E}) Alterations</strong> – Samuel Klemmner, MD</td>
<td><strong>AACR Annual Meeting Abstract:</strong> ctDNA Assay Performance for Detection and Monitoring KRAS Mutations in Urine for Patients with Advanced Cancers</td>
<td><strong>PCR Mutation Enrichment-NGS Method for Absolute Quantitation and Monitoring of Circulating Tumor DNA Fragments in Urine or Plasma of Cancer Patients</strong> – Filip Janku, MD (MDACC)</td>
<td><strong>Comparison of Clinical Sensitivity Performance in Plasma ctDNA: Trovagene Assays Versus ddPCR</strong> – Bardelli</td>
</tr>
<tr>
<td><strong>IASLC 16th Annual Targeted Therapies of Lung Cancer Meeting Clinical Advisory Board Meeting</strong></td>
<td><strong>AACR Pancreatic</strong>&lt;br&gt;<strong>Detection and quantification of ctDNA KRAS mutations from patients with unresectable pancreatic cancer</strong> – Johansen, MD</td>
<td><strong>Monitoring Daily Dynamics of Early Tumor Response to Targeted Therapy by Detecting ctDNA in Urine</strong> – UCSD</td>
<td><strong>Comparison of Clinical Response Rates to Rociletinib in NSCLC Patients Positive for T790M Mutation by Tissue, Plasma and Urine</strong> – Heather Wakelee, MD</td>
</tr>
<tr>
<td><strong>ASCO</strong>&lt;br&gt;<strong>Abstract:</strong> Quantitative Urinary KRAS for Treatment Decisions in Patients with Metastatic CRC – Barzi&lt;br&gt;<strong>Oral Presentation:</strong> Epidermal Growth Factor Receptor (EGFR) Genotyping of Matched Urine, Plasma and Tumor Tissue from NSCLC Patients Treated with Rociletinib – Wakelee</td>
<td><strong>ASCO</strong>&lt;br&gt;<strong>Abstract:</strong> mRNA Detection of EGFR and KRAS Mutations in Urine of NSCLC Patients Treated with EGFR inhibitors – Barzi</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected in Q1 2016</td>
<td>Expected in Q2 2016</td>
<td>Expected in Q3 2016</td>
<td>Expected in Q4 2016</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------</td>
<td>---------------------</td>
<td>---------------------</td>
</tr>
</tbody>
</table>
| **Personalized Medicine World Congress**  
Oral Presentation  
Revolutionizing Cancer Care with ctDNA | **Noninvasive Urine Testing of EGFR Activating Mutation and T790M Resistance Mutation in NSCLC: A Case Report**  
– David Benz, MD | **Detection and monitoring of EGFR mutations in matched urine and plasma ctDNA of NSCLC patients treated with Rociletinib (CO-1686)**  
– Karen Reckamp, MD | **ESMO 2016 Abstract**  
**EORTC-NCI-AAACR Molecular Targets and Cancer Therapeutics Abstract** |
| **Research Brief: Complete Response to BRAF-MEK Combination in Colorectal Neuroendocrine Tumors Harboring Oncogenic BRAFV600E Alterations**  
– Samuel Klempner, MD | **AACR Annual Meeting**  
Abstract: ctDNA Assay Performance for Detection and Monitoring KRAS Mutations in Urine for Patients with Advanced Cancers | **PCR Mutation Enrichment-NGS Method for Absolute Quantitation and Monitoring of Circulating Tumor DNA Fragments in Urine or Plasma of Cancer Patients**  
– Filip Janku, MD (MDACC) | **World Conference on Lung Abstract**  
**AMP (Pathology) Oral Presentation** |
| **IASLC 16th Annual Targeted Therapies of Lung Cancer Meeting**  
Clinical Advisory Board Meeting | **AACR Pancreatic**  
Detection and quantification of ctDNA KRAS mutations from patients with unresectable pancreatic cancer  
– Johansen, MD | **Monitoring Daily Dynamics of Early Tumor Response to Targeted Therapy by Detecting ctDNA in Urine**  
– UCSD | **Comparison of Clinical Sensitivity Performance in Plasma ctDNA: Trovagene Assays Versus ddPCR**  
– Bardelli |
| **ASCO**  
Abstract: Quantitative Urinary KRAS for Treatment Decisions in Patients with Metastatic CRC  
– Barzi  
Oral Presentation: Epidermal Growth Factor Receptor (EGFR) Genotyping of Matched Urine, Plasma and Tumor Tissue from NSCLC Patients Treated with Rociletinib  
– Wakelee | **ASCO Clinical Advisory Board Meeting** | **Prognostic and predictive value of plasma ctDNA KRAS mutations in unresectable pancreatic cancer patients**  
– University of Copenhagen | **Comparison of Clinical Response Rates to Rociletinib in NSCLC Patients Positive for T790M Mutation by Tissue, Plasma and Urine**  
– Heather Wakelee, MD |

---

Copyright ©2016 Trovagene, Inc. | Confidential
Lung Cancer: Clinical Utility in Stage IV Disease

MOLECULAR DIAGNOSIS AND RESECTABLE DISEASE
- Success of surgery
- Re-staging of cancer
- Adjuvant radiation/chemo or not?

STAGE IV METASTATIC DISEASE
- Selection of correct first line therapy within days of diagnosis – patients go on right treatment early (anti-EGFR or chemo?)
- Re-staging of cancer, response and emergence of resistance
- Replacement of second biopsy and selection of correct second line therapy (anti-T790M or Chemo?)

CLINICAL UTILITY

SUSPICIOUS NODULE
NSCLC
Tissue Biopsy
Surgery
Adjuvant Therapy
First Line Treatment
Imaging (every 6-8 weeks)
Tissue Biopsy
Second Line Treatment
Imaging (every 6-8 weeks)

Molecular Detection & Response Monitoring
Detection of EGFR activating & resistant T790M mutations in urine
The major mechanism of resistance for lung cancer patients is T790M mutation

- T790M – >60%
- Her2 Amplification
- NFkB Upregulation
- MET Amplification
- AXL Upregulation
- Histologic Transformation
Assessment of *EGFR* mutations in matched urine, plasma and tumor tissue in NSCLC patients treated with rociletinib (CO-1686): Interim analysis of 63 patients

**Primary Objective:**
Examine T790M mutation detection sensitivity in urine and plasma of patients with metastatic NSCLC

**Blinded Multi-Institutional Study:**

1. Gadgeel et al., ACR-NCI-EORTC Meeting 2015 │ November 5-9 │ Boston, MA
Urine testing for T790M has high sensitivity with pre-specified urine volume acceptance criteria and identifies patients missed by tissue testing.

When analysis was restricted to samples with the optimum urine volume, >90mL, the clinical sensitivity increased to 93% (13/14).

Urine ctDNA testing identified an additional 4 individuals who were T790M positive.

All four patients samples had matched plasma which were also positive.

---

Gadgeel et al., AACR-NCI-EORTC Meeting 2015 | November 5-9 | Boston, MA
### Sensitivity of Trovagene Plasma vs Tissue

<table>
<thead>
<tr>
<th>T790M</th>
<th>FFPE Tumor, n</th>
<th></th>
<th></th>
<th></th>
<th>total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td>Inadequate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma, n</td>
<td>Positive</td>
<td>32</td>
<td>8</td>
<td>2</td>
<td>42</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>total</td>
<td>35</td>
<td>10</td>
<td>3</td>
<td></td>
<td>48</td>
</tr>
</tbody>
</table>

- In plasma, the clinical sensitivity versus tissue truth is **91% (32/35)**.
- Plasma ctDNA testing identified an additional **10** individuals who were T790M positive.
- Of the **8** patients who were positive in plasma but negative by tumor tissue, all had matched urine. Seven of **8** were confirmed T790M positive in urine.

---

1Gadgeel et al., ACR-NCI-EORTC Meeting 2015 | November 5-9 | Boston, MA
Clinical Performance of *EGFR* T790M Test

<table>
<thead>
<tr>
<th></th>
<th>cobas® Blood¹</th>
<th>Trovagene Blood²</th>
<th>Trovagene Urine (all Volumes)²</th>
<th>Trovagene Urine (≥ 90 mL Volumes)²</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Sensitivity</strong></td>
<td>64% (21/33)</td>
<td>91% (32/35)</td>
<td>76% (19/25)</td>
<td>93% (13/14)</td>
</tr>
<tr>
<td><strong>Clinical Specificity</strong></td>
<td>98% (61/62)</td>
<td>94% (60/64)</td>
<td>98% (106/108)</td>
<td>98% (106/108)</td>
</tr>
</tbody>
</table>

² Gadgeel, et al. AACR-NCI-EORTC, 2015; Manuscript in preparation
Quantitate Drug Response: Lung Cancer

Monitoring dynamics of T790M in urine before and during treatment with 3rd generation EGFR TKIs

Overview & Study Design

Primary Objective:
Monitor for early detection of EGFR T790M mutation in urine of metastatic NSCLC patients treated with erlotinib

Secondary Objectives:
Examine dynamics of EGFR signal in urine during first week of treatment with 3rd generation EGFR TKIs

Study Design:
• Patients with metastatic NSCLC treated with EGFR TKIs
• Urine was collected q3-6 weeks on 1st generation anti-EGFR TKIs and daily on 3rd generation anti-EGFR TKIs

1Husain et al, World Lung Conference, 2015; Manuscript Submitted

Investigator: H. Husain (UCSD)

Serial Urine Collection

Baseline

-6 week -3 week 0 1 2 3 4 5 6 7 days 3 weeks 6 weeks

CT Scan CT Scan Drug

3rd generation anti-EGFR TKI first administered on day 0 and then continued until progression

UC San Diego
Moores Cancer Center

CT Scan
Pharmacodynamic Biomarker for Drug-induced Apoptosis and Early Assessment of Patient Response to Targeted Therapy Within First Week After Therapy\textsuperscript{1}

\textsuperscript{1}Husain et al, World Lung Conference, 2015.
Pharmacodynamic Biomarker for Drug-induced Apoptosis and Early Assessment of Patient Response to Targeted Therapy Within First Week After Therapy

![Graph showing changes in urine EGFR copies/100K GE over time for Patient 1.](Image)

<table>
<thead>
<tr>
<th>Time on Drug</th>
<th>T790M Copies/100K GE (95% CI)</th>
<th>Exon 19del Copies/100K GE (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 0</td>
<td>24 (19 – 38)</td>
<td>167 (125 – 267)</td>
</tr>
<tr>
<td>Day 1 (4 hrs)</td>
<td>&lt; LOD</td>
<td>&lt; LOD</td>
</tr>
<tr>
<td>Day 1</td>
<td>221 (168 – 361)</td>
<td>87 (65 – 139)</td>
</tr>
<tr>
<td>Day 2</td>
<td>34 (28 – 55)</td>
<td>117 (88 – 187)</td>
</tr>
<tr>
<td>Day 3</td>
<td>48 (39 – 78)</td>
<td>36 (27 – 58)</td>
</tr>
<tr>
<td>Day 4</td>
<td>&lt; LOD</td>
<td>&lt; LOD</td>
</tr>
<tr>
<td>Day 5</td>
<td>15 (13 – 25)</td>
<td>&lt; LOD</td>
</tr>
<tr>
<td>Day 6</td>
<td>&lt; LOD</td>
<td>19 (14 – 30)</td>
</tr>
<tr>
<td>Day 7</td>
<td>&lt; LOD</td>
<td>&lt; LOD</td>
</tr>
</tbody>
</table>

LOD (T790M) = 2 copies (12 copies/100K GE)
LOD (Ex 19 del) = 1 copy (6 copies/100K GE)
SLD = Sum of the Longest Diameter of Lesions

Correlation between Longitudinal ctDNA and Radiographic Response

*BRAFV600E burden in urine correlates w/ radiographic response.*

*BRAFV600E allele burden in urine changes dynamically with therapy.*

*Hyman et al., Cancer Discovery 2015 Jan;5(1):64-71*
Large Decrease in Urine BRAF V600E Levels Correlates with Radiographic Response to BRAF-MEK Combination Therapy in Patient with High Grade Colorectal Neuroendocrine Tumor$^1$

$^1$Klempner et al., Cancer Discovery, 2016
Commercial Opportunities

Core Technologies

Direct to Physician CLIA Testing Service

Clinical Trial Services & Translational Medicine Support

Tech Transfer & TrovaCloud Exchange
Adoption and Reimbursement Strategies

**QUALITATIVE**

**Stage 1**
Tumor Status

- Demonstrate concordance of oncogene mutation status between ctDNA and tumor tissue
- **Clinical Utility:** Determine mutational status of actionable biomarkers in ctDNA when tissue biopsy is not available

**QUANTITATIVE**

**Stage 2**
Tumor Dynamics

- Expand mutational coverage of the PCM platform
- **Clinical Utility:** Quantitatively assess mutational status in ctDNA longitudinally, as an indicator of responsiveness to therapy, disease status, and emergence of resistance mutations

**STANDARD OF CARE**

**Stage 3**
Improve Patient Outcomes

- Demonstrate, in multi-institutional trials, that results from ctDNA-based monitoring of actionable mutations increases patient progression-free survival (PFS) and overall survival (OS)
- Demonstrate health economic benefits of noninvasive oncogene mutation monitoring
- **Clinical Utility:** Quantitatively assess patient mutational status in ctDNA longitudinally for mutational status and early detection of resistance to therapy as a decision tool for therapy selection
## Current Contracts

<table>
<thead>
<tr>
<th>Contracts</th>
<th>Lives Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACPN</td>
<td>22+ million</td>
</tr>
<tr>
<td>MultiPlan</td>
<td>68 million</td>
</tr>
<tr>
<td>FedMed</td>
<td>40 million</td>
</tr>
<tr>
<td>Fortified</td>
<td>4 million</td>
</tr>
<tr>
<td>TRPN</td>
<td>14 million</td>
</tr>
<tr>
<td>Galaxy</td>
<td>3.5 million</td>
</tr>
<tr>
<td>stratose</td>
<td>8.6 million</td>
</tr>
</tbody>
</table>
Trovagene 2016 Focus

Clinical Studies
- 29 clinical studies
- Top academic institutions & Comprehensive Cancer Centers

Clinical Evidence
- 8+ abstracts
- Posters
- Oral presentations
- Up to 9 publications

Marketing & Adoption
- Real world case studies
- High clinical interest and strong service levels
- Sales & marketing scale up

Reimbursement
- >100 million covered lives
- Prospective health-Economic study plan

Strategic Partnerships
- Clinical trial services
- Translational research collaborations
- Global presence
Thank You

For Additional Information Please Contact:
David Moskowitz, VP Investor Relations
dmoskowitz@Trovagene.com