Human Microbiome Platform for Next Generation Diagnostics and Therapeutics R&D Technology and Clinical Research Overview
Vision

Metabiomics is translating advances in microbiome science and technology into the creation of new personalized medicine, diagnostics, and therapeutics products and services that will improve human healthcare and well-being.

Mission

Our mission is to continuously advance and apply our patented MultiTag™ DNA sequencing technology and metagenomics discovery platform to pursue innovative molecular systems biology, biomarker discovery, and clinical research aimed at developing diagnostics and therapeutics for the prevention of colon cancer and other gastrointestinal cancerous, autoimmune, and infectious diseases.
Metabiomics Team

Metabiomics management and clinical research team has built a strong technology and business foundation for rapid growth

Thomas J. Kuehn, Ph.D.
Chairman and CEO
• Visionary Entrepreneur and Inventor
• Systems Engineer with 35 year career developing high-tech companies

Louis Y. Korman, MD
VP and Chief Medical Officer
• Leading Gastroenterology Practitioner
• Past Chairman, Crohns and Colitis Fdn
• Am. Soc. Gastrointestinal Endoscopy

Gregory J. Kuehn, MBA
President and COO
• Marketing, PR, Finance, Project and Information Technology Management
• Molecular Biology, Computer Science

Patrick M. Gillevet, Ph.D.
Chairman, Life Sciences Advisory Board
• Pioneering molecular ecologist
• Former director of Harvard Genome Laboratory

Robert Hardi, MD, AGAF, CPI
VP Clinical Research
• Gastroenterology & Internal Medicine
• National Board Crohn’s and Colitis Fdn
• President, APCR Clinical Research

Chris Metz
VP Sales and Business Development
• Experienced Executive, Sales and Reimbursement for Healthcare Products + Services
Metabiomics Leadership

Founders Established Patent Portfolio Prior to Rapid Expansion of Microbiome Field

Google Search Trends for “Microbiome” Interest Over Time

<table>
<thead>
<tr>
<th>Patent 2</th>
<th>NIH - HMP</th>
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<tbody>
<tr>
<td>MultiTag™ Sequencing</td>
<td>Human Microbiome Project Start-Up</td>
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<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2004</td>
<td>Patent 1: Microbiome Colon Disorders Diagnostics</td>
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<tr>
<td>2005</td>
<td>Microbiome Translational Clinical Research</td>
</tr>
<tr>
<td>2006</td>
<td>MetaHit: European Microbiome Project</td>
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<tr>
<td>2007</td>
<td>Microbiome MDx Clinical Studies</td>
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<tr>
<td>2008</td>
<td>Awarded MultiTag US, EU Patents Colon Disorders EU</td>
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<td>2009</td>
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<td>2010</td>
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<tr>
<td>2012</td>
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<td>2013</td>
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Metabiomics Vision
Multi-Disciplinary Approach to Human Microbiome Health and Precision Medicine

Microbiome MDx & Rx Development
- MultiTag™ Sequencing Patent, Colon Disorders Biomarker Patent
- Easy-to-Use Stool Sampling Kits (Home + Rectal Swab)
- Rigorous Clinical Studies w/ colonoscopies + pathology
- Gastroenterology and Pathology Experts
- Systems Biology Approach, Multivariate Statistics, Supervised Learning, Data Mining Tools
Microbiome Value Chain Development

Metabiomics has forged agreements and alliances to build the capability to develop and commercialize new products.

- **Capital Digestive Care, Metropolitan Gastroenterology Group, & INOVA Health System**
- **George Mason University University of Colorado Anschutz Medical Center**
- **Cooley LLP, Baker Tilly, Boston Healthcare**
- **Janssen and/or Mayo Clinic**
- **Kaiser / ACO’s**

**Leading Microbiome University Partnerships**
Translational Research and Development, Biomarker Discovery, Clinical Studies, DNA Sequencing

**Leading GI Clinical Partnerships**
GI/Endoscopy Center Clinical Study Collaborators and Key Opinion Leaders in Gastrointestinal Health

**Advice and Consulting**
World Class engagements for IP Development, Patent Prosecution, Accounting, Regulatory and Reimbursement Consulting

**Strategic Alliances / R&D Collaboration agreements / Licensing Agreements**

Key Stakeholders Main customers will be Accountable Care Organizations such as Kaiser Permanente which are incentivized to make our tests available to their patients.
NGS Molecular Diagnostic Pipeline

Metabiomics MDx systems biology platform powers our biomarker discovery and molecular diagnostics pipeline aimed at early detection and diagnostics of complex GI cancers, inflammatory, and autoimmune diseases.

### Diagnostics Value Chain

<table>
<thead>
<tr>
<th>Clinical Research Biomarker Discovery</th>
<th>Biomarker and Assay Development</th>
<th>Clinical Validation and Trials</th>
<th>CLIA LDT Services</th>
<th>IVD Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>16s rRNA Bacterial ID and Infectious Disease MDx*</td>
<td>CPT Code 16s rRNA</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>NGS Personal Microbiome Health and Dysbiosis Assays*</td>
<td>CPT Code 16s rRNA</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NGS MultiTag™ Sequencing MDx and Clinical R&amp;D*</td>
<td>NGS Gapfill Codes</td>
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<tr>
<td>Colon Polyps and Colorectal Cancer**</td>
<td>LDT Validation FDA-PMA</td>
<td></td>
<td></td>
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<tr>
<td>IBS/IBD and Other GI Diseases**</td>
<td>LDT Validation FDA-PMA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDx and MRx Discovery*</td>
<td>Clinical R&amp;D</td>
<td></td>
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</tbody>
</table>

Chart Key: * Patents  ** Patent Pending or Proprietary
MultiTag™ Sequencing Platform and Clinical Research CLIA/CAP Reference Laboratory
A Fast Track to Profitability in Emerging NGS and MDx Markets
MultiTag™ Sequencing MDx Diagnostic Platform

MultiTag™ and Illumina MiSeqDX Platform provides disruptive breakthroughs in molecular diagnostic by lowering costs and enabling streamlined workflow.

Express Sampling • MultiTag Assay Kits • Automated Sample Prep • NGS Sequencing • IVD-MIA Diagnostics

- Patient and Physician Friendly Sampling Kit
- MultiTag™ Sequencing Kits 96 Samples/Run
- Automated Sample Prep
- DNA Extraction
- NGS Sequencing FDA Approved for MDx
- Computational Diagnostics HIPPA Compliant Cloud Portal

- 90%+ reductions in assay cost
- Patented platform and assay
- High throughput MultiTag™ Sequencing
- Computational Diagnostics MDx Cloud Portal and Reporting
- Global Clinical MDx Database for Monitoring and Data Mining
- Platform Supports MDx Pipeline
Proven Sampling Methods and Kits

Innovative sampling methods and kits that can be used by the patient at home or by the physician during an examination

- Advanced Puritan Hydraflock® swabs and RNA/DNA preservative for transport at ambient temperatures

- Simplified and minimal home stool sampling direct from toilet paper to the swab with no stool contact
Patent Portfolio
Freedom to Operate and Commercialize Microbiome Diagnostics

**MultiTag™ Sequencing**

- Unbiased PCR amplification and abundance profiling
- Sample-Specific Tagging Enables Cost Savings and High-Throughput Microbial Community Analyses
- 1) Community Amplification, 2) Sample Multi-plexing, 3) NGS 4) community de-multi-plexing
- US Patent 8603749 Awarded
- EP 2082063 Awarded

**Colon Disorder Diagnosis**

- Compositions and Methods for Diagnosing Colon Disorders
- Interrogation of microbial communities applied to diagnosing, monitoring, prognosing disease
- US 2009/0197249 Pending
- EP 1815016 Awarded
Investment Milestones

Series A
$2.5 Million

Milestones
- Build professional management, science, computational, and business team at Anschutz Medical Campus in Denver, CO
- Complete MB01 and MB02 Clinical Study of 600-750 CP-CRC screening patients
- Develop computational, biomarker discover, and clinical R&D platform based on CP-CRC clinical study & data analysis.

Use of Funds
- Operating capital, salaries, and expenses
- Clinical R&D, regulatory, pre-market market development from services.
- Intellectual property development,

Series B
$7.5 Million

Milestones
- Complete MB03 Clinical Study of Multi-index and multi-omic CP-CRC assay and MIA algorithm and start FDA clinical trials.
- Complete world-class NGS Microbiome Reference Laboratory with CLIA/CAP certification to support Clinical R&D and services.
- Commercialize GI molecular laboratory and diagnostic assays in health markets and achieve profitability in CLIA/CAP lab operations.

Use of Funds
- Operating capital, salaries, and expenses
- Clinical R&D, regulatory, market development and commercialization of products and services.
- Intellectual property and out-licensing
Metabiomics Colon Cancer MDx

Metabiomics is developing a non-invasive, easy-to-use, stool test for the earliest detection and prevention of colon polyps and colorectal cancer based on an advanced interrogation of the human microbiome.
Metabiomics Colon Cancer MDx Clinical Studies

Neoplasia Clinical Research Study Goals
• Determine Sensitivity to Polyps, Neoplasia
• False Negative Rate for Cancer not Inferior to Gold Standard

MB-01 Protocol

Specific Aim: to determine the sensitivity and specificity of the Metabiomics Colon Polyp and Colorectal Cancer Assay (CP-CRC).

Patient population: 200 patients undergoing routine CRC screening by colonoscopy

3 types of samples collected and analyzed per patient

Chesapeake IRB and MGG Trial Sites

IRB approved within one month of protocol submission

Study implementation within two weeks of Regulatory Binder completion.

2 endoscopy center sites

ClinicalTrials.gov: NCT02141945

Study Progress

Enrollment
  • High level of patient interest

Sample Collection and Processing

Sequencing

Segmentation/Classification

Predictive Model Development

MB-02 Protocol

Specific Aim: to determine the false negative rate for patients with CRC

Patient Population: ~200 post-colonoscopy/ pre-surgery patients diagnosed with cancer

3-4 Planned Sites

ClinicalTrials.gov: NCT02151123
MB-01 Enrollment and Samples

**MB01 Enrollment (Sample Sets 1-8)**

- **Total Number of Patients Enrolled**
  - 8/12/14: 0
  - 9/19/14: 10
  - 9/26/14: 32
  - 10/3/14: 46
  - 10/10/14: 51
  - 10/17/14: 68
  - 10/24/14: 75
  - 11/1/14: 107
  - 11/8/14: 130
  - 11/15/14: 185
  - 11/22/14: 213
  - 11/29/14: 262

- **Date of Report**
  - 7/1/14: 0
  - 7/8/14: 5
  - 7/15/14: 20
  - 7/22/14: 24
  - 7/29/14: 31
  - 8/5/14: 42
  - 8/12/14: 50
  - 8/19/14: 56
  - 8/26/14: 111
  - 9/2/14: 111
  - 9/9/14: 111
  - 9/16/14: 111
  - 9/23/14: 131
  - 9/30/14: 202

**MB01 Sample Sets 1-8 by Collection Type**

- **Accumulative Number of Samples**
  - 7/10/14: 0
  - 7/17/14: 5
  - 7/24/14: 12
  - 7/31/14: 40
  - 8/7/14: 56
  - 8/14/14: 80
  - 8/21/14: 100
  - 8/28/14: 131
  - 9/4/14: 168
  - 9/11/14: 205
  - 9/18/14: 263
  - 9/25/14: 330
  - 10/2/15: 455
  - 10/9/15: 552

- **Number of Samples Per Batch**
  - 7/10/14: 0
  - 7/17/14: 5
  - 7/24/14: 12
  - 7/31/14: 40
  - 8/7/14: 56
  - 8/14/14: 80
  - 8/21/14: 100
  - 8/28/14: 131
  - 9/4/14: 168
  - 9/11/14: 205
  - 9/18/14: 263
  - 9/25/14: 330
  - 10/2/15: 455
  - 10/9/15: 552

**Legend**
- Patients Enrolled
- Colonoscopies
- Pepsis
- Esophagitis
- Biopsy
- H. pylori stool
- Faecal sample
- Total
Early Detection Saves Lives
Opportunity for Colon Cancer Interception

5 Year Survival Rate by Stage of 1st Detection

- Survival Rate
- CRC Management Costs

Pre-Cancer: 100% survival rate, $160,000
Stage 1: 90% survival rate, $140,000
Stage 2: 80% survival rate, $120,000
Stage 3: 70% survival rate, $100,000
Stage 4: 60% survival rate, $80,000
Pre-Cancer: $0
Existing Non-Invasive CRC Test Accuracy

Opportunity for Colon Polyp test and CRC prevention

**Non-Advanced Adenoma**
Sensitivity / Specificity

**Advanced Adenoma**
Sensitivity / Specificity

**Cancer (Stages I-IV)**
Sensitivity / Specificity

Colorectal Cancer Screening for Average-Risk North Americans: An Economic Evaluation
EXAS - Cologuard Exec Summary
Confidential – Not for Distribution
Metrics that Matter

Metabiomics test is the only non-invasive test that can detect polyps & non-advanced adenomas with high accuracy

- The most valuable screening test is the one that get’s done
- Colonoscopy and Sigmoidoscopy are invasive and expensive
- CT Colonography requires rigorous colon prep
- Exact Sciences stool DNA test requires the handling of large amounts of stool
- FIT and FOBT are not sensitive to non-advanced adenomas
## CRC Screening Test Key Attributes

Competitive tests all have at least one sub-optimal feature

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Sensitivity Non-Advanced Adenoma</th>
<th>Sensitivity Cancer</th>
<th>Specificity</th>
<th>Screening Frequency</th>
<th>Ick Factor/Disc (comfort)</th>
<th>Price/COGS</th>
<th>Cost Screening + managing hypothetical 100k patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metabiomics (targeted)</td>
<td>80-100%</td>
<td>90-100%</td>
<td>85-100%</td>
<td>1-2 Years</td>
<td>Low, swab used toilet paper</td>
<td>$300-$400</td>
<td>$35-50</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>85%</td>
<td>96%</td>
<td>100%</td>
<td>10 Years</td>
<td>High, colon prep + colonoscope</td>
<td>$800-$3160</td>
<td>$2,100</td>
</tr>
<tr>
<td>CT Colonography</td>
<td>76%</td>
<td>96%</td>
<td>89%</td>
<td>Rigorous colon prep</td>
<td>$440-900</td>
<td>$2,400</td>
<td></td>
</tr>
<tr>
<td>Exact Sciences Stool DNA</td>
<td>N/A</td>
<td>92.3%</td>
<td>86.6%</td>
<td>3 Years</td>
<td>Patients handle large volume stool</td>
<td>$600 $110</td>
<td>TBD</td>
</tr>
<tr>
<td>FIT Fecal Immunochemical</td>
<td>7-18%</td>
<td>66-73.8%</td>
<td>91-96%</td>
<td>Annual</td>
<td>Low</td>
<td>$10-$30</td>
<td>$1,800</td>
</tr>
<tr>
<td>FOBT Fecal Blood</td>
<td>3-5%</td>
<td>10-50%</td>
<td>95%</td>
<td>Annual</td>
<td>Low</td>
<td>$6-$18</td>
<td>$2,200</td>
</tr>
</tbody>
</table>

source: CRC screening for Average-Risk North Americans: An Economic Evaluation

Colorectal Cancer Screening for Average-Risk North Americans: An Economic Evaluation
# Metabiomics Will Benefit All Key Stakeholders

Interviews with key opinion leaders indicate a winning combination

<table>
<thead>
<tr>
<th></th>
<th>Today</th>
<th>Tomorrow</th>
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<tbody>
<tr>
<td><strong>Patients</strong></td>
<td>• High Cost, invasive, low adherence</td>
<td>• Lower cost, less invasive</td>
</tr>
<tr>
<td></td>
<td>• High morbidity and mortality</td>
<td>• No bowel prep</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• High performance = Peace of Mind</td>
</tr>
<tr>
<td><strong>Primary Care Physicians</strong></td>
<td>• Refer patients to GI’s for colonoscopy and sigmoidoscopy</td>
<td>• PCP’s to perform test</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Charge for in-office rectal swab sampling procedure</td>
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<tr>
<td><strong>Gastroenterologists</strong></td>
<td>• Dissatisfied with currently available tests</td>
<td>• motivated patients for medically necessary colonoscopy</td>
</tr>
<tr>
<td></td>
<td>• Intrigued by microbiome</td>
<td>• Charge for polypectamy procedure</td>
</tr>
<tr>
<td></td>
<td>• Under pressure to justify utility of tests</td>
<td>• Increased Billable Throughput</td>
</tr>
<tr>
<td></td>
<td>• Adenoma Detection Rate</td>
<td>• Increased ADR</td>
</tr>
<tr>
<td><strong>CMS Insurance Companies Accountable Care Org’s</strong></td>
<td>• $14B a year spent on CRC</td>
<td>• Reduction in healthcare costs</td>
</tr>
<tr>
<td></td>
<td>• $140,000+ per patient for late stage cancers</td>
<td>• Effective screening and optimized use of colonoscopy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Increased Screening Program Patient Adherence</td>
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<tr>
<td></td>
<td></td>
<td>• Compliance with Guidelines</td>
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</table>
“The opportunity that stands before microbiologists today is akin to a reinvention of the microscope...Metagenomics will generate knowledge of microbial interactions so that they can be harnessed to improve human health.”

Metabiomics Safe Harbor Statement: This slide deck contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the potential results and future outcomes our clinical research and business plan; ability to discover biomarkers and diagnostic tests, including the ability of the company’s tests to impact clinical practice. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the results of clinical and developmental studies and any resulting products and services; the regulation of our tests by the FDA and other agencies abroad; and the other risks set forth in the company’s business plans and presentations. These forward-looking statements speak only as of the date hereof. Metabiomics disclaims any obligation to update these forward-looking statements.
The Human Microbiome Advantage in Colorectal Cancer Diagnostics and Prevention

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