Agenda

1. About Scientia Advisors

2. Oncology overview

3. Influence of MDx on oncology
   - Early Detection
   - Prognosis
   - Theranostics

4. Conclusion
Science, Knowledge and Skill for your competitive advantage.

Scientia Advisors is an international strategy and management consulting firm with a concentration in life sciences. We have one mission, to ensure that our clients consistently outperform the market and their competitors.
We understand the dynamic forces shaping today’s Life Sciences markets and can guide your organization to exploit growth opportunities

- Identify and define specific strategic market opportunities
- Assess growth options and paths, both organic & inorganic
- Develop strategies for achieving and sustaining leadership

Our understanding of the technology and context of individual Life Sciences sectors enables us to provide realistic viewpoints on market opportunities

- Discovery, Diagnostics, Therapeutics, and Environment Sciences
- Buyer insights, supplier positions, regulatory issues, etc.

Successful execution of strategy relies upon operational realities. We bring a working appreciation of key operational areas, enabling you to link strategy with action

- Sales, marketing, and client interaction
- Product life-cycle management (development, distribution, evolution)
- Partnerships, alliances, licensing, intellectual property, etc.
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Cancer incidence
Lung, Breast, and Colon are the most common cancers worldwide

For cancers of high incidence rates such as breast cancer and colorectal cancer, National Cancer Institute (NCI) recommends screening of the general population for these cancers on a regular basis.

Source: Cancer Journal for Clinicians
The traditional treatment care cycle involves repeated trial-and-error to find the right treatment regimen for each patient.

Traditional Treatment Care Cycle for Breast Cancer

1st Line Treatment
- Surgery
  - Histology
    - Node -
    - Node +
      - Further surgery

2nd Line Treatment
- Radiation

3rd Line Treatment
- Therapeutics

Source: Scientia Analysis
Understanding the Cancer Treatment Paradigm

Breast cancer (BC) traditional treatment paradigm
Complex care cycle with most researched and developed treatment options

Colorectal cancer (CRC) treatment paradigm
Research and development of treatment options are second only to breast cancer

Lung cancer (LC) traditional treatment paradigm
Complex care cycle with few treatment options once cancer advances

Note: All numbers are U.S. annual numbers

First line of treatment
Second line of treatment
Third line of treatment

Source: Scientia analysis, American cancer society, National comprehensive cancer network, colonanswers.com

Note: All numbers are U.S. annual numbers

Source: Scientia analysis, Breast cancer.org, American cancer society, Genomic Health, Medscape, WebMD, and 2004 DataMonitor report
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Oncology has been an early adopter of MDx tests, pointing the way for other diseases

Multiple factors underlie the penetration of molecular diagnostic into cancer care

Medical Need
Cancer remains a leading killer in the developed world, driving researchers, physicians, patients and payors to seek solutions

High Cost
Cancer treatment is expensive:
In 1999-2000, cancer accounted for $60.9 billion in direct medical costs and $15.5 billion for indirect morbidity costs\(^1\)

Research Effort
Over $200 Bn has been spent on cancer research over the last 40 years\(^2\) resulting in significant advances in understanding of pathway biology

Lack of Effective Therapeutics: Overall, only 25% of cancer treatments are effective\(^4\)

Nature of Disease
Cancer is a heterogeneous disease, with over 200 types identified so far\(^3\); each is unique and requires a different therapeutic approach

Standard of Care
has always included sample biopsy of cancer tissue, a requirement for effective personalized molecular diagnostics

Sources: (1) Chang et al. (2004) J Clin Oncol. 22:3524. (2) Scientia analysis; the NCI alone has spent ~$112Bn over the last 40 years (inflation-adjusted; NCI, http://obf.cancer.gov/financial), the remainder consisting of other government sources, industry and charities; does not include basic science research not specifically targeted to cancer. (3) http://www.cancer.gov/cancertopics/alphalist (4) Spear et al. (2001) Trends Mol. Medicine.
MDx tests are having a large impact on oncology care cycle and is likely to greatly influence treatment decisions.

**MDx Screening**: large scale screening of general population periodically

**Imaging**

**Biopsy of suspicious mass**

**Positive Diagnosis & Staging**

**Surgery**

**Node -**

**Node+**

**Radiation**

**Further surgery**

**Therapy (Chemo or Targeted)**

**MDx Predisposition**

Test that screens for cases linked to familial cancer cases (e.g. BRCA)

**MDx Detection**

Detection: Dx of cancer only when doctor suspects it

**MDx Prognosis**

Test that predicts the aggressiveness of cancer (e.g., Genomic Health’s Oncotype Dx)

**MDx Theranostics**

Test that indicates patient’s response to prescribed therapy (e.g. HER2/Neu test for Herceptin)

Source: Scientia Analysis

* Histology
MDx not only provides effective patient treatment, but also assists in monitoring and management.

**Screening & Detection**: Test that screens for cases linked to familial cancer cases (e.g. BRCA) and difficult to diagnose cancers (e.g. Agendia CUP Print).

**Differential Diagnosis & Prognosis**: Test that predicts the aggressiveness of cancer (e.g. Genomic Health’s Oncotype Dx).

**Theranostics**: Test that indicates patient’s response to prescribed therapy (e.g. HER2/Neu test for Herceptin).

**Surveillance & Monitoring**: On-going monitoring to analyze recurrence of cancer (e.g. Agendia Mammaprint for recurrence of Breast Cancer).

**Management**: 

Source: Scientia Analysis
E.g. The breast cancer patient care continuum has been enhanced by MDx tests

E.g. Breast Cancer Care Continuum:

- Biopsy
- Tissue Analysis (e.g. IHC)*
- Surgery
- MDx
- Chemotherapy
- MDx
- Targeted Therapy (e.g. Herceptin)

**Value Proposition of MDx**

- **Early Detection**
  - *Early detection of cancer missed by tissue analysis*

- **Prognosis**
  - *Preventing unneeded chemotherapies*

- **Theranostics**
  - *Tailored therapy leading to reduced adverse effects and high efficacy*

- MDx based early detection will dramatically increase the use of Rx and bundling with early detection tests will give pharma an opportunity to allow Rx to be introduced earlier in the cancer care paradigm
- The use of MDx in prognosis will reduce unnecessary therapies; thus reducing healthcare costs
- The use of MDx theranostics will lead to better drugs that can in turn command premium price

Source: Scientia Analysis

* Immunohistochemistry
The overall MDx oncology tests landscape - 2005
Numerous players emerging with novel biomarkers

Source: Scientia analysis

Scientia Confidential
The overall MDx oncology tests landscape - 2007
Numerous players emerging with novel biomarkers

Source: Scientia analysis

Scientia Confidential
MDx Oncology
Significant growth expected due to novel biomarkers

Key Trends and Growth Drivers
- MDx has changed cancer management, by providing critically information and by reducing expensive downstream tests
- The market is entering a new phase of growth as emerging tests achieve clinical validation and regulatory approvals (e.g. Genomic Health, Veridex)
- With the exception of HPV screening; screening test for all other cancer Dx has exceptionally high barriers to entry

Key Success Factors
- Strong channel to pathology labs and oncologists
- Content is the most critical driver in the oncology. Discovery and validation of content is essential, Multiple clinical studies and publications for validation
- Platform with medium-high throughput, fully automated, with high multiplexing capabilities
- Strong assay development skills, reg. & reimb. expertise

Unmet Needs
- Huge unmet needs in early diagnosis, accurate staging, and determining patient prognosis and eventual response to therapy

The MDx Oncology Market ($ M)

Source: Scientia Analysis
**MDx oncology tests**

We will focus on 3 types of tests: early detection, prognosis, and theranostics.

MDx oncology tests include predisposition, screening, early detection, prognosis, and theranostics tests. We will focus on early detection tests that enable early and accurate detection of disease, prognosis tests that provide disease recurrence free survival information, and theranostics tests that enable increased treatment efficacy and reduced adverse events.
Agenda

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Early detection
Improved methods of detection and better understanding of disease leading to higher oncology Rx sales

• Detection of cancer is currently done using Pathology
  » Based on an optical method of detection
  » Only detects one cancer cell in 200 normal cells
  » Can lead to mis-classification of tumors

• MDx personalized medicine test will improve the detection/staging of Cancer
  » More sensitive than optical methods of detection, can detect one cancer cell in 10 million normal cells; leading to earlier detection of cancer
  » More accurate classification of tumors
  » Early cancer detection will not only lead to increased patient population implying higher oncology Rx sales, but will also give pharmaceutical companies access to a wider range of patients at an earlier point of the cancer care paradigm

Source: Scientia Analysis
Breast cancer detection

Today’s detection methods (Histology) may miss micro metastatic levels of cancer leading to poor prediction of disease outcome and treatment.

**Stage 0** (LCIS/DCIS)

**Stage I**

**Stage II**

**Stage III** (III A/B)

**Stage IV**

Unmet Needs

- Current methodologies may misclassify tumor as benign/localized based on histologic appearance (at least one cancer cell must be present in every 200 normal cells for detection) when the tumor could have micro metastatic levels of cancer cells.

- Unfortunately 30% of patients considered to have benign/localized cancer end up developing metastatic cancer (due to misclassification).

Promise of MDx is very sensitive detection (ability to detect one cancer cell in $10^7$ normal cells) and accurate quantification of clinically relevant micro metastatic cells.

No clinically validated biomarkers available for detection yet.

Agenda

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Prognosis
*A reduction in unnecessary therapies; thus reducing healthcare costs*

- Predicts aggressiveness of cancer, which was not possible by traditional pathology methods, thus addresses an unmet need in oncology today
- Identifies patients with high risk of recurrence who may benefit from adjuvant chemotherapy (improved recurrence-free and overall survival)
- Applies only to early stage patients with inherently good chances of survival (who may be cured with local/regional therapy alone)
- Will reduce unnecessary chemotherapies, leading to fewer adverse side effects
- Are not theranostic tests, but influence key therapy decisions

Source: Scientia Analysis
Breast cancer prognosis

Today, surgeons are having difficulty in predicting tumor recurrence and MDx is addressing this problem

Unmet Needs

- No means to predict recurrence free survival
- Major challenge in determining which women with early stage BC will gain benefit from adjuvant chemotherapy
- No rapid means to predict if more extensive surgery of lymph nodes is necessary

MDx based prognosis assay quantifies the likelihood of breast cancer recurrence to assist in treatment planning (eg. Genomic Health)

MDx based sentinel node assay can rapidly and accurately tell surgeons whether breast cancer has spread and requires more intensive surgery (eg. Veridex)

Exagen with 3 gene panel for prognosis seems to be in final stages of product launch

Celera / Labcorp are also developing a panel of Prognosis markers

Source: Scientia analysis, Genomic Health, Veridex press release on BC sentinel node assay
Prognosis tests are high value diagnostics that reduce healthcare expenditure
e.g. Oncotype Dx from Genomic Health

Key Features

- Predicts likelihood of recurrence and benefit of chemotherapy for early stage (N- ER+) breast cancer
- Test based on algorithm and proprietary 21-gene panel using quantitative RT-PCR
- Genomic Health Financials:
  - ~$25M Revenue 2006, $110M expected by 2008
  - $3,460 price per test

Drivers of Success

- 7 studies with over 2600 patients, published in peer-reviewed journals and presented at national meetings validate the correlation between test results and the need for chemotherapy
- Studies have been conducted with Kaiser Permanente to show economic benefit
- Sales modeled around sales for big pharmaceutical companies, with clinical validation to help secure reimbursement
- Increasing adoption and reimbursement
  - Over 27,000 tests have been ordered by over 5,500 Physicians since 2004
  - Approximately 80% of the population is covered for the test

* Provide critical information that helps physicians make clinically relevant decisions; as a result command premium prices

Source: Scientia Analysis; Genomic Health company financials

^ Other breast cancer prognosis tests provided by Agendia, ABT-CRA, Ipsogen, Exagen, Aviara; with Veridex (JnJ) and Roche entering the market in the future
Agenda

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Theranostics (Thx) are therapy specific diagnostics that can be used to select patients for treatments that are particularly likely to benefit them and to minimize side-effects.

Thx can also provide an early and objective indication of treatment efficacy in individual patients, so that (if necessary) the treatment can be altered with minimum delay.
Major trends and drivers of theranostics

*Key stakeholders see clear benefits to adopting personalized medicine*

**PHARMACEUTICAL COMPANIES**
- Potential for higher pricing due to higher efficacy
- Enables focused trials – smaller groups for shorter periods with better results
- Dx facilitates better Rx sales by enabling better market penetration and expansion

**REGULATORS**
- Greater integration of Rx and Dx for more efficient and safer clinical trials (e.g. critical path initiative)
- Increased vigilance on drug approvals
- Increased approval of genetic tests that influence safety and efficacy of drugs

**DIAGNOSTIC COMPANIES**
- Research advances in biomarker discovery and systems biology is translating into more Dx tests
- Many new companies are emerging that are focused on Dx

**PATIENTS AND PRESCRIBERS**
- Increasing influence of patient advocacy groups
- Personalized medicine reduces unnecessary therapies, leading to fewer side effects

**PAYORS**
- Payment for performance
- Payors are pushing for Rx-Dx integration, especially diagnostics that reduce healthcare expenditure e.g. Oncotype Dx

Source: Scientia Analysis
Regulators are pushing for theranostics

Approval of numerous MDx theranostics tests in recent years that improve safety and efficacy of existing Rx

**On Aug. 22 2006, the FDA approved UGT1A1 test, for use in identifying patients that may be at increased risk of adverse reactions to irinotecan HCl**

**On Dec. 24 2004, the FDA approved AmpliChip CYP450 test, the first FDA approved PGx test**

**On Feb. 6 2007, the FDA approved Agendia’s MammaPrint Dx for breast cancer recurrence, the first IVD Mia test**

**On May 2005, Zarnestra was not approved by the FDA for AML because Johnson & Johnson did not have evidence in their trial that the drug was more effective than chemo. FDA’s Oncologic Drug Advisory Committee on Zarnestra believed that the trials would have more effective if a diagnostic was utilized to determine patients that were not eligible for chemotherapy**

**On Sept. 18, 2007 the FDA approved the first genetic test for Warfarin sensitivity, “Verigene”**

**On Dec. 12, 2007 the FDA relabeled Carbamazepine to include Recommendation of Genetic Test for Patients with Asian Ancestry**
Plagued by low efficacy & safety, Oncology Rx will be one of the chief adopters of theranostics tests

Oncology Rx problem: low efficacy & safety

**Oncology Rx have low efficacy**

- 50% of oncology Rx are not as efficacious for the entire population as prescribed
- Oncology Rx has the lowest efficacy compared to other Rx
  - Historically, oncology compounds tend to have a significantly lower success rate in clinical development than compounds in other areas, such as cardiovascular disease

Solution: Personalized medicine tests

- Fewer rates of adverse reactions
- Better response to Rx, with correct dosages
- Rx provided only when necessary; leading to reduced healthcare costs
- Faster approval of drugs, with smaller test population, in shorter period
- Faster rate of R&D with improved drug discovery targets
- Revival of drugs that failed in the past

Source: Scientia analysis, Trends in Molecular Medicine, Journal of clinical oncology, CDC
Growth in oncology therapeutics will be highly influenced by targeted approaches

Targeted oncology Rx has a higher CAGR as compared to traditional oncology Rx

Key Takeaways

- Targeted oncology Rx have a higher growth potential than traditional oncology Rx
- Thousands of cancer patients are already benefiting from several targeted Rx such as Avastin and Gleevec, personalized medicine tests will enhance the safety and efficacy of these targeted Rx
- Targeted oncology Rx are most likely to be influenced by personalized medicine tests
  - Example: BCR/ABL test enhances the efficacy of Gleevec
  - Example: UGT1A1 test improves the safety of Irinotecan
- High growth potential of targeted Rx will in turn drive the growth of personalized medicine tests
- In addition to oncology, infectious disease Rx such as HIV Rx have also readily adopted personalized medicine tests (e.g. HIV viral load, resistance tests)

Source: Scientia analysis, 2007 Cowen report on therapeutics
Targeted therapies with theranostics have proven the blockbuster potential

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Drug Developer</th>
<th>Test Name</th>
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<td>Herceptin</td>
<td>Genentech</td>
<td>Hercep Test</td>
<td>Dako-Cytomation</td>
<td>FDA approved test to identify breast cancer patients who over-express HER-2. Over-expression of HER-2 = candidate for Herceptin.</td>
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<td>Erbitux/Tarceva</td>
<td>ImClone/OSIP+/Genentech</td>
<td>EGFR pharma Dx kit</td>
<td>Dako-Cytomation</td>
<td>Detection of colorectal cancer patients whom may benefit from treatment with Erbitux/ Detection of non-small cell lung cancer patients whom may benefit from treatment with Tarceva</td>
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<td>Gleevec</td>
<td>Novartis</td>
<td>Ventana Dx c-Kit</td>
<td>Ventana Medical Systems</td>
<td>Detect the presence of the c-Kit protein in GIST. c-Kit = asset in selecting patients who may benefit from treatment with Gleevec.</td>
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<td>Tarceva/Iressa</td>
<td>OSIP+Genentech/AstraZeneca</td>
<td>EGFR</td>
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<td>For non-small cell lung cancer</td>
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<td>Gleevec</td>
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<td>BCR/ ABL</td>
<td>Genzyme Genetics</td>
<td>The test detects all secondary BCR-ABL mutations and therefore predicts resistance to Gleevec for CML</td>
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### Estimated Cancer Targeted Therapy Sales 2006 ($B)

- **Genentech**: $5.2
- **Roche**: $3.9
- **Novartis**: $2.6
- **BMS**: $0.8
- **Others**: $2.1

Source: Scientia Analysis; Kalorama Information, Feb 2007
The pharma oncology pipeline has begun to respond to ongoing unmet needs and research efforts.

The diagram represents the regulatory phases of clinical trials for various cancers, including Lung, Breast, Colorectal, and Prostate. The WW Incidence (in 1000s) for each cancer type is also indicated:
- Lung: 1,352
- Breast: 1,151
- Colorectal: 1,023
- Prostate: 679

The diagram uses colored circles to represent different types of agents:
- Yellow: Receptor Tyrosine Kinase (RTK) Inhibitor*
- Green: Non-RTK Inhibitors^*
- Red: Chemotherapy Agent
- Blue: Unspecified MOA**

* Includes Her-2/Neu, VEGF, EGFR, SRC/Abl, etc.
^ Includes HDAC, DR5-targeted pro-apoptotic receptor etc.
** Unspecified method of action

Source: Scientia Analysis; SG Cowen & Co Report; Company Websites; ClinicalTrials.gov

Scientia Confidential
There are two types of theranostic tests
Both are essential for improved outcomes

Theranostic Tests

- Adverse Drug Reaction Tests
  - Identify people likely to have adverse drug reactions to particular drugs
  - Adverse Drug Reactions are the 6th leading cause of death
  - Includes drug metabolism tests, used to determine right dose
  - One-time tests that cost between $300 and $800
  - Examples: CYP450, UGT1A1

- Drug Responder Category Tests
  - Distinguish between responders and non-responders to a specific drug or set of drugs
  - Includes Targeted Therapy tests, focused on identifying suitable patient subsets for targeted therapies
  - Most well-known category of personalized medicine tests

When combined, these tests provide a comprehensive profile that can be used for treatment decisions

MDx theranostic tests that have focused on identifying suitable patient subsets for targeted therapies

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<tr>
<td>Trofile™</td>
<td>Monogram</td>
<td>Maraviroc/ Selezentry™</td>
<td>Pfizer</td>
<td>For HIV. Identifies patients infected with the R5 virus, which should guide therapeutic use of maraviroc, a CCR5 coreceptor antagonist.</td>
</tr>
</tbody>
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Most well-known targeted therapy tests are in oncology

Source: Scientia analysis
MDx theranostics tests that identify patients with significant adverse reactions to particular therapeutics

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<td>Roche/ Affymetrix</td>
<td>Various</td>
<td>Various</td>
<td>Microarray scan for CYP2D6 and CYP2C19 gene polymorphisms that affect metabolism of common drug classes, including antidepressants and schizophrenia drugs.</td>
</tr>
<tr>
<td>Invader UGT1A1</td>
<td>Third Wave</td>
<td>Irinotecan</td>
<td>Pfizer</td>
<td>FDA approved molecular assay used to identify patients who may be at increased risk of adverse reaction to the chemotherapy Irinotecan. Based on polymorphisms in UGT1A1 metabolism.</td>
</tr>
<tr>
<td>CYP2C9/ VKORC1 genetic test</td>
<td>PGLX Laboratories/Tm Biosciences; Nanosphere</td>
<td>Coumadin</td>
<td>Bristol-Myers Squibb</td>
<td>Identify patients with Warfarin sensitivity, based on polymorphisms in metabolism of Warfarin. Used to adjust dosage and avoid severe bleeding.</td>
</tr>
<tr>
<td>TIM Test</td>
<td>PharmaNetics</td>
<td>Angiomax</td>
<td>The Medicines Company</td>
<td>To monitor patients being treated for angina, myocardial infarction, stroke, and pulmonary and arterial emboli. The tests assess blood-clot formation and dissolution.</td>
</tr>
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</table>

Current tests apply to both specific drugs and multiple classes of drugs, predominantly related to polymorphisms in common or important drug metabolism pathways.

Source: Scientia analysis
Agenda

1. About Scientia Advisors

2. Oncology overview

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Conclusion

- Cancer is complex, multi-fac torial disease comprising more than 100 similar diseases. Current diagnostic tools, including various blood marker based immunoassays, imaging techniques, and biopsy analysis, provide valuable information but remain effective only when the tumor frequency is greater than 1% to 10%

- Molecular diagnostics (MDx) are a game changing innovation that provide previously unavailable patient and disease specific information to oncology treatment care cycle. This new paradigm will eventually change the entire healthcare ecosystem and has shown the greatest initial traction in oncology

- MDx tests are influencing oncology care cycle by:
  - Improving the early detection of cancer
  - Providing a method to predict prognosis of early stage oncology patients, hence helping reduce unnecessary Rx and adverse side effects
  - Improving efficacy and reducing side effects of targeted therapies

- MDx oncology competitive landscape is robust teeming with players exploring competing approaches
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SCIENTIA ADVISORS

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GO-FORWARD DECISIONS