

Building an industry



October 2006

Mårten Wigstøl
Executive Chairman NorDiag ASA

Introduction



- **Mårten Wigstøl**
 - Executive Chairman Nordiag ASA 2005 -
 - Executive Chairman Genpoint AS 2005 -

- **16 years management experience from the biotech industry**
 - CFO in Dynal Biotech (now Invitrogen) 1990 - 1998
 - Co-founder and CEO in GenoVision – (now Qiagen) 1998 - 2002
 - Managing Director Qiagen – transplantation diagnostic division 2002 – 2005
 - Professional board member and investor 2005 -

- **Dynal was the world leader in preparing samples for biological analysis using magnetic beads**

- **GenoVision was a spin out of Dynal Biotech – the first company with a commercial launch of a system for automated isolation of DNA using magnetic beads**

A good model for building industry?



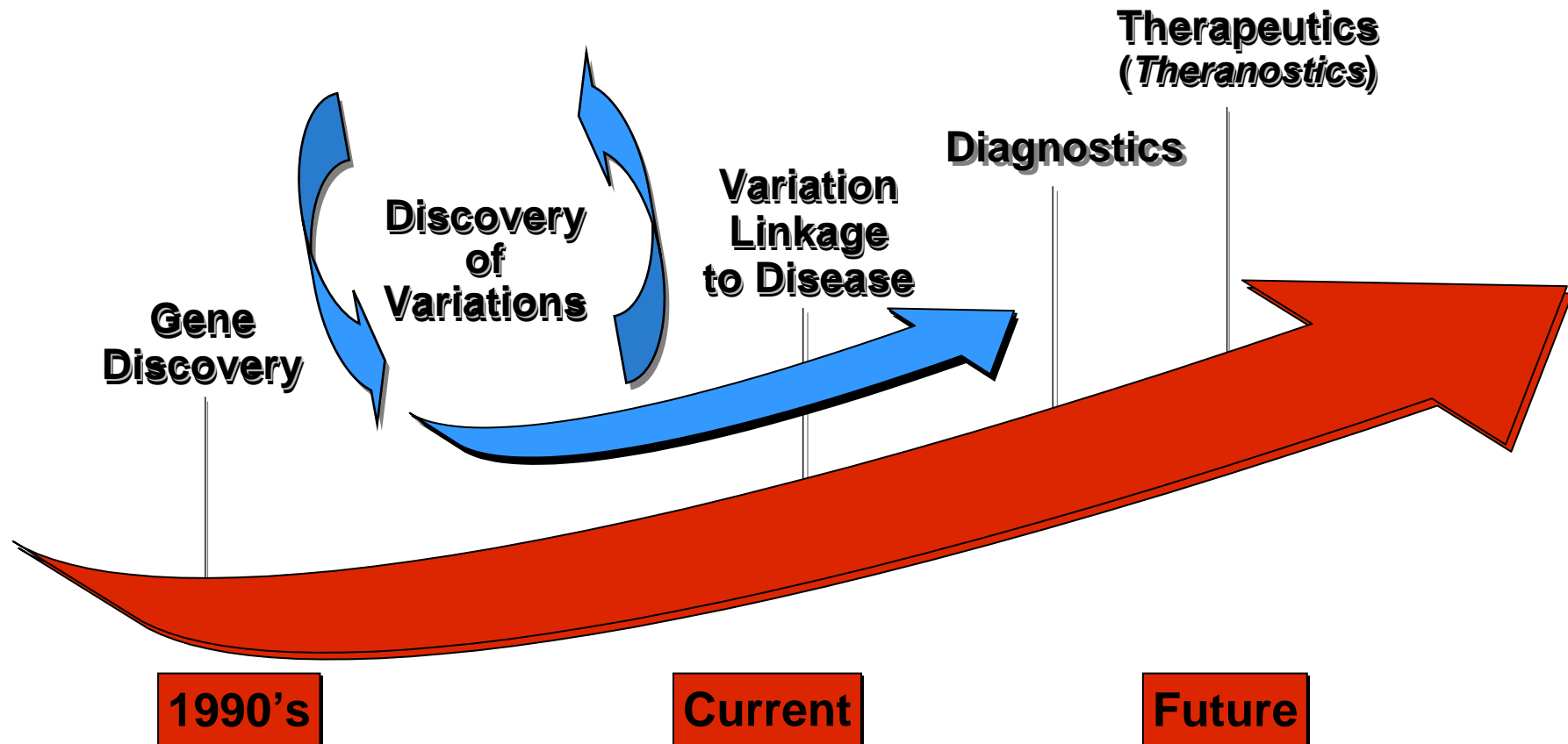
- **Destiny of my previous employers**
 - Dynal Biotech has been acquired by Invitrogen
 - GenoVision has been acquired by Qiagen – the Norwegian office is closed down 3 years after the deal was closed – technology is now transferred to Germany
- **What does this tell us?**
 - It is possible to build successful biotech companies in Norway and clusters builds success – magnetic beads is such a cluster
 - To sell successes to other companies with fat vallets is not necessarily a good model for building biotech as an industry in Norway
- **Alternative routes?**
 - Dynal should have gone public in 1996 – they had the chance both in Oslo and New York (Nasdaq)
 - GenoVision was sold too early – the products have been tremendously successful – the company could have been public today

Nordiag – an early phase IPO



- **The shareholders of Nordiag decided a different route than both Dynal and GenoVision**
- **Nordiag went public very early in its company lifecycle**
- **It is too early to draw conclusions whether this is the correct move or not – the company has still a lot prove**
- **Nordiag ploughed ground for other young biotech companies**
- **Investors recognized that going public on Oslo Stock Exchange is possible**
- **Nordiag has now an opportunity to grow through strategic moves in addition to organic growth.**

Genomics Continuum



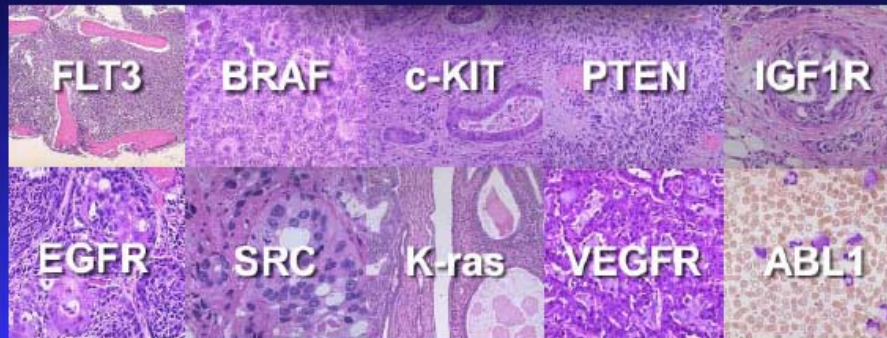
October 2006

Source: Transgenomic Inc

Cancer: A highly heterogenous disease



NorDiag



*Cancers, like individuals,
are distinct...
...even at the molecular level*

Cancer, like the human race, is heterogeneous, dynamic, and full of surprises...



October 2006

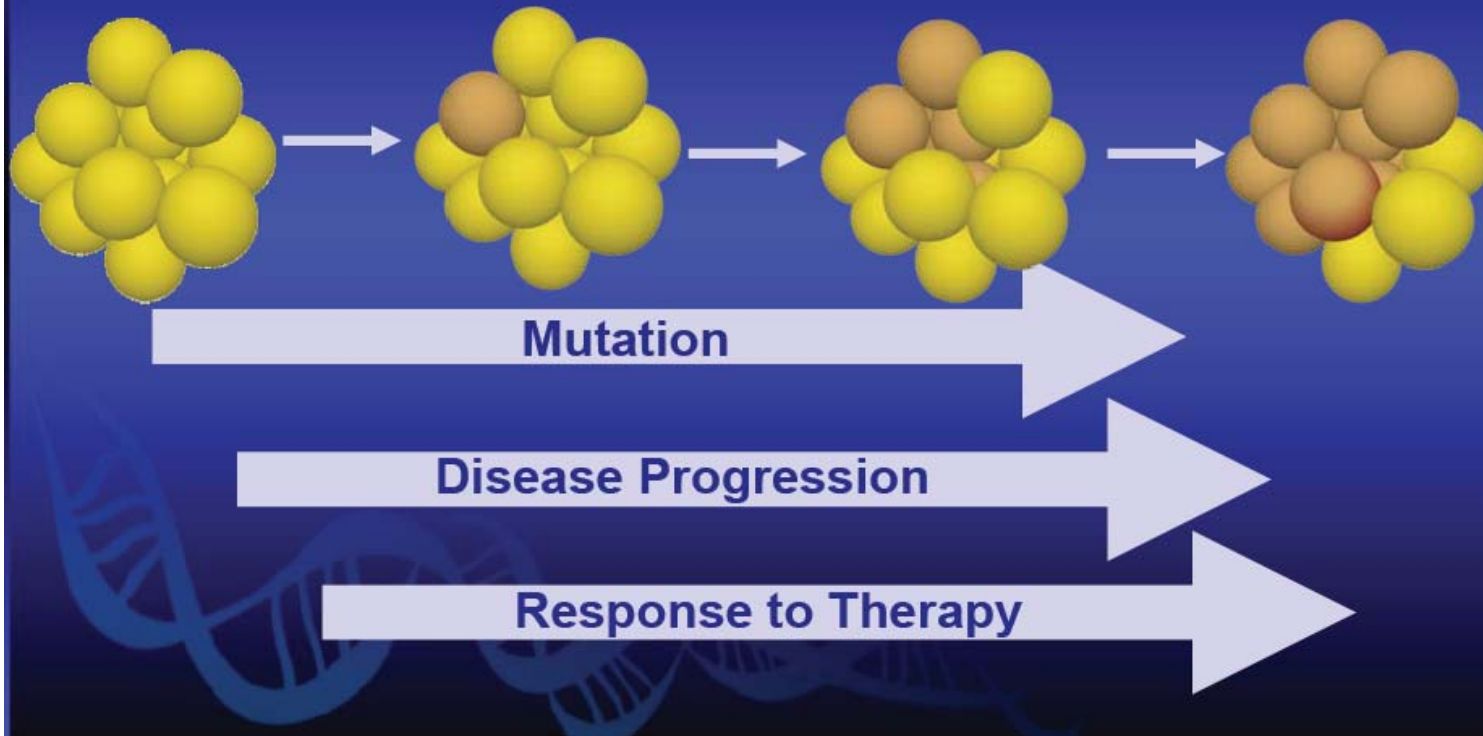
Source: Transgenomic Inc

Cancer: A progressive genetic disorder



NorDiag

Sporadic mutations in individual cells drive disease initiation, progression & responsiveness to therapy



October 2006

Source: Transgenomic Inc

Early mutation detection can save lives

A diagram illustrating the progression of cancer cells. It shows three clusters of spheres representing cells. The first cluster has one brown sphere (mutated cell) among many yellow spheres (normal cells). The second cluster has more brown spheres. The third cluster has a majority of brown spheres. Red circles highlight the brown spheres in each cluster. White arrows point from left to right between the clusters. A large white arrow points from right to left, with the text "How low do we need to go?" written inside it.

How low do we need to go?

- *Heterogeneity of cancer demands highly sensitive mutation scanning method for early detection of important genetic changes*

Briefly about NorDiag

Making a difference in cancer diagnostics

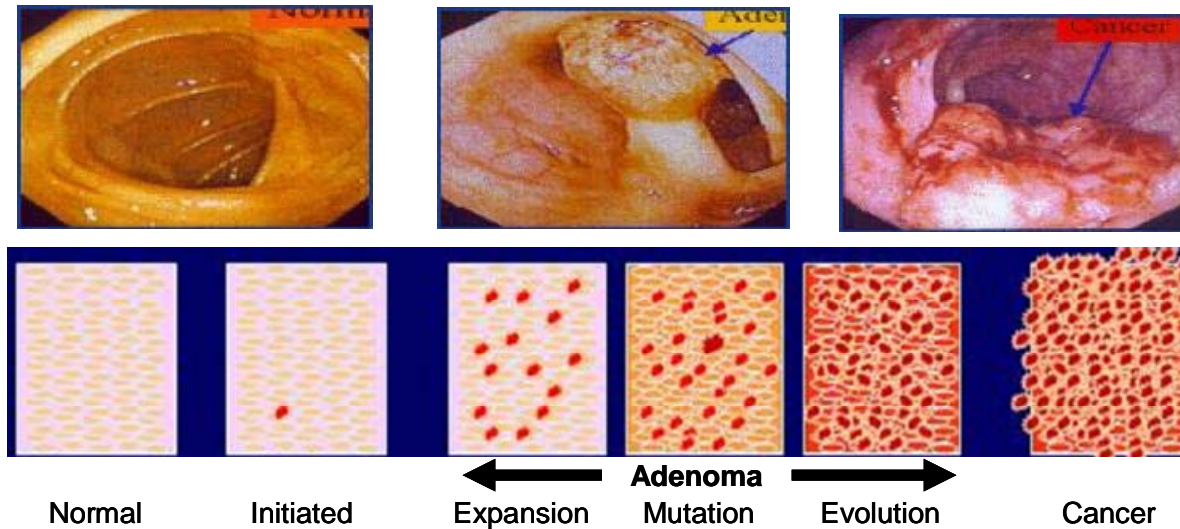


- **Aiming for market leadership in genetic cancer diagnostics**
- **Strong IP**
 - Own patents, in-licensed markers
 - Strong technology basis in DNA isolation and mutation detection
- **Developing a strong product portfolio**
 - Launched Genefec™ for colorectal cancer diagnostics
 - Developing new genetic test for colorectal cancer screening; Screenfec™
 - Exploring opportunities in lung cancer and pancreatic cancer



October 2006

Genefec™ enables earlier detection



Adapted from: American Society of Clinical Oncology; Waun Ki Hong, Reuben Lotan

Briefly about NorDiag's business

Colorectal cancer



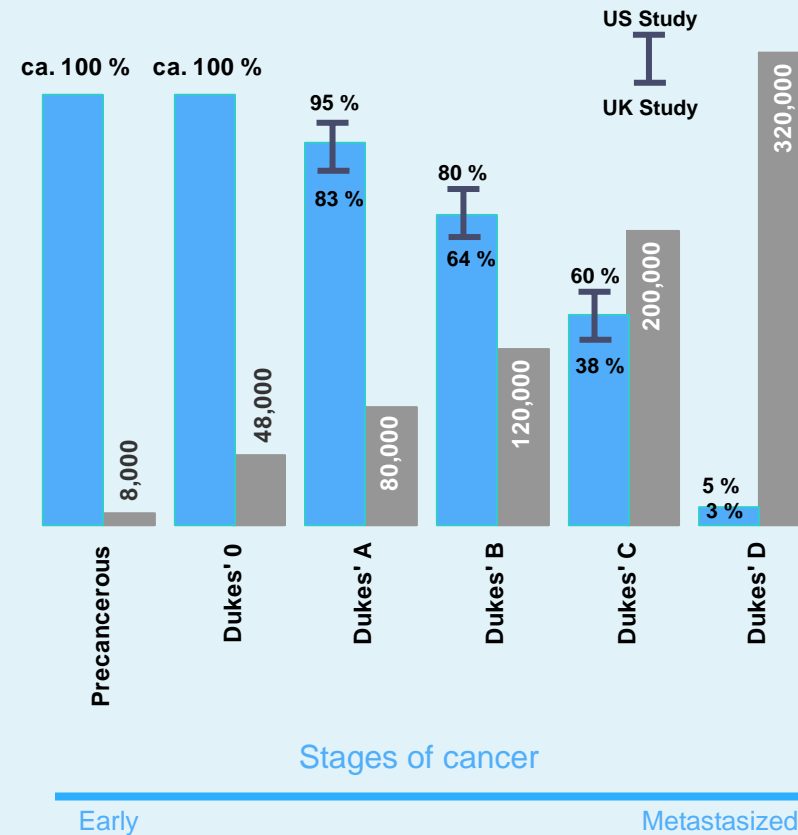
Colorectal cancer is a common disease

- Affects 1 in 20 persons
- Over 1 million new cases per year

Early detection is crucial

- Early treatment dramatically increases survival chances
- Early treatment substantially lowers treatment costs

Treatment cost and survival rate



Sources: US National Cancer Institute; UK National Screening Committee; MD Buyline

Product positioning for Screenfec™ - differentiation

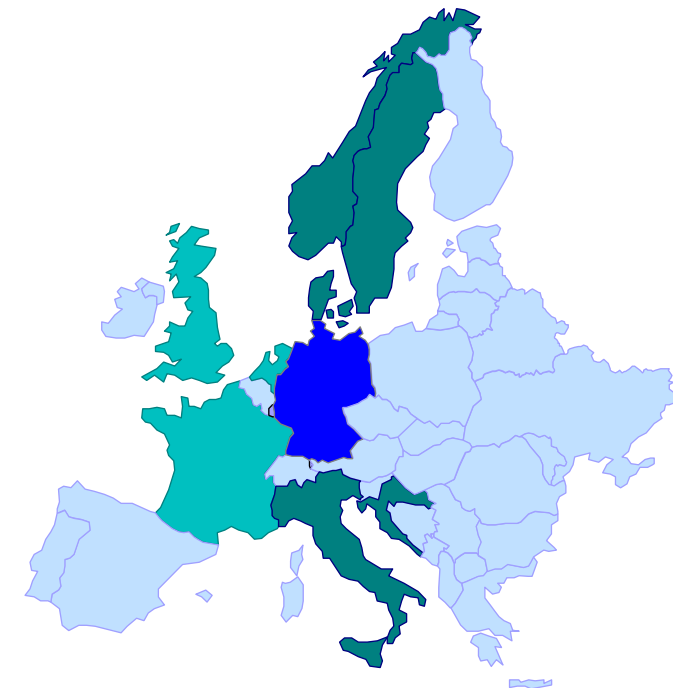


Requirements	Current method - FOBT	Screenfec™ targets
Performance	Positive predictive value for colorectal cancer of 12%	Sensitivity to colorectal cancer above 60% and specificity above 90%
Ease of sample collection	Dietary requirements and samples collected from three bowel movements	No dietary requirements, sample collected from one bowel movement
Automation/scalability	Easy to perform in high volumes	Simple and automatable on off-the shelf instrumentation
Cost efficiency	Cheap but not cost effective High number of follow-up tests (colonoscopies)	More expensive than FOBT but more cost effective High sensitivity and specificity

Screening of populations is driving the market



- **Several countries are considering public screening for colorectal cancer**
 - UK: screening for all aged 60-69 years (2006)
 - France: 22 screening pilots running
 - Similar measures evaluated elsewhere
 - USA recommends regular screening from age 50
- **Market potential in western Europe**
 - 100 million persons in relevant age group
 - Potential volume of 12 million tests per year



- Pilot study underway
- Screening starts 2006-07
- Colonoscopy screening

Outlook



- **Development of Screenfec™ opens the large screening market**
- **Sensitivity improvement of Genefec™ by adding new markers will make the position as a diagnostic test stronger**
- **Launch of Genefec™ and Screenfec™ in major new markets**
- **Test for lung cancer treatment being explored (personalized medicine)**
- **Developing a diagnostic test for early detection of pancreatic cancer**
- **Continued strengthening of the technology base**
- **Conversion from being a service provider to also supplying solutions (kits and reagents)**
- **Explores M&A opportunities to further strengthen the company**

October 2006

Success factors and pitfalls (general)



- **Start parallel processes**
 - Marketing & product positioning must start early - before prototypes are completed
 - Collaborate with the local medical expertise in the preparation of clinical documentation - be aware that clinical documentation might be needed in individual markets
- **Be open to acquire new and complementary technologies from external sources through licensing**
 - The not invented here syndrome could be the end of the beginning
 - Patents do not always stand up – freedom to operate is more important
- **Bring in experienced personnel with international experience**
 - Don't be afraid of hiring someone who is better than yourself
 - Not all positions can be filled through internal recruitment – trial and error management can be dangerous

Success factors and pitfalls (general)



- **Know your market**
 - What is driving the market
 - Define your customers – target market
 - Listen to the market – the customer is always right
 - Use correct market potential (applicable market) for the product – don't fool yourself
- **Product differentiation**
 - A successful product must be more than just a technological superb solution – other factors such as ease of use, cost efficiency could be just as important
 - Make sure you have differentiation in >75% of the important factors
- **What is the competitive edge of a young biotech company**
 - It can do development faster and cheaper than the large diagnostic companies
 - How does this fit with the often used excuse that investors must understand that it takes time and money to reach goals promised yesterday

Government contribution



- **Government**
 - Change the R&D funding system
 - Grants to fund commercialization – not only development
 - Go for the winners/winning projects
 - 100% funding?
 - Equity participation – operational loans?
- **SBIR funding in the US**
 - Phase 1: Everyone get this as long as they have a good business idea and can submit a well documented application – funding amount approximately USD 100'
 - Phase 2: Only the successes from phase 1 get this - funding amount approximately USD 500-700
 - Funding is 100%

Research community



- **Be nice to each other – researcher can be very nasty with each other - collaborate**
- **Listen to and respect the commercial expertise**
 - Be open to starting the commercialization activities early in the process
 - Be open for launch before the system is 100% perfect – 95% is often good enough
- **Be aware of and avoid the not invented here syndrome**
 - Arrogance has killed many biotechnology companies and research projects
 - Respect the capital being invested into projects

Medical community



- **More open for collaborations with the industry – your expertise is important in both product development, clinical documentation and a successful launch**
- **Understanding that the clinical documentation for a diagnostic test is not the same as for a pharmaceutical product**
- **Be more acceptable for DNA based methods – yes they are more expensive but also often more accurate**
- **Be more forgiving – Nordiag is given rough treatment from time to time in the medical doctors own magazine – sometimes deserved – sometimes not**

BY THE END OF THE DAY – ALL PARTIES INVOLVED WILL BENEFIT FROM SUCCESSFUL PRODUCTS FROM NORDIAG OR OTHER NORWEGIAN PLAYERS INVOLVED IN DEVELOPING DIAGNOSTIC TESTS OR BIOSENSORS



WE NEED EACH OTHER IN ORDER TO MAKE SUCCESSES AND MAKE THE PIECES COME TOGETHER