Marketing Biosensors: Opportunities and Pitfalls Based on Real-World Experience

Biomedical Sensor Foresight
Workshop October 6-7, 2005

Agenda

- The Biacore story
  - » What is Biacore?
  - » The story
  - » Experiences learned

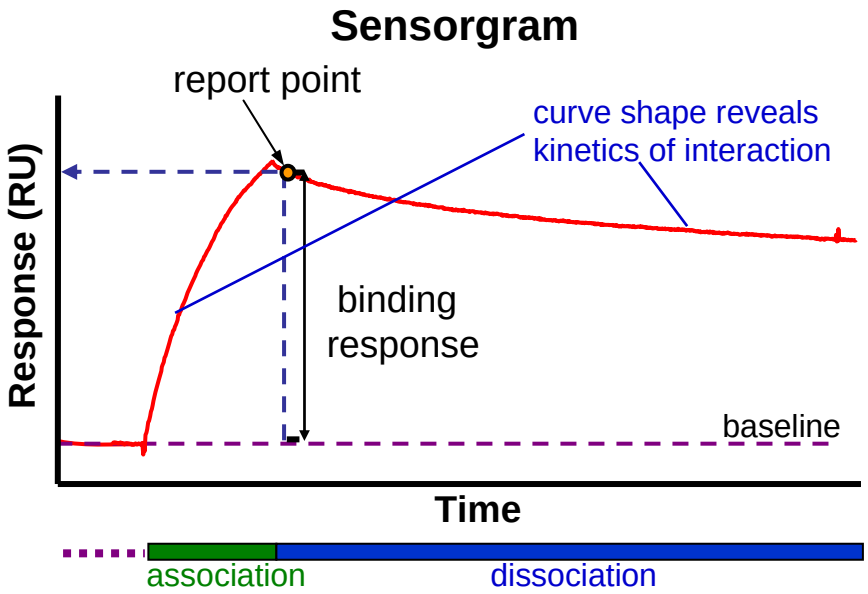
- The emerging Cellectricon story
  - » What is Cellectricon?
  - » Experiences applied

What is Biacore?

A detailed knowledge of molecular interactions is fundamental to the understanding of all biological systems

Biacore has pioneered a technology that provides unique functional information on molecular interactions which is crucial for developing new and better drugs

What is protein interaction analysis?



Follow interactions of proteins with native or recombinants proteins, antibodies and LMW compounds

Critical and unique information from one system

- Characterize proteins as they interact with other proteins, nucleic acids or small molecules:

Detect

Yes/No

Identify

Specificity

Binding partners

Characterize

Affinity

Kinetics

Concentration

Thermodynamics

Product offering

Application expertise and service

Instrument platform

Reagents and sensor chips

Intelligent software

Regulatory compliance

Product portfolio addresses specific market segments

Basic Research → Drug discovery & development → Lead characterization & optimization → Preclinical & Clinical development → Manufacturing & QC

GxP requirement increases

BIACORE® X

BIACORE A100

BIACORE S51

BIACORE C

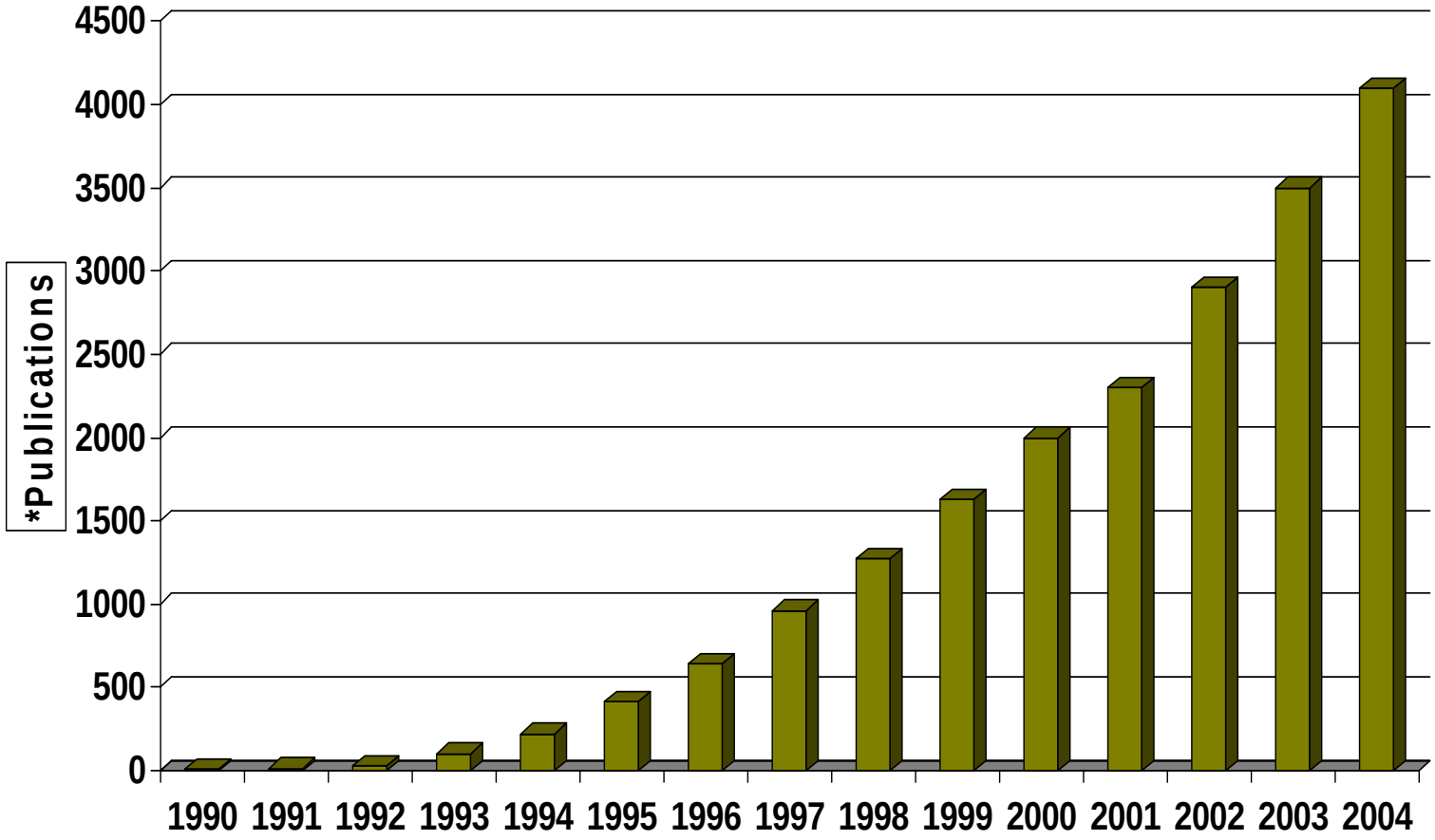
Flexchip

BIACORE 3000

BIACORE T100

Growing Recognition of Biacore's Value

(Cumulative)



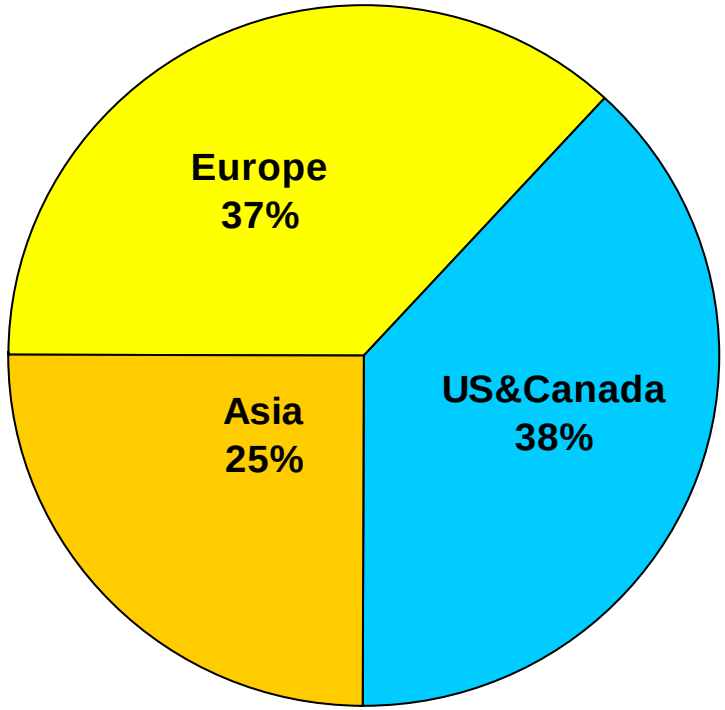
Publications included in Biacore Reference Database

www.biacore.com

Biacore – the company

- Commercial operations since November 1990
- Proven technology for label free protein interaction analysis
- Installed base of over 2500 units; ASP 250kUSD
- Technology cited in more than 4000 scientific references
- High end research, development and manufacturing applications
- Distribution in US, Europe, Japan and Asia-Pacific
- Biacore® - well established brand name
- Listed on SSE since 1996
- Profitable since 1994

Geographic segmentation



Biacore’s sales, 2004

How did it start?

1980 – 1984: Scientific publishing of possible concepts to do real-time and no-label detection.

- Work performed by University of Linköping and National Defence Research Institute defining concepts for detection and surface immobilisation technology.
- Discussions with LKB and Pharmacia for commercialization.

How did it start?

1984-1986: Pharmacia decided to finance an explorative team to develop a first prototype.

- Staff was recruited from Pharmacia, University of Linköping and National Defence Research Institute to form a research group within Pharmacia Fine Chemicals and work started January 1985.
- First generation prototype was demonstrated to Pharmacia management early 1986.
- Decision from Pharmacia to develop a business plan for commercialisation.

How did it start?

1986-1990: Product development and launch preparations.

- Pharmacia Biosensor AB, wholly owned subsidiary to Pharmacia, was founded in 1987 with the aim of developing and launching products based on biosensor technology for applications in life science research and clinical diagnostics. Sales was to be conducted through existing Pharmacia organisation.
- This was the start point for bringing the basic science underlying the technologies (optical detection, surface chemistry and microfluidics) to a product that met the required market specifications and could be reproducibly manufactured at acceptable cost.
- Notable is that all basic Intellectual Property was applied for during these years.

How did it start?

1990-1994: The run for profitability.

- The first product, named Biacore, was launched end 1990 and aimed for molecular interaction analysis.
- Due to changes in Pharmacia, we built up our own sales force (although utilizing Pharmacia´s infrastructure). The changes also meant that applications for clinical diagnostics were abandoned and focus was set entirely on reaching profitability.
- Positive operative result was reached in 1994 – 4 years after launch.

How did it start?

1994-1996: Establishing the market segment in academia and the move to a stand alone company.

- Expanding the sales capabilities by growing the organisations in US, Japan, UK, Germany, France and Nordic countries. Development of distributor network in Asia and rest of Europe.
- Broadening product portfolio by line extensions of original Biacore product.
- Listing on Stockholm Stock Exchange and Nasdaq in 1996. Company name: Biacore AB.

How did it start?

1996-2004: Move to industry applications and the challenge of moving from research to "routine" use.

- Industry applications opened up by improved performance in 1996 and line extensions thereafter.
- Won key IP case in US court 2001
- Quality control approached in 1999, Lead optimization in 2001 and Clinical trials in 2003.

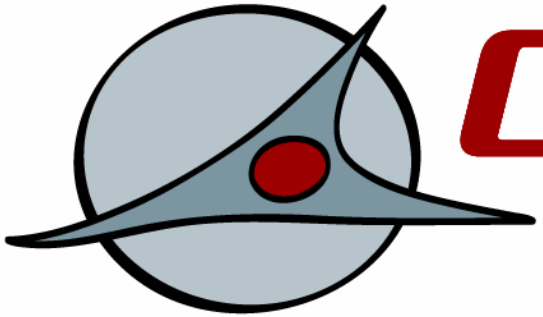
How will it move on?

2004: Industry revenues do not progress as anticipated (market downturn plus time it takes to establish new applications in industry)

- Management change and changed strategic direction towards growth by acquisitions.

Take home message

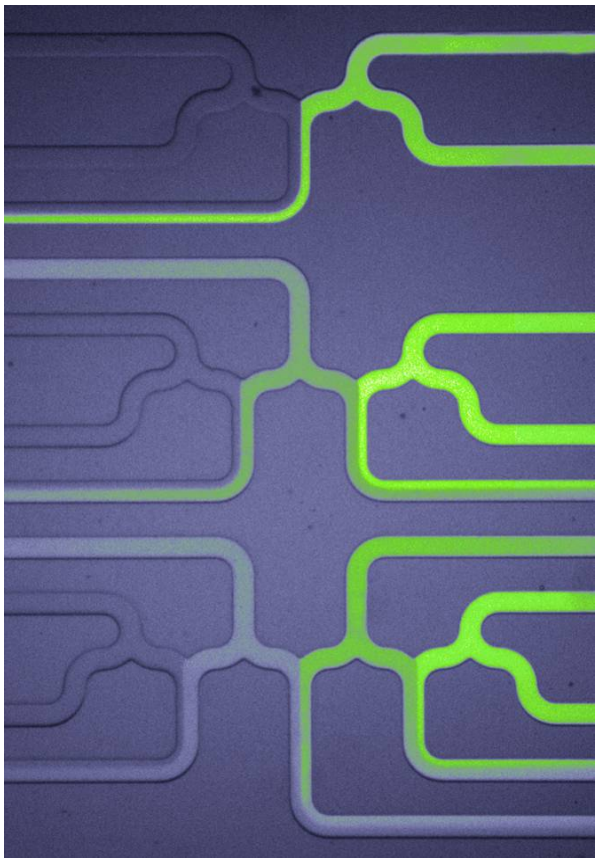
- **Expect pi-rule to happen (plans will take x3 as long and/or cost x3 as expected).**
- **How important is time to market? Consider a slower pace rather than chock-financing that will lead to a series of not so well thought through investments. Investors also have a responsibility to not allow too much money in too short time.**
- **IP is key; freedom to operate is just as important as protecting your own innovation.**
- **Commercialising new technology is challenging – costly and requires sustainability: Biacore took 9 years to breakeven and 500 MSEK accumulated loss.**
- **And rewarding: Biacore accumulated net profit since 1995 is 450 MSEK plus a market capitalization of 2000 MSEK (Sept 2005)**



Cellectricon

Improving productivity in drug discovery

Cellectricon - The Company



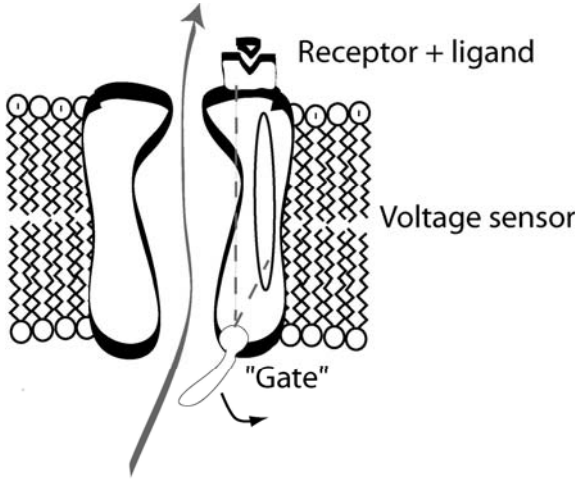
- **Founded in late 2000, and has evolved into an organization of 21 employees. Company's experience is based on research conducted at Chalmers University, Sweden and University of Washington, US.**

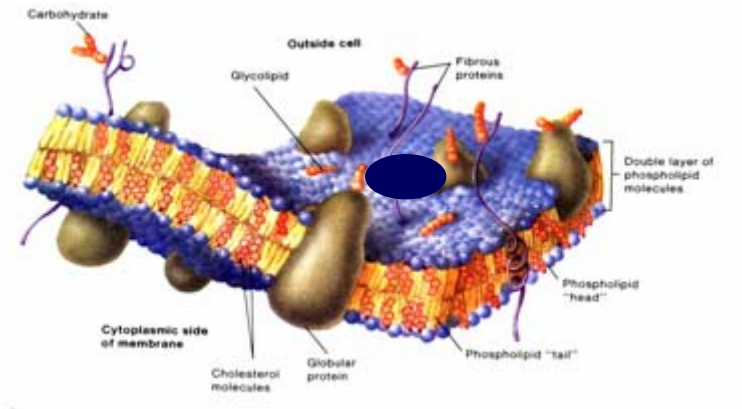
- **Innovative microfluidic solutions for**
  - ion channel **screening and**
  - cell transfection **(gene manipulation)**

  to improve productivity of functional cell-based **assays in the drug discovery process**

- **Unique competencies and a solid patent portfolio in areas such as microfluidics, cell biology, microfabrication and electronics**

Cellectricon Product Lines





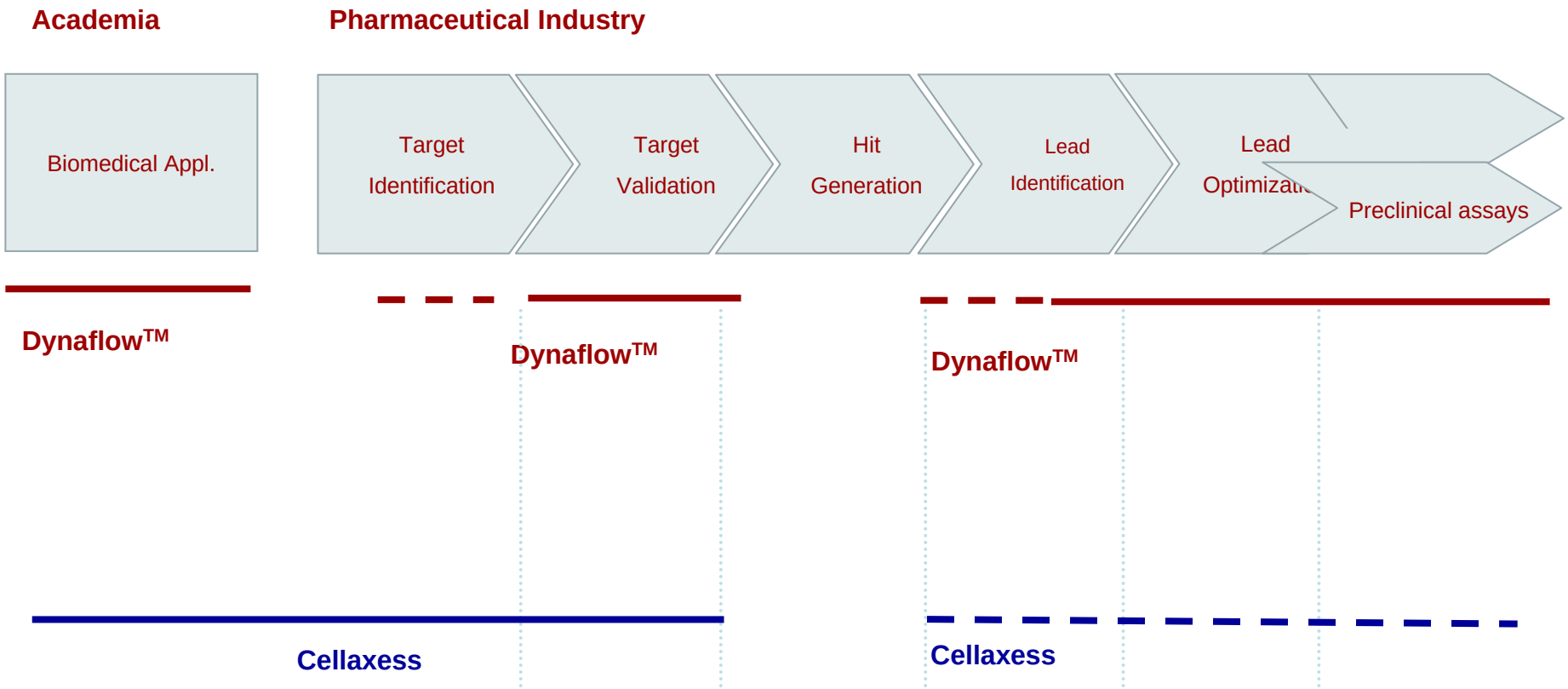
Ion channel drug screening

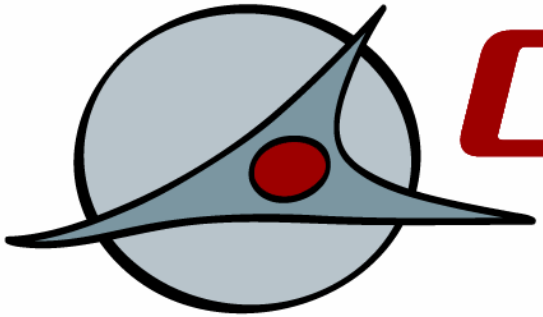
- Dynaflow™ – **products on the market**

Intracellular target screening and iRNA transfection with micro electroporation

- Cellaxess™ - **development**

Cellectricon in the drug discovery process





Cellectricon

Dynaflow™: Cost effective

high throughput electrophysiology

Dynaflow™ – Superior ion channel drug discovery

A computer controlled chip-based system for superior ion channel drug discovery.

Fully integrates with existing patch-clamp equipment and drug dispenser technologies.

Enables cost-effective and easy-to-use high throughput electrophysiology.

Dynaflow™ : application oriented microfluidic chips

DF Pro II 8

- **Designed for cumulative dose-response with long exposure times**
- **Enables longer run time per microchannel**
- **Extracts full dose- response data from single cells**

DF Pro II 16

- **Full dose-response curves with washout between substances**
- **Multiple compound cumulative dose-response curves**
- **Facilitates complex assays**
- **Increased throughput in screening applications**

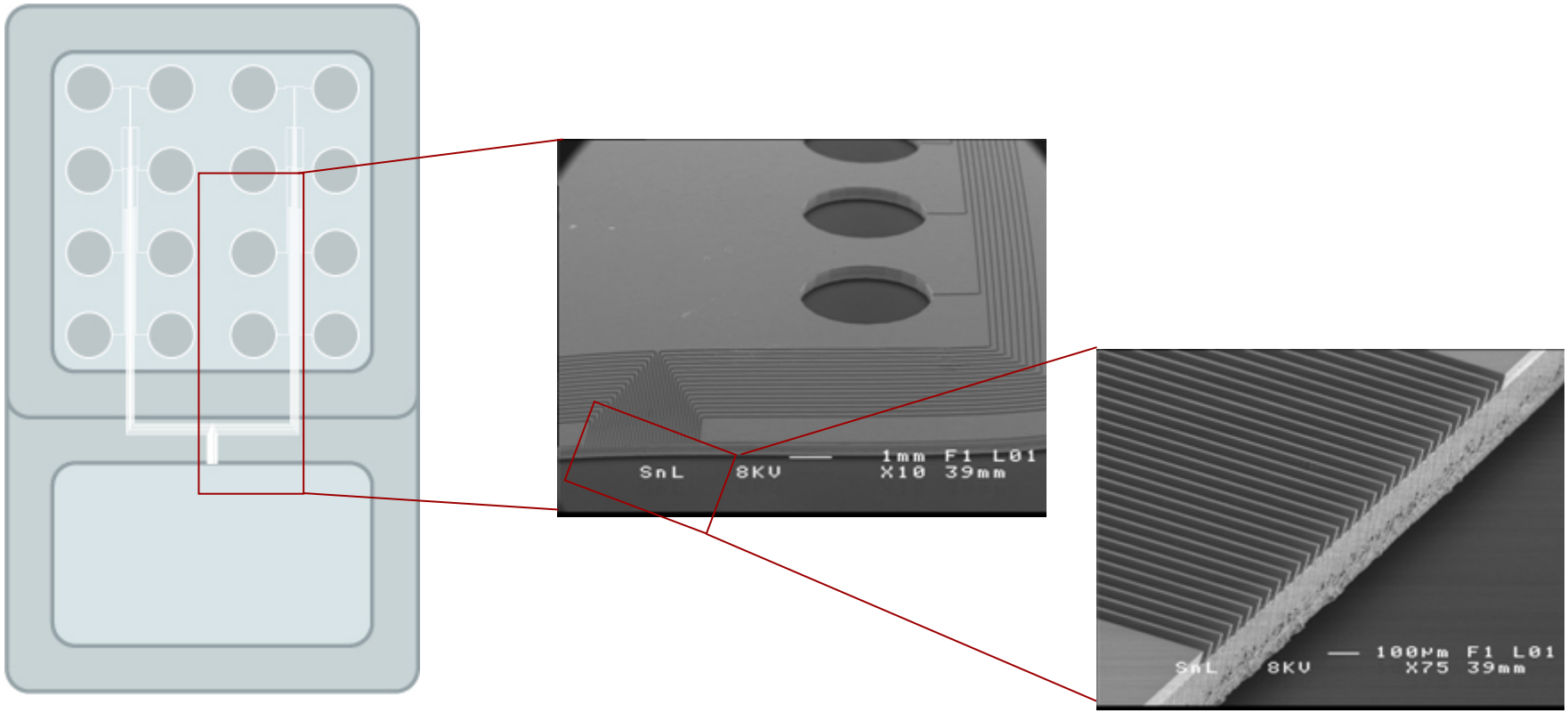
DF 48

- **Multiple compound dose-response curves with automated washout between substances**
- **Facilitates highly complex assays**
- **Maximized throughput in screening applications**
- **Complete campaigns in weeks instead of months**

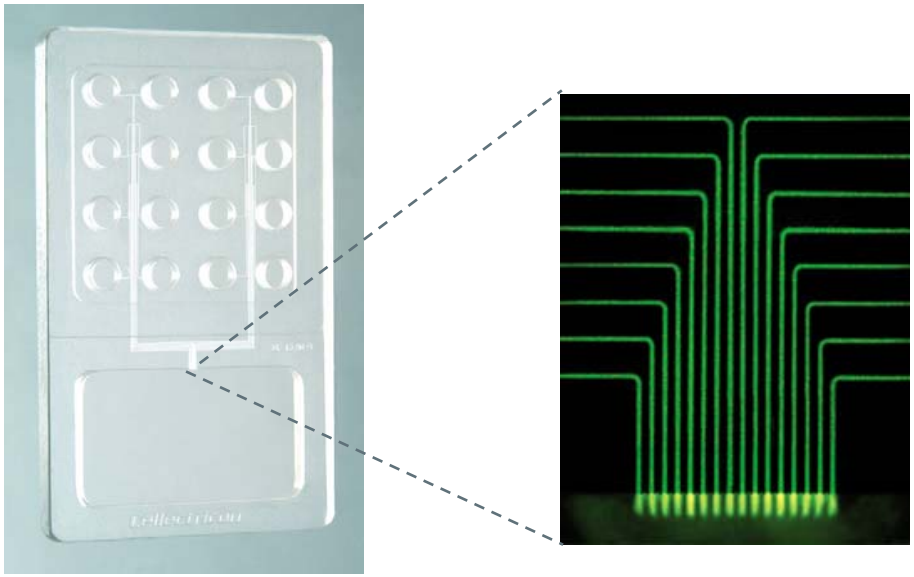
Drug Discovery the Microfluidic's Way

Dynaflow™ Chip Design

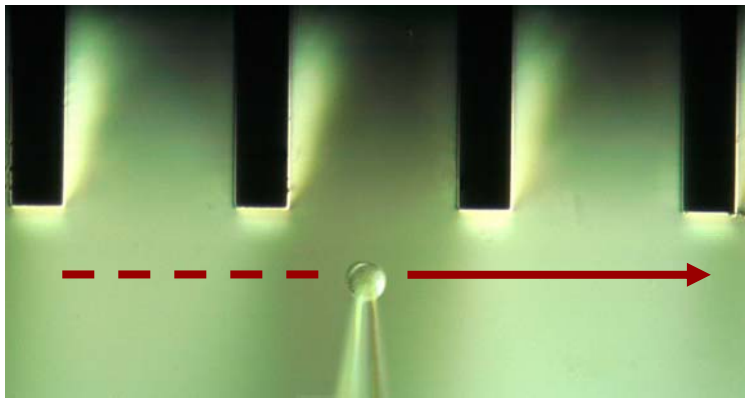
Large arrays of microchannels entering open volumes can be created using microfabrication methods



Microfluidic chips – enabling superior performance



In microstructures, liquid flow is laminar due to low Reynolds number.



Cells are scanned across well defined solution environments

Satisfied Dynaflow™ users

gsk GlaxoSmithKline

ORION

Johnson & Johnson

MERCK

AstraZeneca

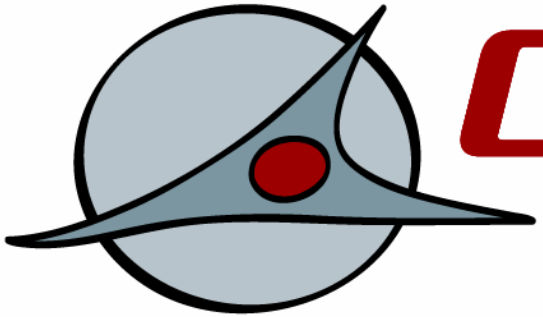
Xention

Group sanofi aventis
Because health matters

Pfizer

Roche

MEMORY SCIENCE WORKING FOR THE MIND



Cellectricon

Cellaxess™: The efficient, universal and ease of use transfection system for **all** cell types.

The Gene – Transfer Market

- The market can be grouped in the research market and the emerging clinical market.

- The “buzz” is currently dominated by RNAi (gene-silencing) in research but the hope is that the methodologies will provide us with tools needed to gene manipulate against diseases.

- As with most other clinical tools, an emerging technology need to be embraced by the research market to win for clinical applications.

- The current focus for Cellaxess is therefore the research market

Cellaxess – The opportunities

- Open up the possibility to transfect primary and stem cells with equal yields as stable cell lines.
- Significantly improved productivity in drug discovery gene silencing and other high throughput applications by making the transfection possible on adherent cells.

Reaching acceptance and proof statements in research market will allow us to approach partners for OEM the technology for clinical applications.

Experiences from Biacore applied in managing Cellectricon

- **Expect pi-rule to happen (plans will take x3 as long and/or cost x3 as expected) – Planning with a touch of optimism necessary; investors know the pi-rule.**
- **How important is time to market? Consider a slower pace rather than chock-financing that will lead to a series of not so well thought through investments. Investors also have a responsibility to not allow too much money in too short time. Dialogue with investors.**
- **IP is key; freedom to operate is just as important as protecting your own innovation. Cannot be overemphasised.**
- **Commercialising new technology is challenging – costly and requires sustainability: Biacore took 9 years to breakeven and 500 MSEK accumulated loss. Current major challenge for Cellectricon**
- **And rewarding: Biacore accumulated net profit since 1995 is 450 MSEK plus a market capitalization of 2000 MSEK (Sept 2005). Still to be proven**

Thank you for your attention