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### **FOBIS: Business – cases and key observations**

Oslo, October 31, 2006

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KUNNSKAPSBASERT NÆRINGSUTVIKLING BASERT PÅ BIOMEDISINSKE SENSORER



### **Topics**



- Definitions and delimitation
- Cases start-ups in medical sensors + consortium
  - Chempaq
  - Sense
  - Wireless Patch
- Some key figures for Denmark
- Nordic potential?







- Medical sensors: Sensors that in one way or another is incorporated in health care
- Biosensor: A sensor incorporating at least two processes. One is a biochemical reaction defining the specificity of the sensor; the other is the physical part that – as a consequence of a biomedical reaction – provides for a readout signal.
- E.g. a hearing aid device involves a sensor but not a biosensor – and is used in order to overcome a medical deficiency. But
- an SPR sensor (Biacore) is a biosensor





### **Example 1: Chempaq**

- A company based on research at the Technical Univ. of Denmark/MIC
- Point-of-care diagnostics at hospitals and GPs
- Very small sample is needed
- Very fast response
- Does require that the GP performs a test that othervise may be performed at a central laboratory
- Mostly in-house development of product and production
   Marketing close to end-users

### Chempaq - Unique testing

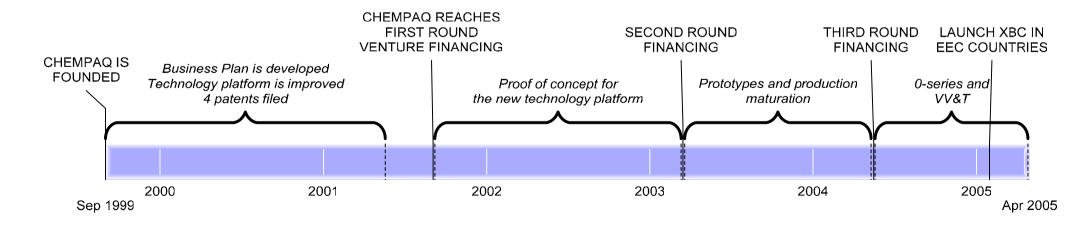




#### History



CHEMPAQ A/S: Founded in 1999 Employees: 20 Key shareholders: Five venture investors and Founder Situated in Copenhagen, Denmark in Symbion Science Park Sales: From March 2005: 100+ Readers and 30.000+ cassettes





#### Changing the paradigm of - The Hematology test flow



By offering a simple 3 minute test providing:

Total Leucocytes (WBC)
Lymphocytes (LYM)
Monocytes (MON)
Granulocytes (GRN)
Hemoglobin (HGB)

Requires only one droplet of undiluted capillary or venous blood sample.

### Within hematology testing, technology hasn't changed for 50 years – until now!

The shown instruments use the same basic technology





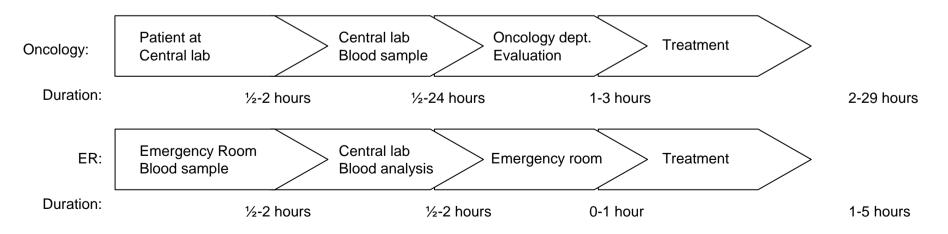




#### Today's "flow" of blood testing

# Primary Care Physician office Central lab Physician office Treatment Chempaq Physician office Central lab Physician office Treatment Total Blood sample ½-1 day ½-2 days 0-1 day 1-4 days

#### Hospitals



#### The Chempaq XBC Solution offering

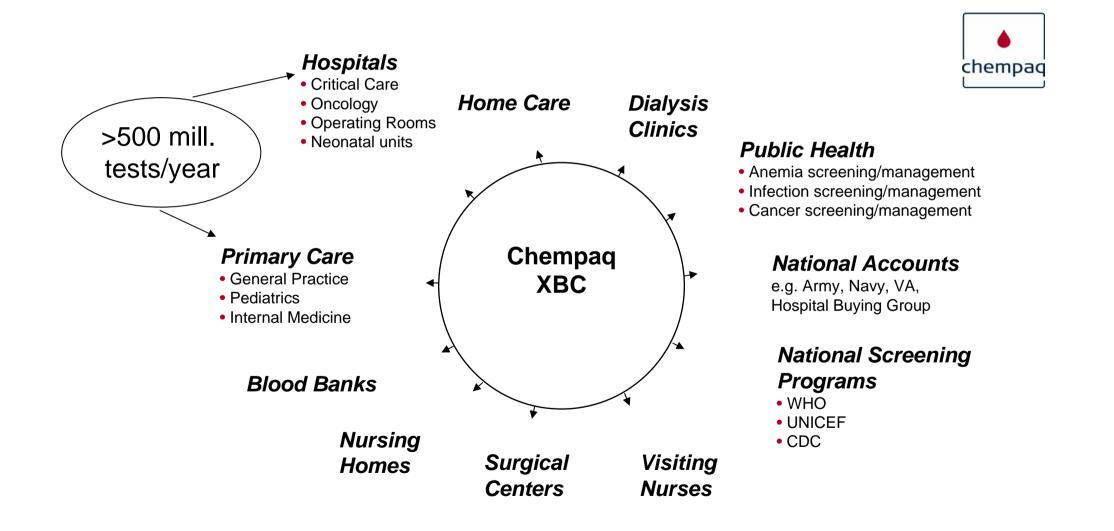




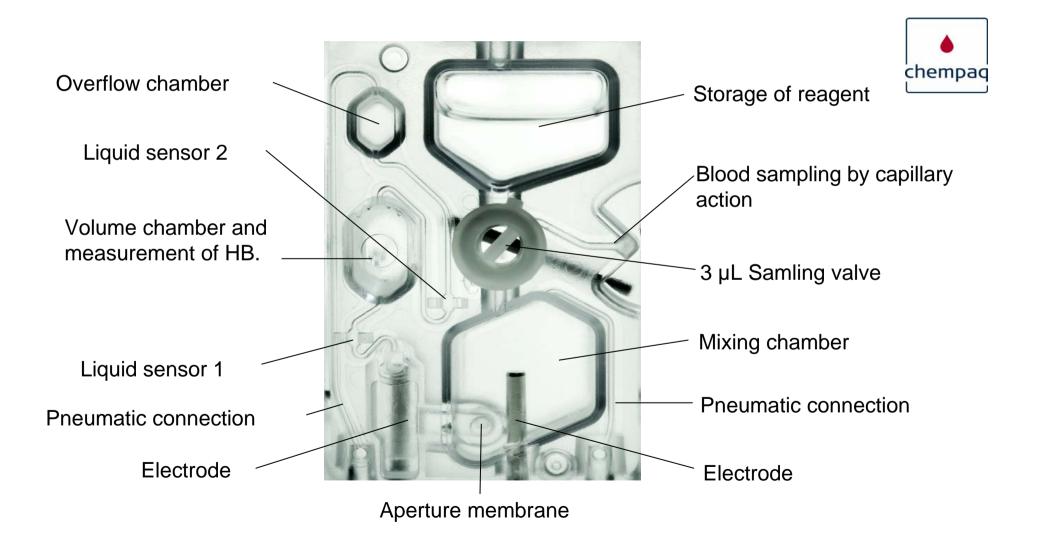
Statement	GP	Hospital
State-of-the-art performance	x	x
Simple/1-step analysis	x	x
Faster diagnosis/3 minutes	x	x
High user comfort	x	x
Low investment	x	x
Improved patient service	x	x
Total cost at equal level		x
Profit	x	
Efficiency – patient mngmt.	(x)	x

Reference to "XBC concept and messages"

Broad application opportunties with the most commonly made/ordered blood tests



#### The PAQ Cassette concept



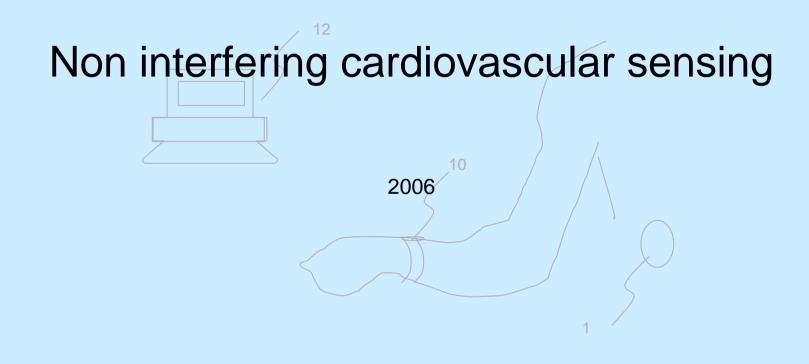




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### Example 2: Sense A/S

- A company based on research at STC, Risø, The Danish Technological Institute, and two hospitals
- Cardiovascular sensing
- Continuous blood pressure and non interfering
- A very preliminary state
- ✓ Very little is done in-house
- ? Based on an early 'exit'



- Established on the basis of an idea for breast milk measurements
- A novel concept was devised and verified
- A large potential market but uncertain of the customers would accept the product
- Cardiovascular measurements
- Wireless, low-cost, disposable sensor a technology has been devised. (Patents applied for)
- Blood pressure is well established
- However, traditional methods do have important drawbacks: Non invasive but <u>not</u> non interfering!
- Continuous measurements during normal activity including sleep.
- Little innovation among traditional vendors
- A substantial market
- Potentially a very attractive ROI

### Some relevant concepts

#### A sensor:

- A device that provides information about the state of a physical system
- Compact and robust
- Tailored to the environment not the other way around

Non invasive:

Does not penetrate any protecting membranes Wireless:

No wires connected tot he sensor

Passive:

No batteries (or wired power connection)

### **Blood Pressure variations**

Studiet viser således, at døgnblodtryk har en overlegen prognostisk værdi for død og kardiovaskulær sygdom i forhold til klinikblodtryk og godtgør anvendelsen af døgnblodtryksmåling også i den almindelige befolkning. *Læge Tine Willum Hansen:* **Den prognostiske betydning af døgnblodtryk i befolkningen (ph.d. 2005)** 

Alle med hypertension bør om praktisk muligt før behandlingsstart have udført en døgnblodtrykseller hjemmeblodtryksmåling for at vurdere, om patienten har betydende konsultationshypertension.

... solid dokumentation for at døgnblodtryk bedre prognosticerer kardiovaskulær morbiditet og mortalitet ...

... natblodtrykket eller nat/dag ratio i nær fremtid vil blive indført som en parameter med klinisk betydning.

Lia E. Bang, Kent Lodberg Christensen, Klavs Würgler Hansen, Karin Skov & Niels Wiinberg: **Diagnostisk blodtryksmåling - på døgnbasis, hjemme og i konsultationen**, Dansk Hypertensionsselskab 2006

Search at PubMed (NIH) on "Blood pressure variations" gave 3432 responses!

### Blood Pressure – traditional instruments

#### Mercury sphygmomanometer

- May be bulky to carry.
- Mercury spills can be hazardous.
- Must be kept upright on a flat surface during measurement; the gauge must be read at eye level for accuracy.
- May not work well for the hearing or visually impaired or for those unable to perform the hand movement needed to squeeze the bulb and inflate the cuff.

#### Aneroid equipment

- Has a delicate and complicated mechanism.
- Less accurate than mercury sphygmomanometers and requires calibrating at least once a year or when dropped or bumped.
- Can be easily damaged without the user's knowledge and requires factory repair and readjustment.
- Gauge can be clumsy to position, and without a D-ring cuff can be difficult to apply by oneself.
- May not work well for the hearing or visually impaired or for those unable to perform the hand movement needed to squeeze the bulb and inflate the cuff.







(Source: American Heart Association)

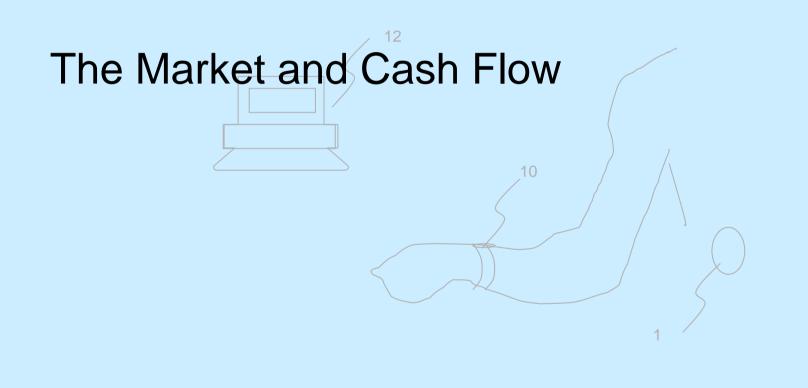
#### Sense A/S

### **Blood Pressure by Sense**

- + Non interfering (minimum)
- + Continuous
- + Wireless and passive sensor
- + Disposable sensor
- + Low cost of sensor
- + Measurements in a non-medical environment
- Calibration
- Mounting
- Obesity

### Cardiovascular measurements

- ⇒ Pulse
- ➡ Compliance
  - Flow
- Composition (pulse oximetry)
- ➡ Blood Pressure

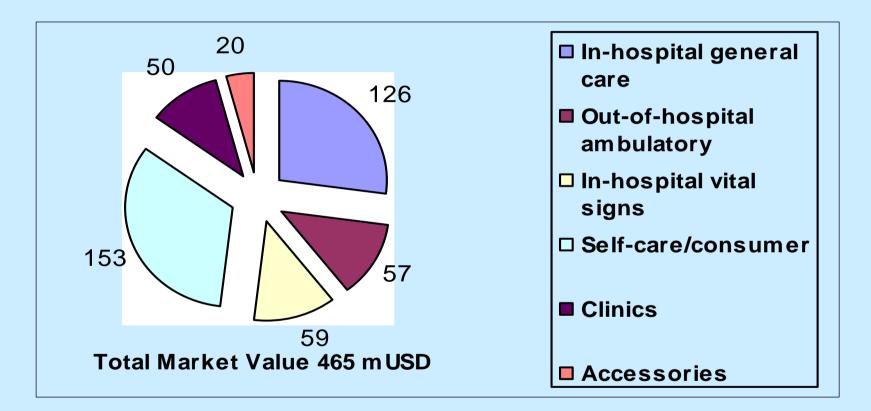


### Welfare diseases

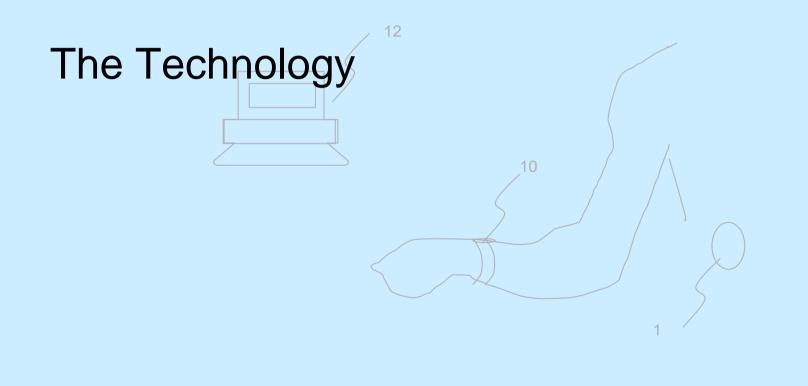
- Diabetes
- Cardiovascular
- Approaching one third of the population in the affluent part of the world – and also growing rapidly in less affluent parts

- Overall numbers are established
- The market structure is researched: user, decision making, reimbursement . . .
- How to approach the market: A novel product + a well established vendor of health care products

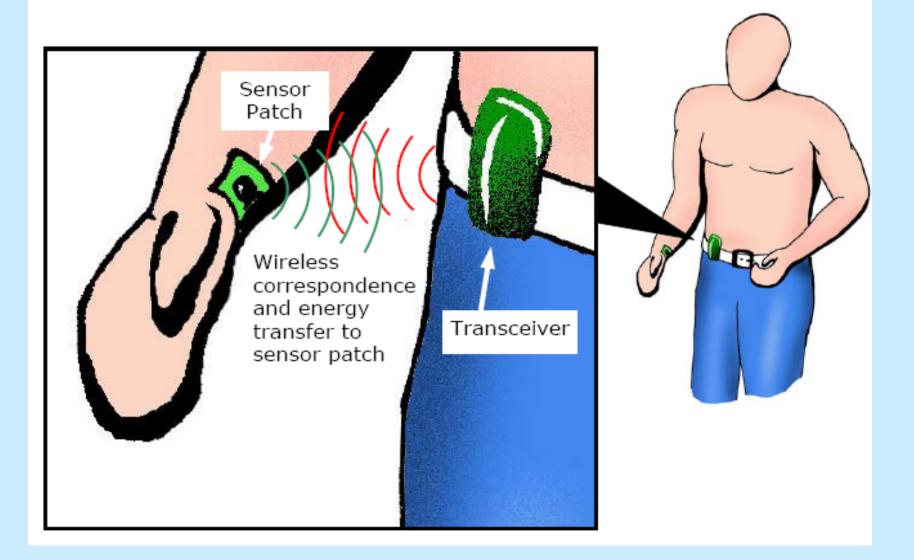
### **BP** Market



Susanne Friis: MBA project



### System lay-out



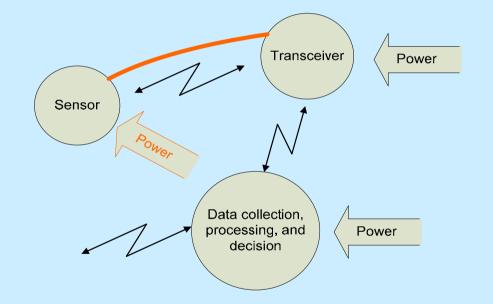
### Verified + Risks

A compilation of what has been verified what needs to be verified and possible risks has been compiled. This is essential for investors

### **Competing products**

Triage (www.triagewireless.com):

- + Same medical objective
- + Wireless 'transceiver' data collection and decision
- Wired 'transceiver' sensor (?)
- Not 'passive' requires batteries in or wired power to the sensor
- An optical scheme measuring density (Sense's optical scheme measures displacement + density)
- + Signal and data processing most likely with the same key elements



### Competing products

- Life Source (A&D Medical)
  - Unlike other monitors that measure blood pressure during deflation of the cuff, the Dual Memory Wrist monitor measures blood pressure during cuff inflation for a faster, more comfortable reading. Each START button stores 30 blood pressure measurements for a total of 60 readings. The average reading feature automatically calculates the "average" of the total readings stored in memory.



### Key personnel and competence centers

- People with a solid background in health care business as well as in R&D
- Key medical experts

Kompetence centers:

- ✓ Microtechnology and Surface analysis (DTI)
- ✓ A leading hospital with experts on BP and cardiovascular diseases
- ✓ MIC (DTŬ)
- ✓ Electronic development
- ✓ Software house

### Other applications

#### Diseases:

- Diabetes
- Blood gas
- Kidney dialysis
- Drug levels
- pH
- Fibrionolysis
- Cholesterol
- Exhaust gas

Structural health monitoring:

Embedded sensors (humidity, chlorine conc., strain ...)

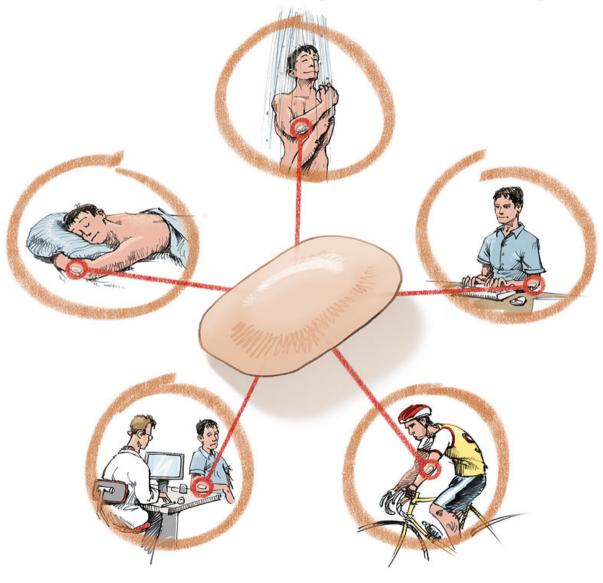




# Example 3: A public-private project on wireless non-interfering sensing

- The wireless technology that can form the basis for a number of wireless medical sensing schemes
- The system architecture
- EMG as a specific example based on research at Univ. of Aalborg/SMI
- Also oxygen in blood, and cardiac . . .

#### The Electronic Patch: Monitoring with no strings attached!

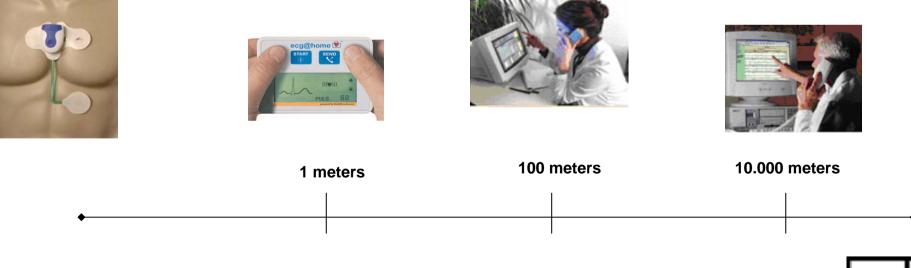




### The Electronic Patch Network

#### From body

- to monitor wireless
- to family or local care via LAN or wireless
- to healthcare centers, hospitals or alarm centrals via the internet and EPR





### **Benefits!**

#### Shorter length of stay at the hospital

- Fewer days of admission
- Maybe even no admission

#### More freedom

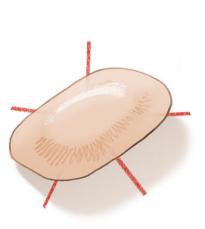
• mobility and sustained ability to work

#### Better data

- ECG's without the "doctor-effect",
- constant monitoring
- monitoring during normal daily chores

#### Less perceived sickliness

- An electronic patch will be barely noticeable by the user or by his/her surroundings
- An aid for prevention and supplementary aid to help t care of our own illness





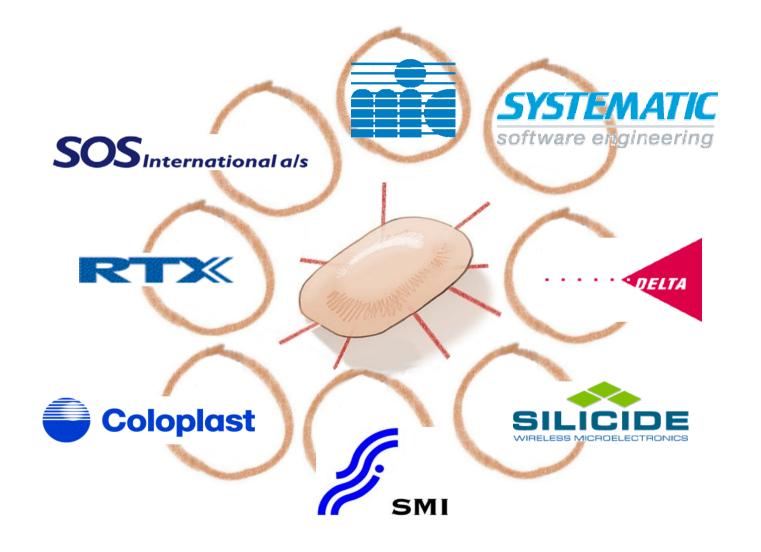
### The EP Project

3 yeas and 28 man-years:

- Research and development of wireless sensors embedded in adhesives for physiological measurements
- New sensors for measurement of oxygen levels in the blood and heart-function
- Experiments on monitor systems for measurements on muscles
- Demonstrations on applications for heart-patients in their own home and firemen in action
- Aid other Danish companies with development and deployment of **a technology platform** for the Electronic Patch in new products and services.



### Partners:





### Meeting reality

- the demonstrations and the result

Measurements on patients with heart conditions

- Sygehus Vendsyssel Frederikshavn
- Hjemmeplejen i Frederikshavn.

#### Firemen

 Århus Brandvæsen (Firebrigade of Aarhus)



## A Platform for future products and services!







### **Observations**



- A novel idea is mandatory but far from adequate
- Small start-ups are generally better at developing and implementing new technology than established companies
- They are not very good at marketing
- Bridging the gab from very early seed capital to venture financing is the most difficult part – and in serious need of new financing schemes
- SBIR in the US could be a model (http://www.sba.gov/SBIR/)
- The Nordic countries do fulfill most but not all of the requirements needed to become a world leading player



### **Nordic shortcommings**



- Bridging the gab . . .
- Cross-disciplinary collaboration
- Enough adequately qualified personnel