Establishment of start-up companies and their operating effectiveness at a later stage – a case study.

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Tomasz Borowik
Magdalena Przybyło

“Conference European Research Infrastructures for Innovation and Development”
Wrocław June 2010

Knowledge based ekonomy is a ekonomy in which knowledge production, distribution and implementation is the main driving forces of wealth generatin and emplyment in the whole economy (OECD 1996, APEC 2000).

The social and economical development of society is correlated with the impelmentation of technological, organizational, menaguing and educational innovations.

The National Nanotechnology Initiative

President Clinton, 2000

OECD – Organisation for Economic Co-operation and Development

APEC - Asia-Pacific Economic Cooperation

"The person who takes medicine must recover twice, once from the disease and once from the medicine."

- William Osler, M.D.

The motivation:

The development in Wrocław the infrastructure for research and development of new generation of pharmaceuticals (targeted drug delivery systems).

Basic concept of the technology

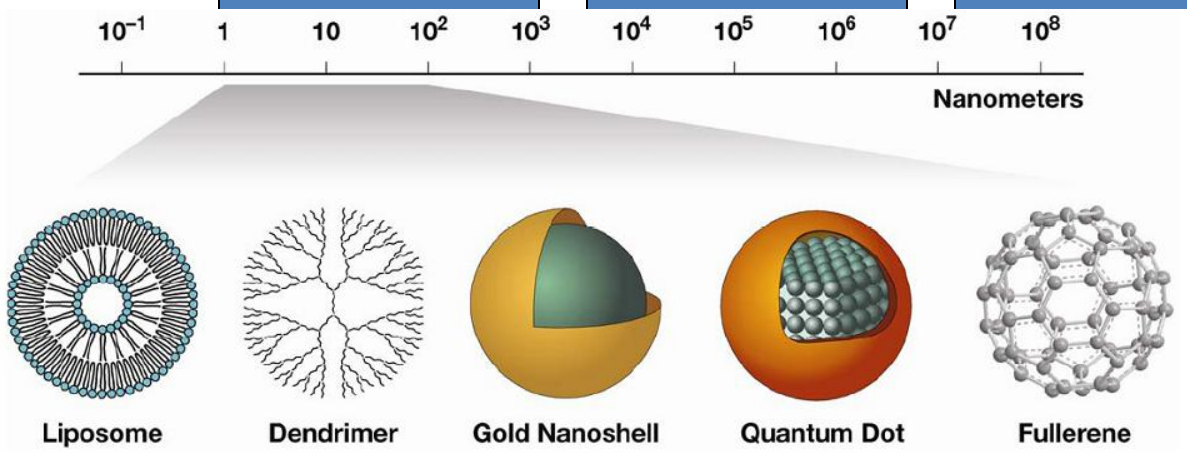
Properties of an effective pharmaceutical

Activity
Specificity
Stability

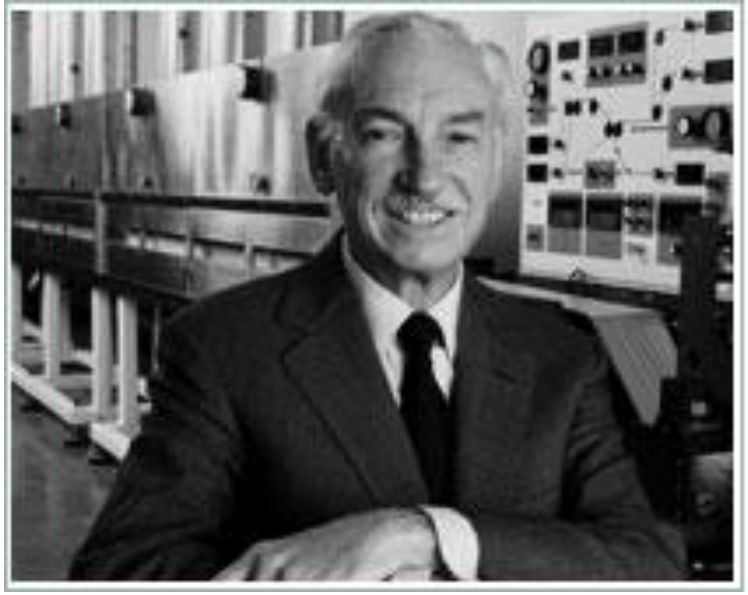
Assigment of different functions to separate chemical entities

Supramolecular aggregates

Activity *Specificity* *Stability*



ALZA



1968 ALZA Corporation was founded by Dr. Alejandro Zaffaroni in 1968 to realize his vision *of **sophisticated pharmaceutical products that precisely control the targeting, timing and dosing of therapeutic compounds***.

Products

- **OROS® Technology**
- **D-TRANS® Transdermal Technology**

  Catapres-TTS® (clonidine), Duragesic® (fentanyl), Estraderm® (estradiol), NicoDerm® (nicotine), Transderm-Nitro® (nitroglycerin)
- **STEALTH® Liposomal Technology** *Doxil® (doxorubicin) an anti-cancer drug for the treatment of ovarian cancer*
- **DUROS® Implant Technology** *Viadur® (leuprolide acetate implant) treatment for prostate cancer*

Multifunctional Nanomedicine

- ✓ **Increase drug solubility**
- ✓ **Prevent drug degradation**
- ✓ **Increase bioavailability**

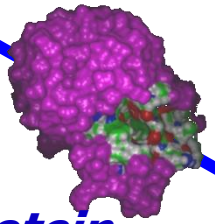
- ✓ **Controlled release in space and time**
- ✓ **Responsive (pH) release**
- ✓ **Increase drug specificity**

- ✓ **Targeting path. tissues and cells**
- ✓ **Minimize non-specific uptake**
- ✓ **Enlarge therapeutic index**

- ✓ **Monitoring pharmacokinetics**
- ✓ **Reporting efficacy**
- ✓ **Personalize medicine**

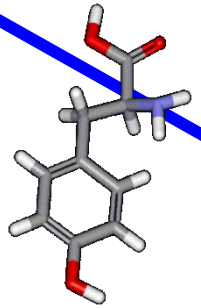
The drug development process ?

Identify disease



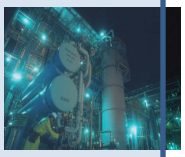
Isolate protein involved in disease (2-4yrs)

Find effective drug against disease protein (2-4 yrs)



Preclinical testing (1-3 yrs)

Scale-up (2-3 yrs)



File IND

Human clinical trials (2-5 yrs)

Formulation (1-3 yrs)

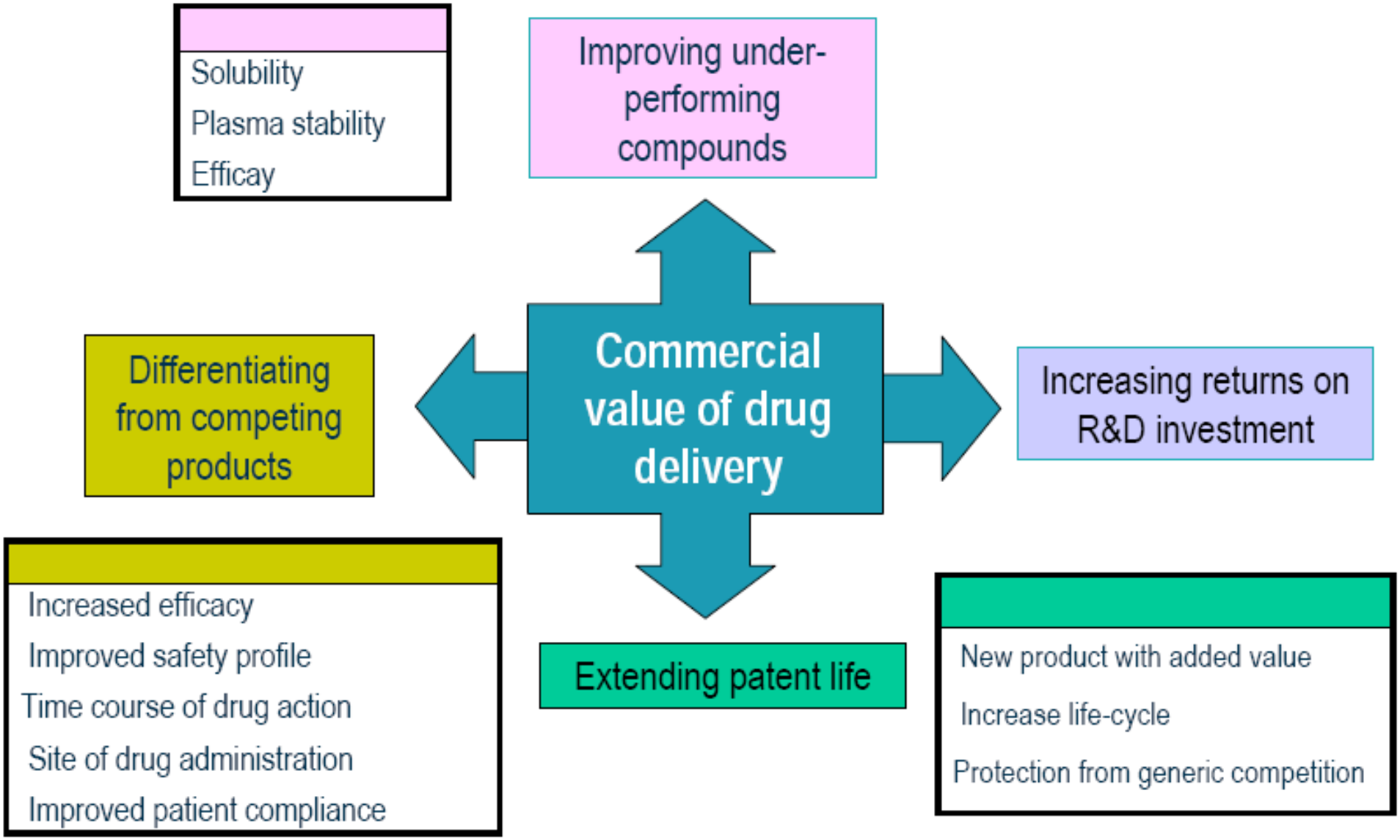
File NDA

FDA approval (2-3 yrs)

12 to 25 years

$400 - $800 M

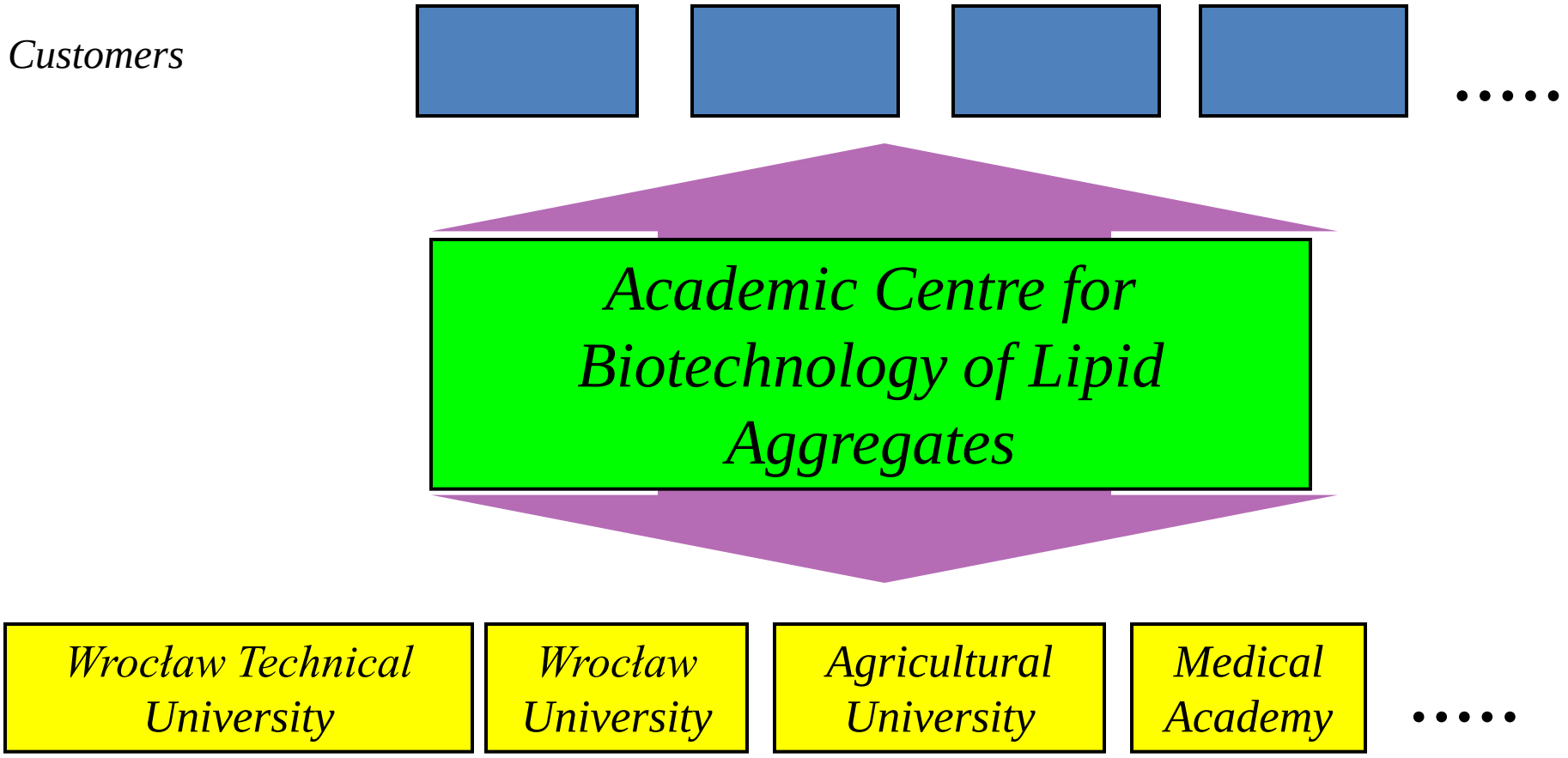
Advantages of value added of targeted drug delivery systems



DRUG DELIVERY SEGMENTS
WORLDWIDE MARKET / GROWTH ($ IN BILLIONs)

TECHNOLOGY	2000	2005	GROWTH
CONTROLLED RELEASE	14.2	26.3	85%
PULMONARY, INHALATION	11.7	22.6	93%
TRANSNASAL DELIVERY	8.2	16.0	95%
TRANSMUCOSAL	2.4	6.5	171%
TRANSDERMAL DELIVERY	6.7	12.7	90%
INJECTABLE/IMPLANTABLE	3.8	7.2	89%
NEEDLE-LESS INJECTION	0.4	1	150%
RECTAL	0.5	1.2	140%
LIPOSOMAL	1.2	3.3	175%
CELL/GENE THERAPY	0	5	0%
MISCELLANEOUS	1.5	2.5	67%
TOTAL	50.6	104.3	106%

Creation of the organization for research on targeted drug delivery systems



Academic Centre for Biotechnology of Lipid Aggregates

Przybyszewskiego 63/77, 51-148 Wrocław,
Tel.:71 3756-233, 71 3756 204, Fax: 3756 208; 71 325 2930, E- mail: afsbc@ibmb.uni.wroc.pl

The Centre operates based on the Agreement of Rectors.

The Agreement defines the Centre organization and functioning .

The Centre is not an independent legal entity.

Founded June, 2001

Problems:

- theren were no procedures for the effective decisions making,

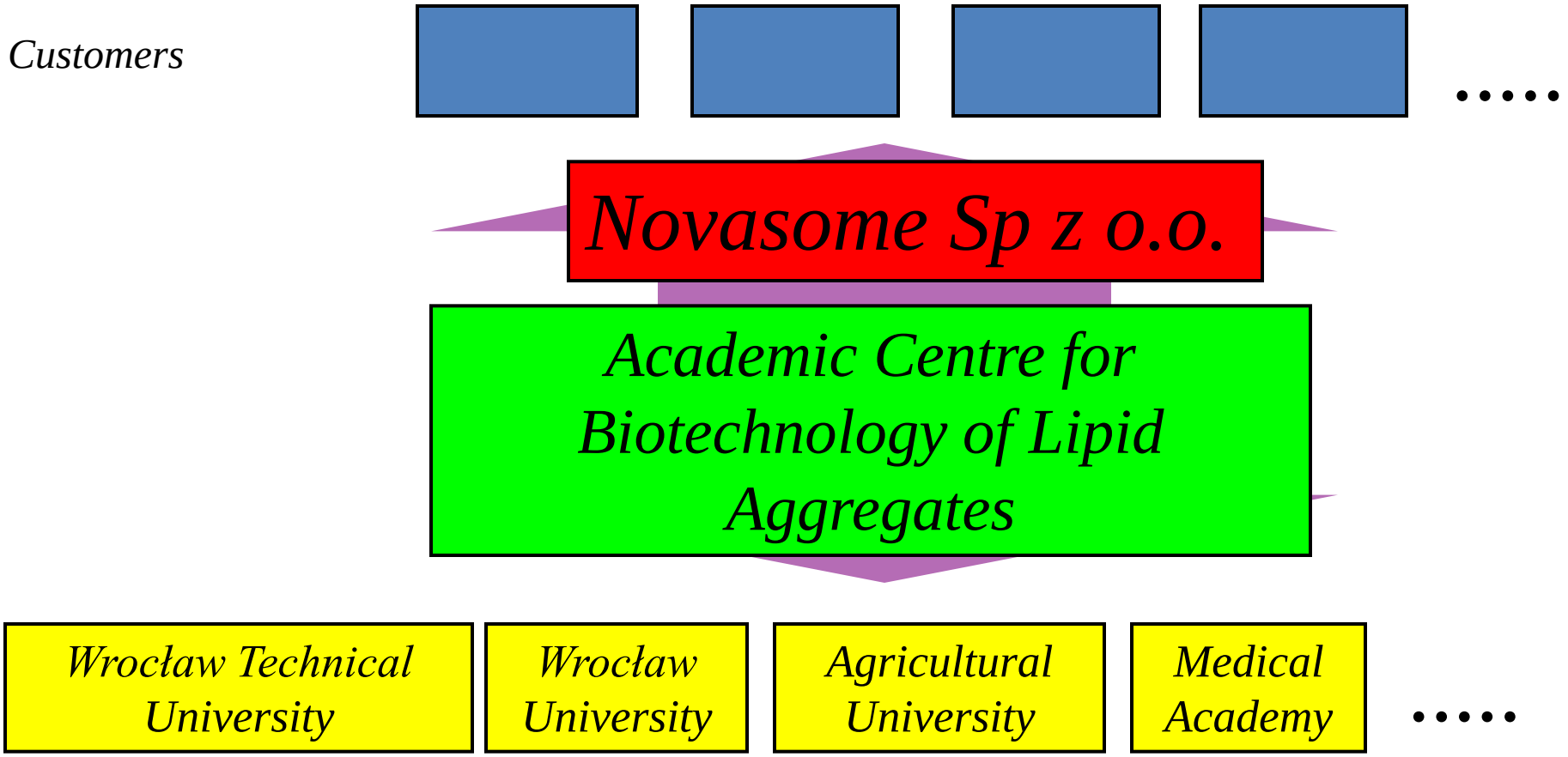
- weak organizational structure,

- no dedicated staff,

- the status of intelectual property rights not well defined,

- lack of the financial independence.

Creation of the organization for research on targeted drug delivery systems



Founded in 2004

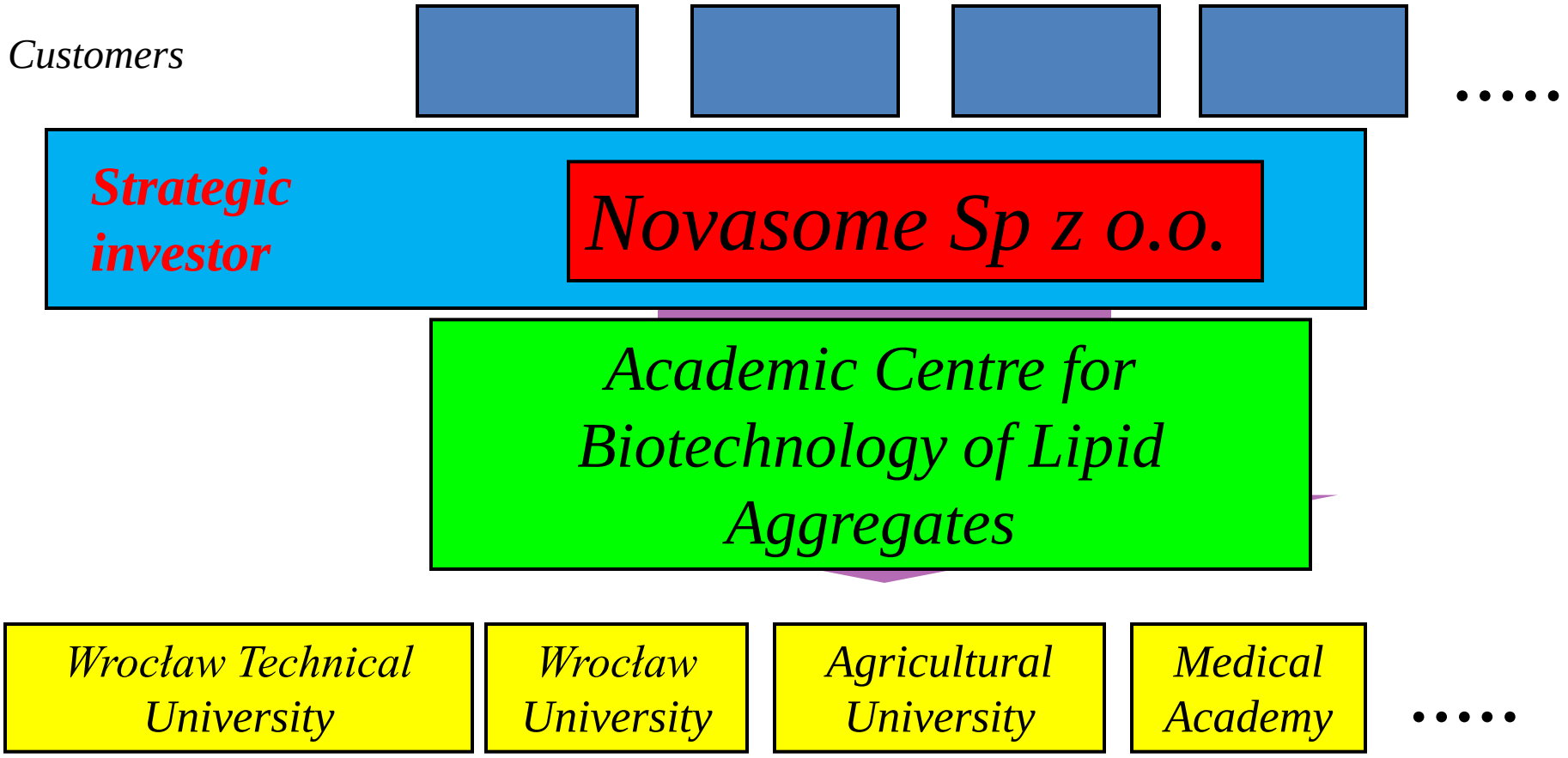
The company objectives

- *The establishment of cooperation with companies copable to implement production of nano-particulates*
- *Reaching GLP standards on all stages of the research and development process*
- *The development of modern technical infrastructure in Wrocław and modernization of educational process.*

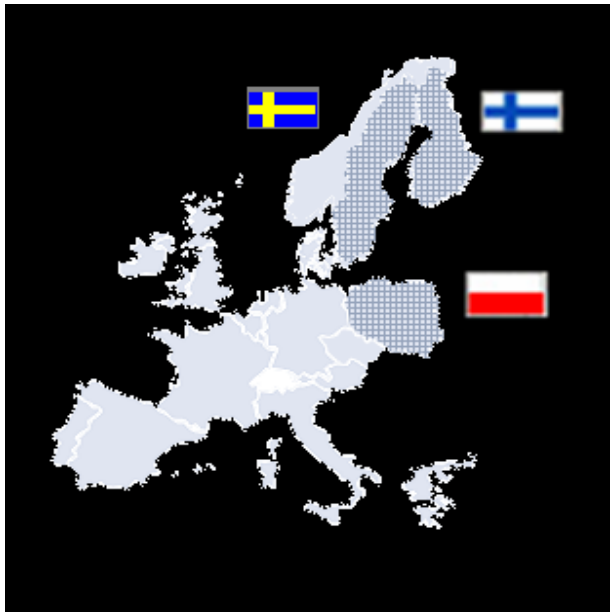
Problems

- *difficulties with cash flow*
- *lack of experience with industrial practices*
- *inefficient administration*
- *problems with reaching the market*

Creation of the organization for research on targeted drug delivery systems



Schareholders



CTT - Cancer Targeting Technologies, Finlandia
Uniwersytet w Helsinkach

prof. dr hab. Tadeusz Więckowski

prof. dr hab. Krzysztof Wójtowicz

prof. dr hab. Mirosław Miller

Ownership structure

Poland (40%)
Finland (57%)
Sweden (3%)

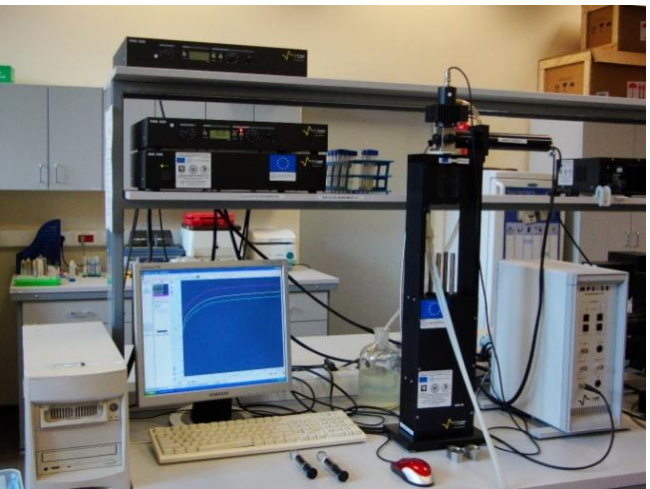
2006-2007 – EU Investment Grant
SPO-WKP 1.4.3.

Biophysics of Macromolecular Aggregtes dr hab. M. Langner	Cell Biology and Biochemistry Prof. A. Sikorski Prof. A. Kozubek dr hab. R. Rzepecki	Cell cultures and in vivo tests Prof. M. Ugorski

Prof.dr hab. Mirosław Miller

The Laboratory for Biophysics of Macromolecular Aggregates

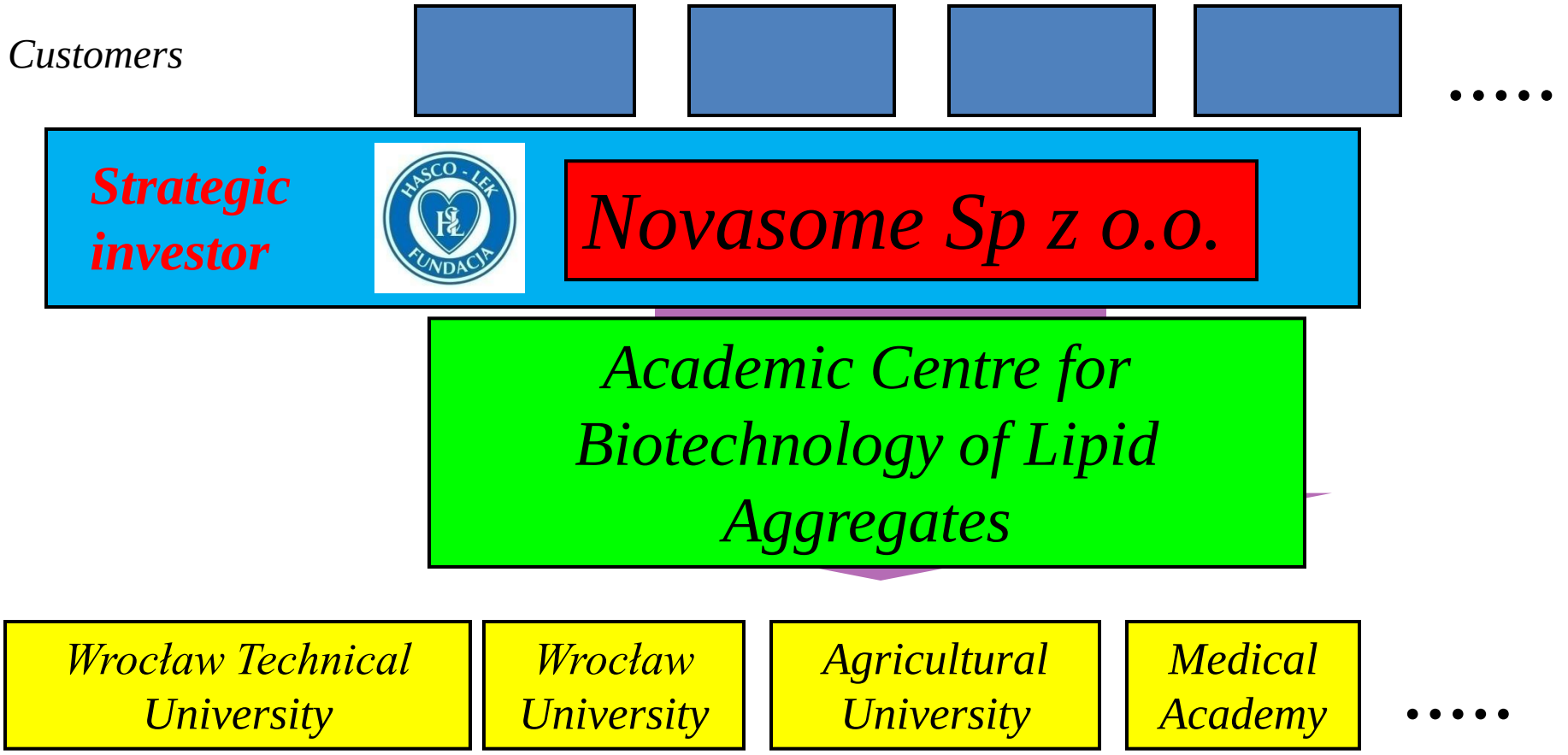
Politechnika Wrocławska



Problems

- *no oparational independence*
- *complex ownership structure*
- *complicated decision making process,*
- *problems with finances*
- *dispersed technical infrastructure*
- ***poore coordintion and lack of quality standards***

Creation of the organization for research on targeted drug delivery systems



NOVASOME
Research & Development Centre

GMP Good Manufacturing Practice

GLP Good Laboratory Practice

ISO 14001

About 20 highly educated emplyees
Modern and complete instrumental infrastructure
Capacity for upscaling and production process development
Efficient administrative and financial services
Consequently introduced qyality and documentation (CTD) systems

Company competence

- *development of new formulations*
- *research services,*
- *educational services,*
- *development of new technologies and production processes,*
- *basic research.*

MICELA
BIOPHYSICAL STUDENT SOCIETY

FACULTAS PHARMACIAE WRATISLAVIENSIS

Wrocław University of Technology

Problems

NOVASOME
Research & Development Centre

Interdyscyplinarny charakter of technology

Knowledge based technology

Problems with adaptation of scintific methods for indutrial practices

Phylosophy of the Company ***– the capital over knowledge and short time horison***

Dominance of strategic investor ***– limited acess to the market***

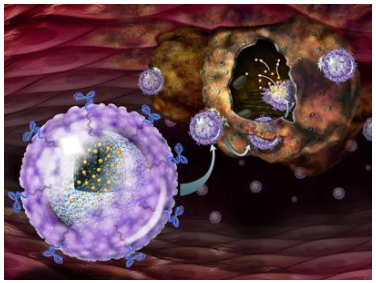
Problems with handling IPR and employees motivation.

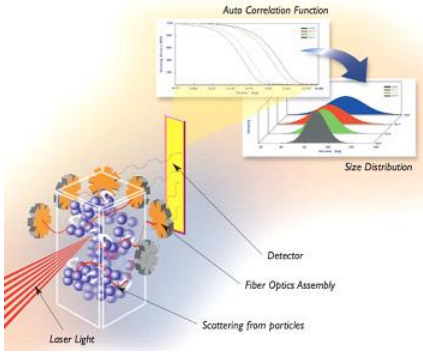
Quality of emplyees !!!!!

lipid systems

Founded in 2010

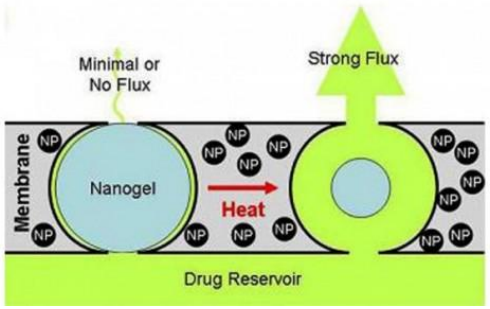
ul. Klecińska 125
54-413 Wrocław
Tel. 664 052 571, 602 380 744
E-mail: lipid.systems@gmail.com



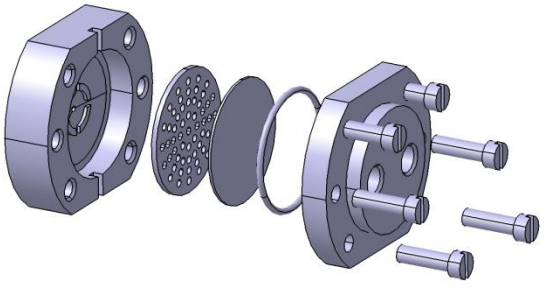


The development of advanced drug formulations.

Development of analytical method requred for a drug registration.



Designing and unsambling of production infrastructure for nano-aggregates production.



NOVASOME

Research & Development Centre

lipid systems