

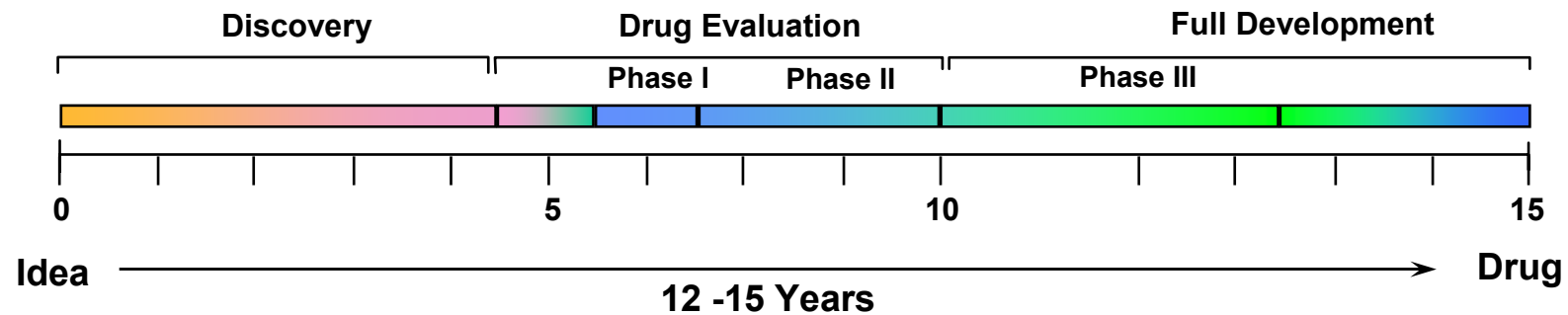
# Licensing & Development in the field of Oncology

**Business Development, International  
Collaborations & Technology Transfer  
Workshop**

**Athens, 16 October 2008**

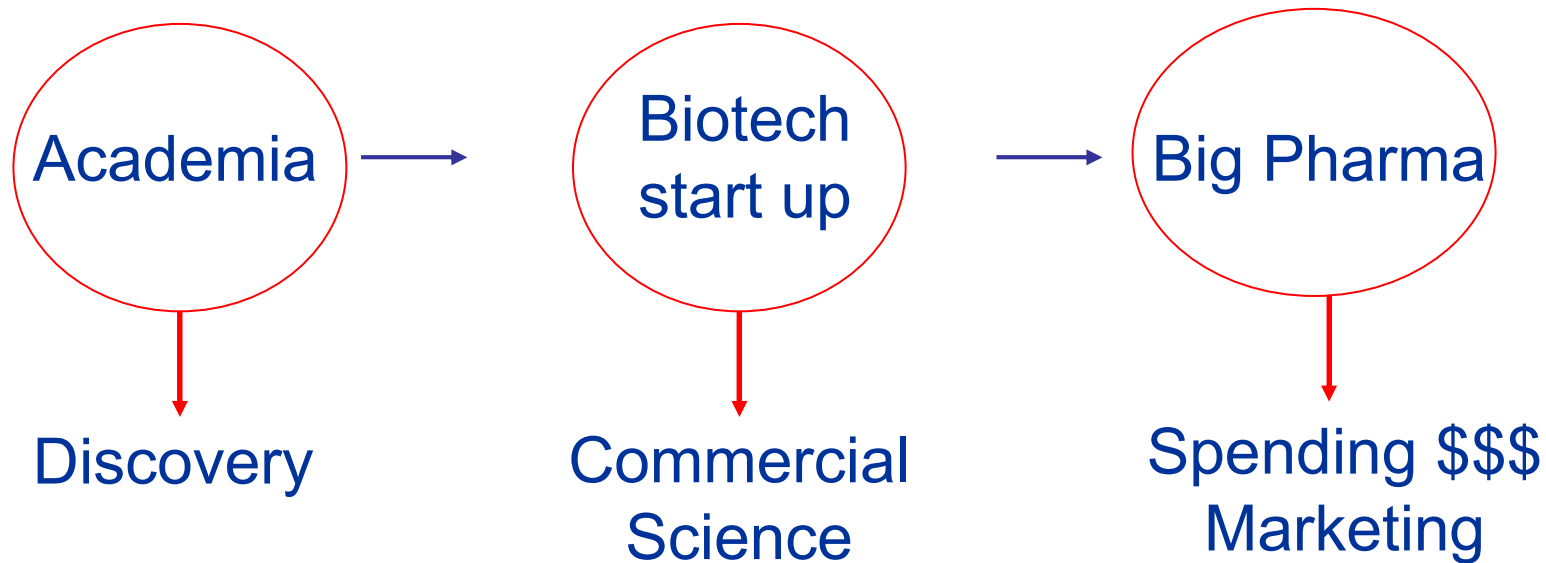
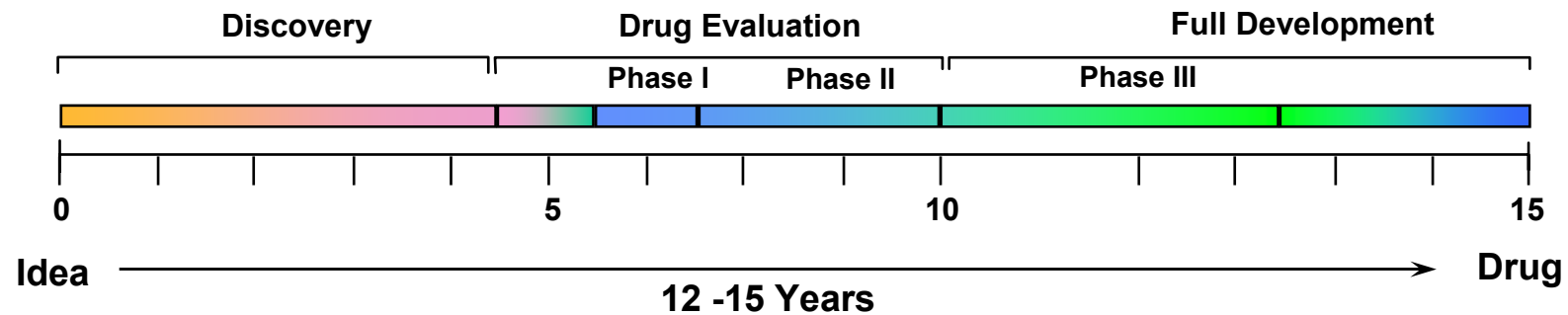
Konstantinos Alevizopoulos Ph.D.  
Medexis SA

# R & D process for pharmaceutical & biotech products (I)

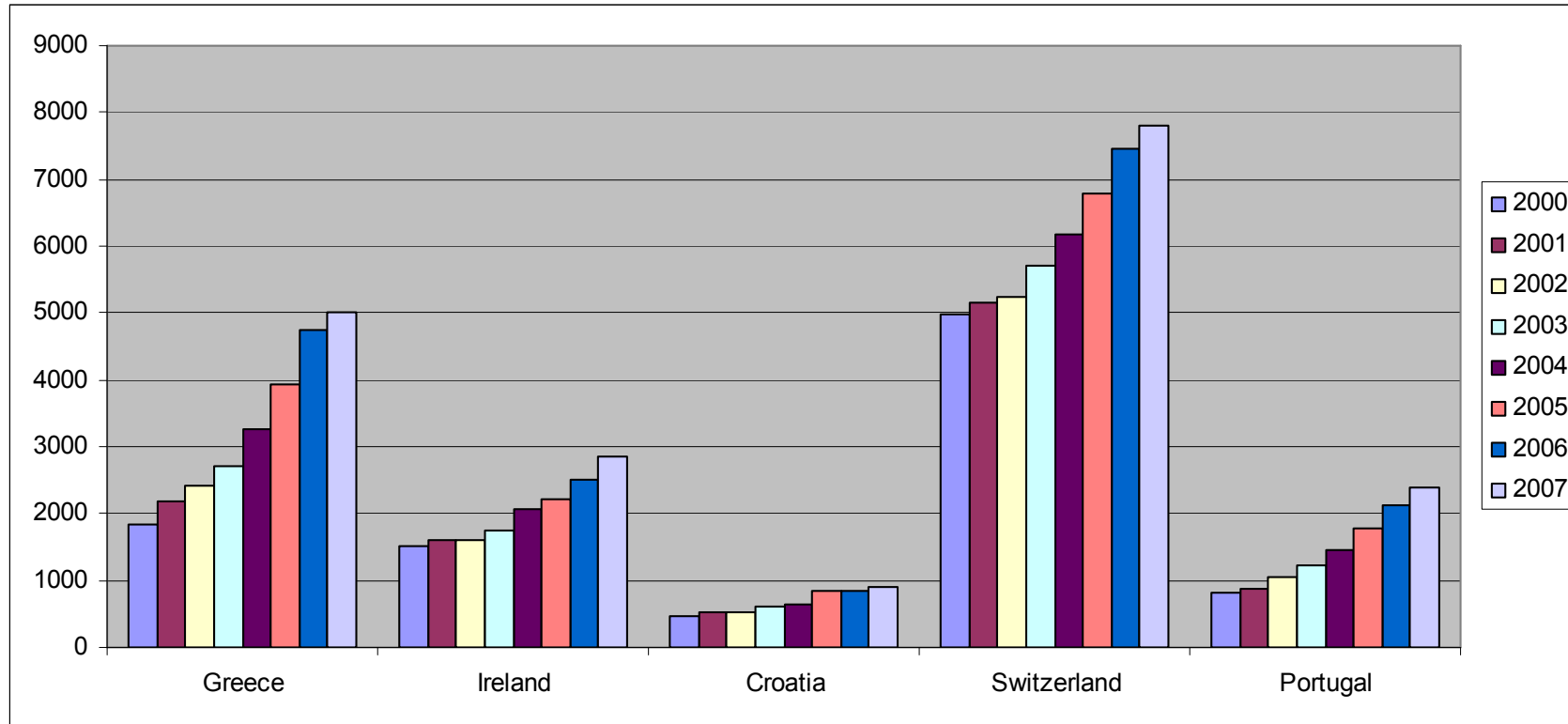


- Expensive business : 1 billion \$
- High Risk : 1 out of 10.000 drug candidates comes to market
- High Return : 100s millions of sales  
: global market
- Candidates can be bought and sold in all phases

# R & D process for pharmaceutical & biotech products (II)



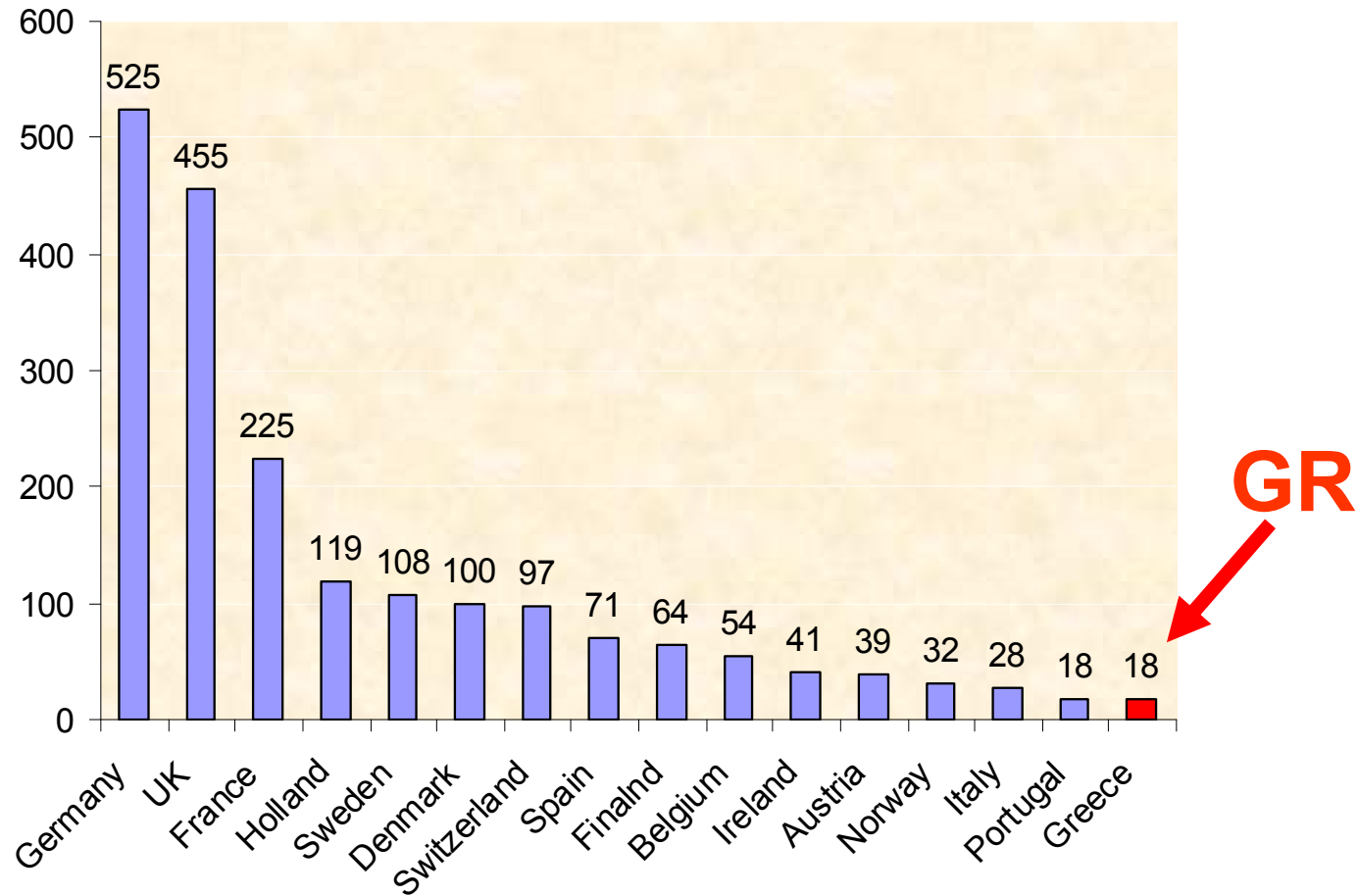
# Life Sciences Performance 2000-2007



Source: Medline

Greece is producing publications

# EU Biotech companies 2003



Limited commercialization of scientific discoveries

## Questions

What are the limitations in Greece?

What can we do to increase interest?

How can a good idea get developed?

How can one target specific companies?

What to expect during contract negotiations?

# Limiting factors (I)

- Limited patent expertise (OBI, Corporate, Tech transfer Offices)
- Inadequate or non-applicable tech transfer legislation
- Scientist promoting his science
- Limited experience in technology licensing
- Limited understanding of the science
- Mentality & Education

## Limiting factors (II)

- Lack of critical mass, scattered centers of excellence
- Lack of qualified business development personnel
- Seed capital not easily available
- Low risk society

# Interest in early ideas

- There is continuous interest in exciting ideas/technologies

## Merck & Co, Inc

- Multinational, big pharma giant
- They screen early projects, active scouting in Southern Europe
- They provide guidelines to help the process
- They define specific areas of interest
- Other companies have the same strategy

# Merck – Oncology Opportunities

## Early Stage Opportunities

- Signal transduction and proliferation/survival
  - PI3K and Ras/Raf/MEK pathways, RTKs
- Developmental pathways/cancer stem cells
- DNA damage/checkpoint
  - p53 pathway modulators, agents selective vs MMR- or HR-defective tumors, checkpoint inhibitors

## Of interest:

- Novel patent-protected formulations of existing products
- Targeted therapies
- Cytokines
- Vaccines
- Hormonal agents

# Developing early ideas

- Although you need all four (science, IP, people and money) solid science is the most important factor
- Brilliant basic Science is not enough
- “Business Science” skills are required
- Biological validation required
- Design IP generating experiments (“surprising factor”)
- Design “company specific” experiments
- Protect yourself from early disclosures

# Example (I)

•A chemist has developed a brand new derivative of paclitaxel. The new compound has a superior IC50 in comparison to the IC50 of paclitaxel in cell lines and shows better anti-tumor action in animals. The new derivative has similar solubility properties, PK profile and toxicity profile like the one of paclitaxel.

•Will the work be published? **YES**

•Can the new compound be patented? **YES**

•Will the compound be developed? **NO**

A biotech company will only evaluate a water-soluble paclitaxel derivative (or a targeted derivative) active in MDR-paclitaxel cell lines, with improved toxicology profile, most likely in the form of a polymer/nanoparticle.

## Example (II)

•A scientist has identified a new heat shock protein 90 inhibitor. The new compound is water soluble, has similar IC50 in comparison to the documented IC50 of other hsp90 inhibitors (in clinical trials). No animal studies are performed. When compared with 17-AAG (a commercial hsp90 inhibitor), in a prostate cell line in vitro, both inhibitors show similar IC50s; however when combined with paclitaxel and AR-antagonists, the new inhibitor shows synergistic effects.

- Will the work be published? **YES**
- Can the new compound be patented? **YES**
- Can combination claims be patented? **YES**
- Will the compound be developed? **YES**

Hsp90 inhibitors in development have poor solubility; the new inhibitor has a better chance to work as a combination in the clinical setting.

## Example (III)

- Based on the previous example, the scientist has screened the literature and further noticed that promising PCa agents include EGFR inhibitors, CDK inhibitors, HDAC inhibitors and novel AR-antagonists. Although he has no access to the drugs tested in the clinic, he can order commercial inhibitors (less active versions of clinical drugs). He then tests his hsp90 inhibitor in combinations with the commercial drugs.

He sees synergy with EGFR inhibitors, antagonism with CDK inhibitors, additive effects with HDAC inhibitors and AR-antagonists.

Based on these results, the scientist can:

- Target EGFR inhibitor developing companies as candidates for licensing**

# Licensing Negotiations (I)

During negotiations with a commercial Partner, one should expect:

- Requests for a complete package of data (under CDA)
- Requirement to negotiate with a TTO or at least with all parties that have contributed to novel inventions/know how and can sign for the 100% of the commercialization rights
- Requirement to provide information about exact employment status, inventorship and ownership
- Requirement to accept to work based on specific milestones, solid reporting
- Specific contract terms

# Licensing Negotiations (II)

- Research funding of less than 100K a year, preferably only on consumables and personnel, linked to tight milestones, reporting and easy exit for non-performance
- No upfront payments
- In case of successful commercialization/sublicensing, low single digit on net sales or income from milestones
- No control on corporate actions
- Corporate partner may out-source part of the project
- Corporate partner to develop project IP portfolio and finance development

# Patenting & Early actions (I)

If science is giving interesting results, an early patenting strategy should be put in place:

- Avoid disclosures in meetings and/or presentations that might influence patentability of a future invention (including Ph.D. theses)
- Opt for a US provisional patent filing (cheaper, no publication)
- One year period to complete filing and obtain new data
- Design IP generating experiments
- Prepare suitable data packages

# Patenting & Early actions (II)

- Become visible internationally
- Cluster / join consortia / obtain critical mass
- Seek synergies with other companies, join forces
- Follow your competitors / market intelligence
- Talk to investors
- Anticipate all possible questions in advance

# In conclusion

- Greece is as competitive as any other country
- Opportunities in the biomedical sector do exist
- Strategy, infrastructure and education need to be improved
- Exploit existing expertise, facilitate interaction between Academia & industry or within industry
- Cluster

**THANK YOU**