

Licensing In / Out Agreements

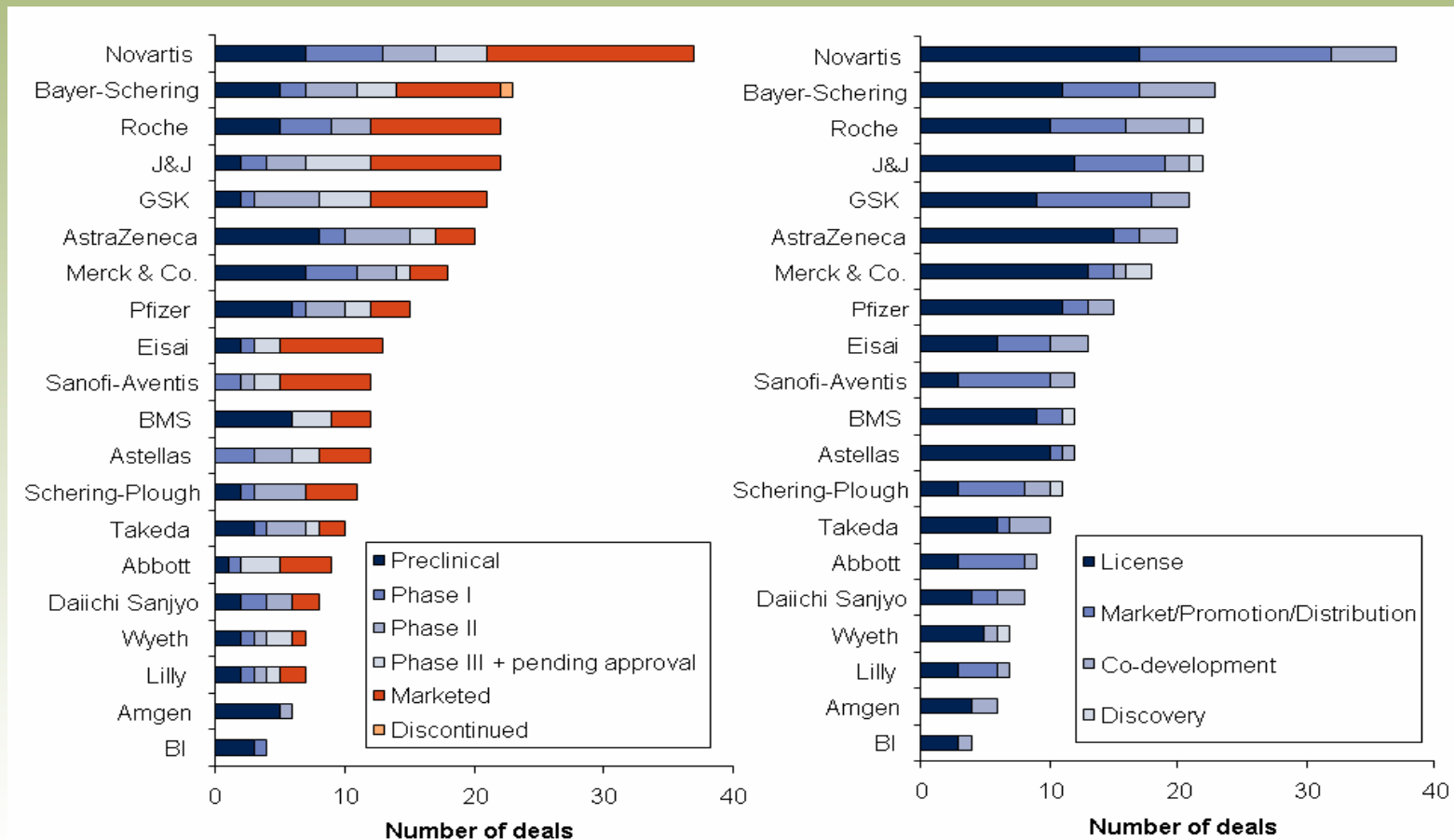
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12/2/2010

Introduction

- With Pharma struggling to maintain its pipelines and portfolios with products developed in-house, companies are increasingly turning to licensing. However, the search for late-stage developmental products is becoming tougher and more expensive, and companies are now looking towards licensing earlier-stage compounds.
- Licensing is not an exact science though, and consequently both licensors and licensees need to do their homework before entering into the actual process of licensing.

Leading Dealmakers



Source: MedTRACK

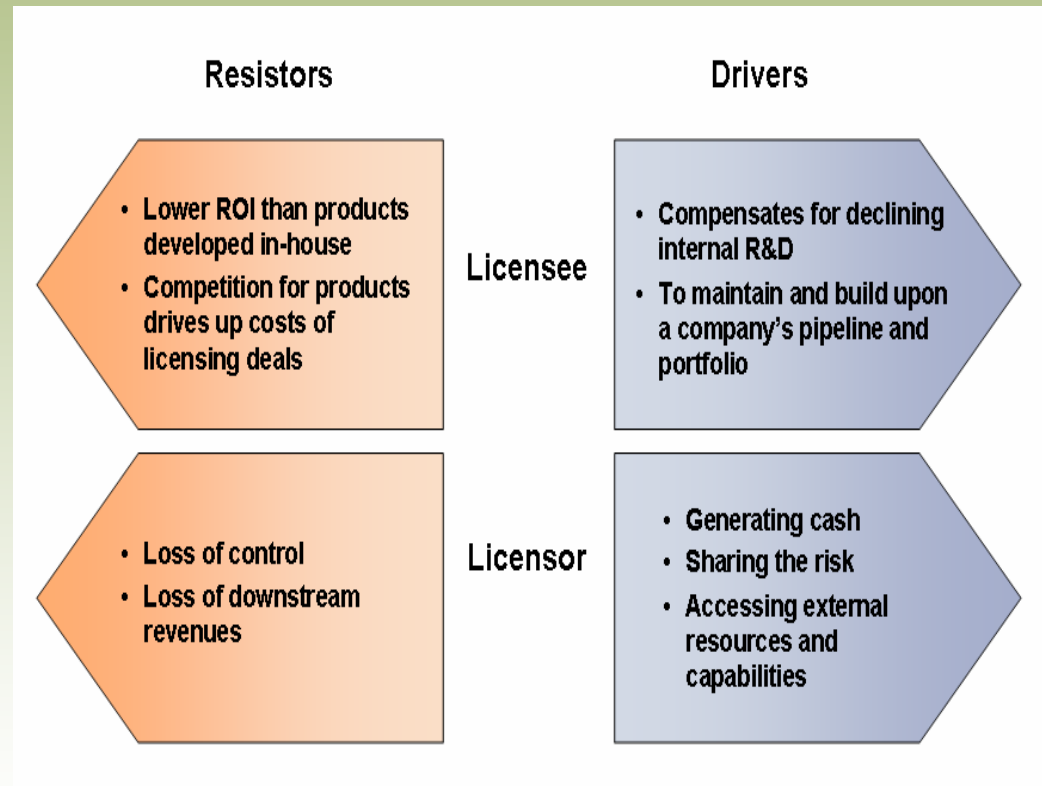
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Both Pharma & Biotech face same challenges

- In today's pharmaceutical industry, although the dynamics and business models of Pharma and Biotech companies differ, they both face a number of key challenges:
 - development and launch of differentiated novel products;
 - pressure to achieve growth and meet profitability targets;
 - managing investor expectations;
 - react to climate change within the pharmaceutical industry (increased genericization, P&R and regulatory issues, higher costs of R&D);
 - balance short-term challenges against a sustainable future.
- However, neither type of company can overcome these challenges alone, and hence licensing deals are increasingly employed to overcome the hurdles faced by the companies in this rapidly changing environment.

Biotech's strengths	Pharma's strengths
Novel products and technology	Financial strength
Differentiated products	Development, sales and marketing expertise
Entrepreneurial business culture	Global positioning and reputation
Creativity	Larger share of voice

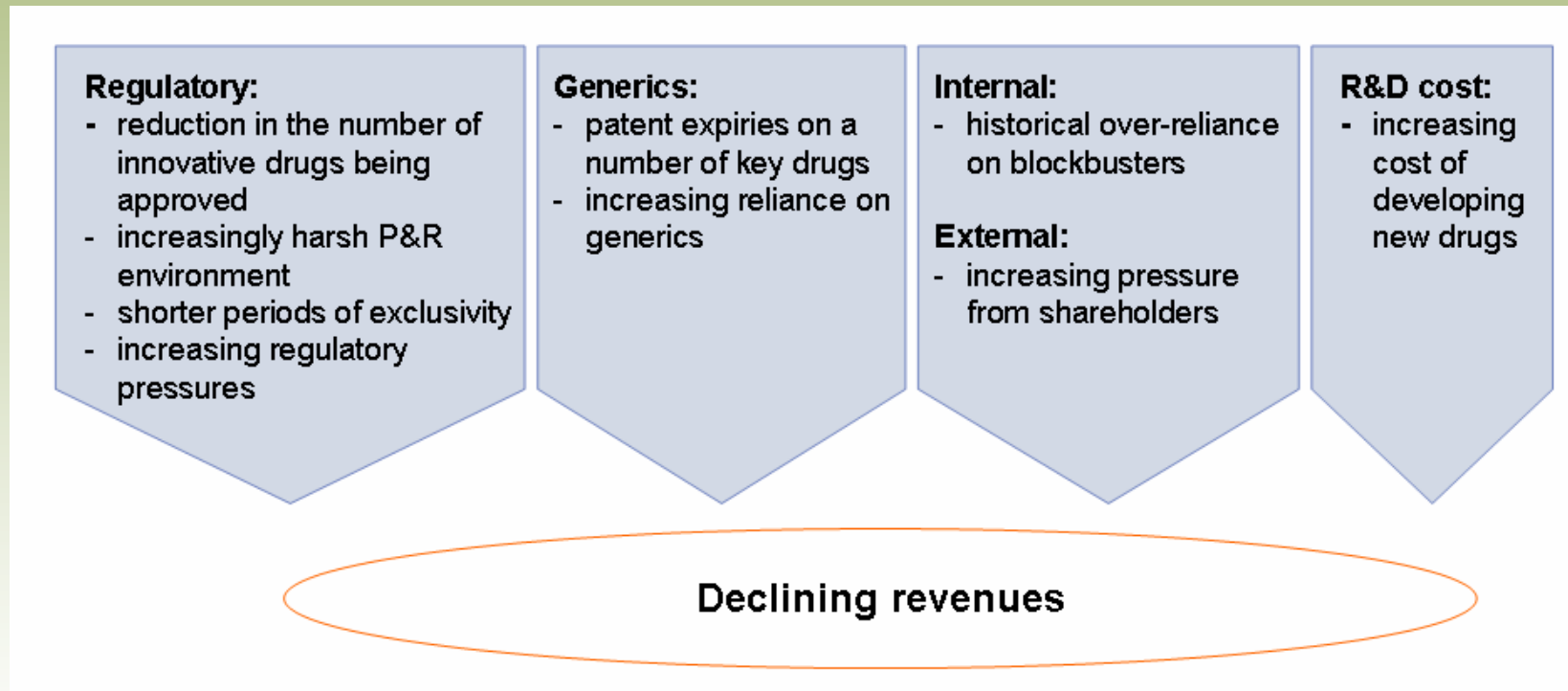
Drivers and Resistors to Licensing



- With the rising number of licensing deals and partnerships made year-on-year, the drivers in today's market increasingly outweigh the resistors.

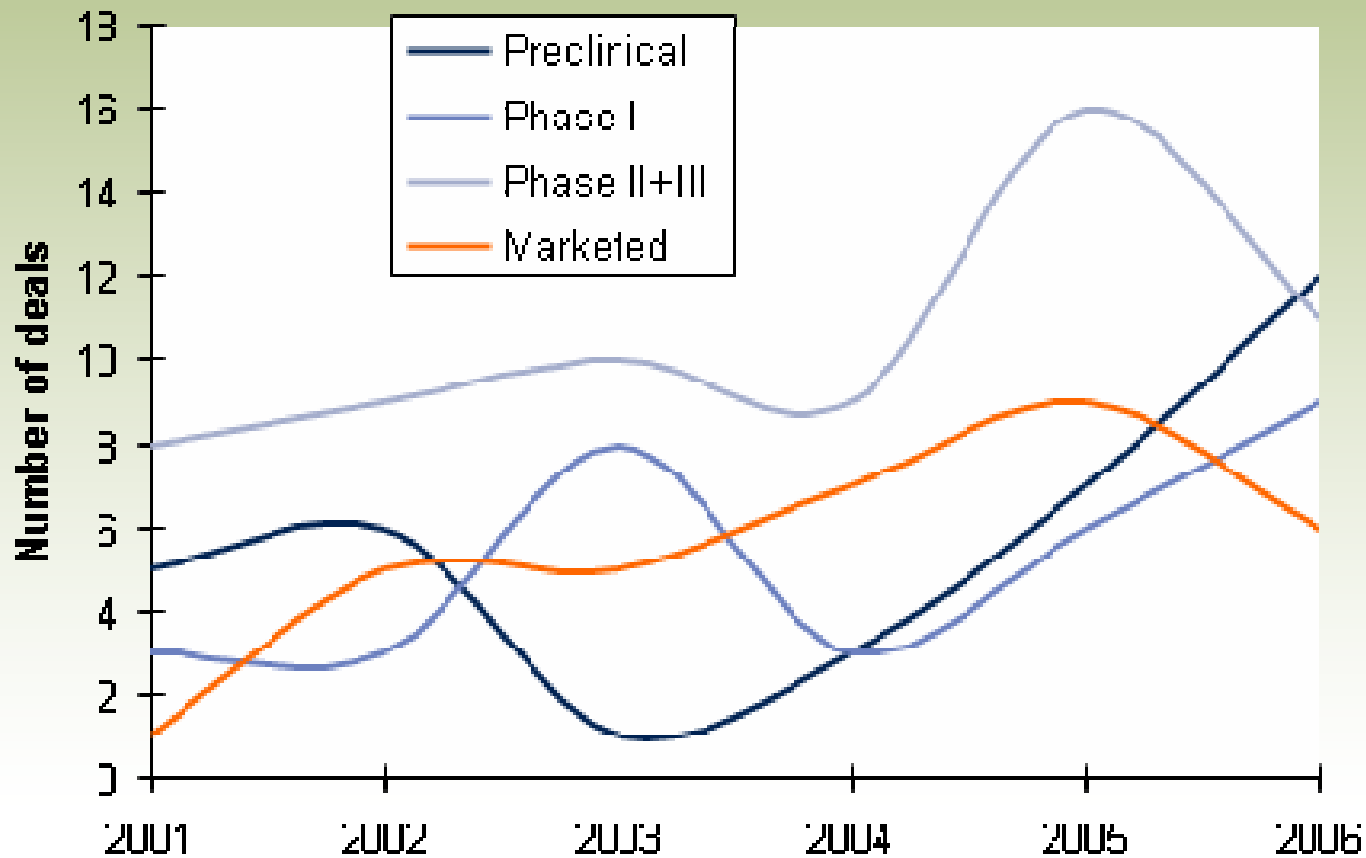
- Nevertheless, both the advantages and disadvantages of each proposed partnership must be evaluated fully before the deal is signed, as failure to do so will greatly compromise the success of a deal, evidenced by the fact that approximately half of all deals are currently unsuccessful.

Drivers and Resistors to Licensing



Licensing Deals

Resurgence in the in-licensing of preclinical compounds, 2005–06



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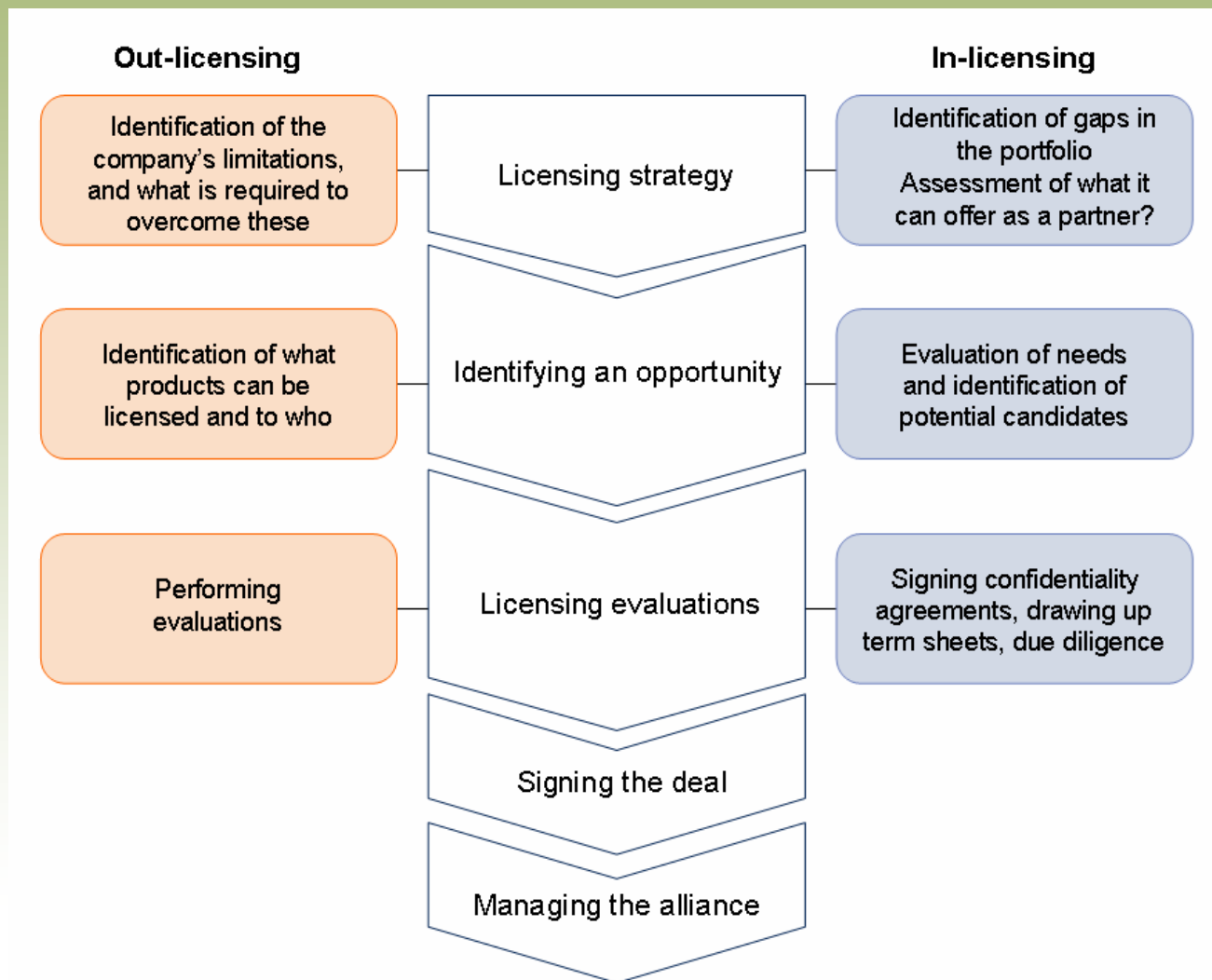
Source: Datamonitor

The Key to Successful Licensing

More than 50% of all alliances are unsuccessful, of which, 15% of failures are attributed to external factors, while 85% are due to poor alliance management

Source: Datamonitor

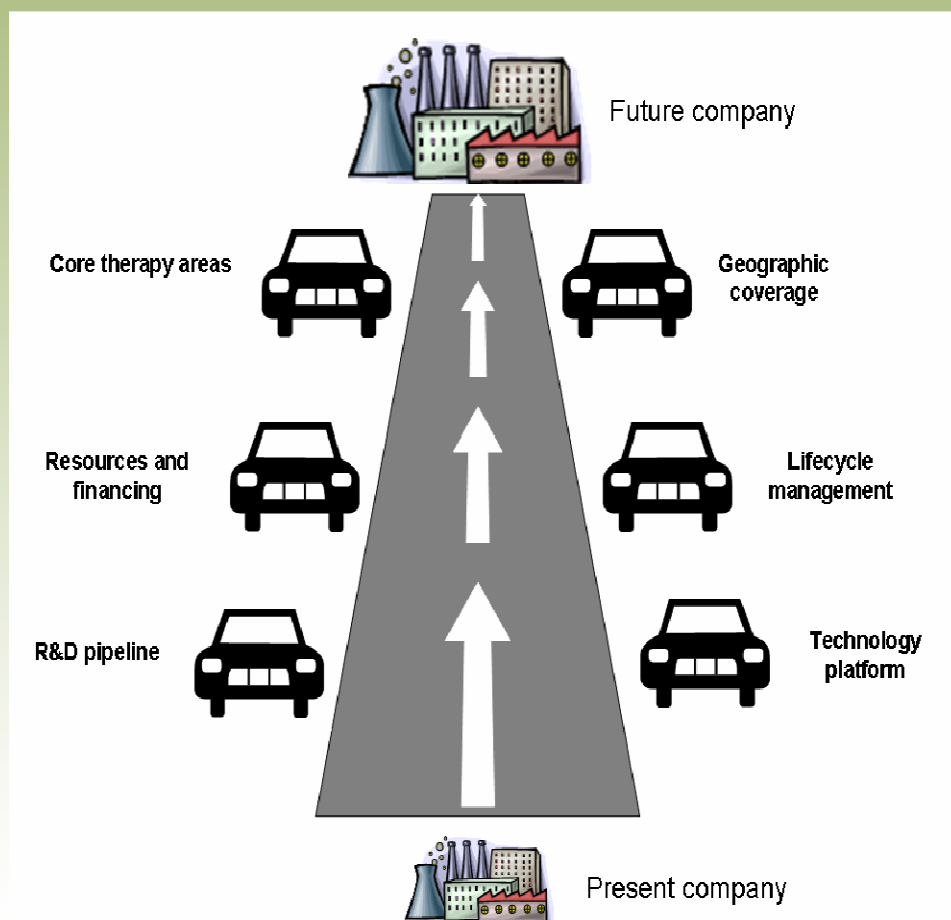
The Key to Successful Licensing



Strategic Issues – Reasons for Licensing

- Current therapeutic and clinician strengths
- Resource & financing (focus on key areas)
- R&D
 - Products in novel development areas (out-license or co-develop?)
 - Back-up or duplicate products (abandon or exploit different markets?)
- Pipeline issues
- Geographical and commercial infrastructure issues (expansion, increase depth of existing activities, consolidate in a narrow therapeutic expertise?)
- Drug delivery and formulation issues

The Licensing Strategy



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At the heart of any licensing deal lies the licensing strategy, which if carefully constructed, and strictly adhered to should guide the deal to a successful conclusion.

It is imperative that the resultant licensing strategy is aligned with a company's overall corporate strategy, and is approved and endorsed by the top-line management.

This provides both internal and external clarity and ensuring that the company has a clear focus, guiding in-house evolution and providing external reassurance for potential partnering candidates of the company's deal-making collateral.

The Licensing strategy - Galenica

✓ Defending Galenica's strength in
ESTABLISHED FRANCHISES
CV-GI-RESP-DERMA

DEFEND

✓ Developing strong positions in NEW AREAS such as
Critical Care -Cancer-Rare diseases

ATTACK

✓ Fuelling the geographic expansion
(Romania, and the Balkans Region)

✓ Capitalising on the flagship products in development
Tributin SR 300, Vomex, Ribrain and OUT LICENSE

BUILD

✓ Buiding on new IN LICENSED products

The Licensing strategy - Galenica

In licensing

GEOGRAPHIC SOURCE

North America-Western Europe-Israel-India-Japan

DEVELOPMENT STAGE

Phase II-III registered and/or marketed products

MARKET POTENTIAL

Products with substantial sales potential

FOCUS ON SPECIFIC DISEASE

With price rewards indications

OPEN TO OPPORTUNISTIC POSSIBILITIES WITH
Significant Business Potential (eg ophtalmology, Urology)

The Licensing strategy - Galenica

In licensing

check first products registered & not marketed in Greece-Cyprus and Romania then Balkans

search Rx products with priority in Cardio, GI, Dermato and Gynaecology, Respiratory, Cancer therapy
breakthrough product(s) in new therapeutical areas

search OTC products and study opportunities of product acquisitions

estimate potential EF price in licensed territory with a reasonable COG

The Licensing strategy - Galenica

✓ Criteria for Product Analysis

Launch Date

Ranking

Mechanism of Action

T Max

Half Life

Indications
(Market potential)

Bioavailability

Dosage

Formulation

Efficacy vs Placebo

Adverse Events

Contraindications

Prices

Reimbursement

The Licensing strategy - Galenica

✓ Areas of Opportunities

POTENTIAL PATIENT POPULATION

HIGH	HYPERTENSION		
	ULCERS	ASTHMA	OBESITY
		BACTERIAL INFECTIONS	ATHEROSCLEROSIS
		DEPRESSION / ANXIETY	
		OSTEOPOROSIS	
MEDIUM		DIABETES	
	MIGRAINE	MALE ERECTILE DYSFUNCTION	HEART FAILURE
		ANGINA	URINARY INCONTINENCE
			RHEUMATOID ARTHRITIS
			EPILEPSY
			SCHIZOPHRENIA
			PARKINSON'S DISEASE
		ALZHEIMER'S DISEASE	
LOW		ARRHYTHMIAS	MULTIPLE SCLEROSIS
12/2/2010	LOW	MEDIUM	HIGH

MEDICAL NEEDS/REQUIREMENTS FOR NEW DRUGS

Inward Licensing

- Define Search Criteria
 - Sales performance
 - Development Criteria
 - Geographical availability
 - Risk
- Identify In-license Partners
 - Desk Research (IMS – MIDAS, Databases)
 - Networking
 - Universities and Medical Institutions
- Target Potential Opportunities
- What do You offer a potential partner?

Evaluating Potential Opportunities

- Areas of evaluation
 - Chemistry / formulation
 - Pharmacology / toxicology / pharmacokinetics
 - Clinical studies
 - Safety
 - Regulatory affairs
 - Marketing / market research
 - IP
 - Manufacturing / QC
 - Pricing
- Stepwise approach
 - Preliminary evaluation
 - Full evaluation / Due diligence
 - Decision

Outward Licensing

- Deciding when & how
 - Timing
 - Preclinical development
 - Beginning of clinical trials
 - Beginning of phase III
 - When a regulatory dossier is compiled
 - When a product obtains regulatory approval
 - Marketed product
 - Type of deal to be sought
- Licensing action plan
- Presentation material
 - Confidential prospectus
 - Non – confidential brochure
 - Presentation slides

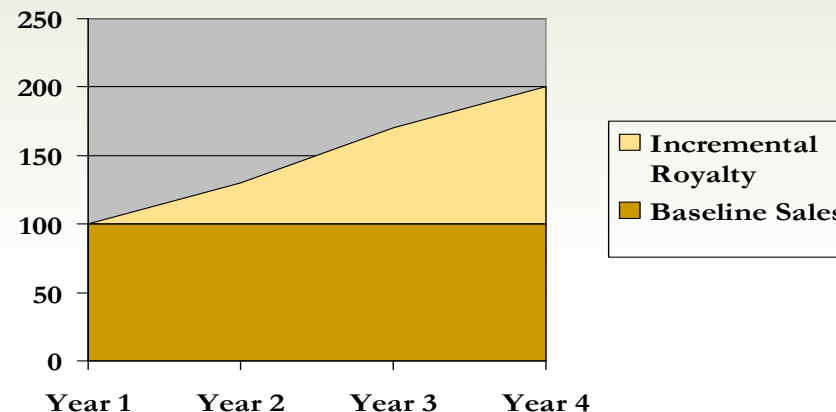
Outward Licensing

- Other in house preparations
 - Intellectual property
 - Lab: samples & test material
 - Review of preclinical and clinical safety
 - Clinical development status
 - Clinical development plans
 - Publications / regulatory / sales & marketing
 - Draft Term Sheet
- Identify out-license partners
 - Target market sectors
 - Key selection parameters
 - Territories
 - R&D product fit
 - Sales & Marketing fit
- Seek and Evaluate Potential Partners

Financial Considerations & Models

- Review sales trends
 - Forecast of future sales
 - Historic trends, maximum market potential, optimum market share, life cycle
- Generally to in-license a marketed product, the licensee must be able to double sales
- A sufficient sales growth will allow both companies to benefit

Split Royalties



Forecast Analysis

1. Market Data

Actual Sales (A)	2010		2011		2012	
	000-s	%	000-s	%	000-s	%
Total market units						
Total market value L.C.*						

Projected Sales (A)	2013		2014		2015	
	000-s	%	000-s	%	000-s	%
Total market units						
Total market value L.C.*						

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Forecast Analysis

2. Competition & information on sales & marketing mix of main competitor

	Product & Company	Form & Strength	Packs Size	Daily Therap.Cost* local curr.	Year of Launch
I					
II					
III					
IV					
V					
(VI)					
(VII)					
(VIII)					

Forecast Analysis

3. Information on Target Audience

Doctor specialties	Number of doctors in entire country	Your Company's target for the product (% of doctors)	Projected Company target for product after 3 years	
			number	%
12/2/2010	Total			

Forecast Analysis

4. Information on Pricing

Proposed Prices (local currency)	I	II	III
CIP / Finished Goods			
Import taxes (% of CIP price)			
Ex-Company Price (local)			
IMS level (ex-wholesalers)			
Retail Pharmacy,if applicable			
Sales tax (% and value)			
Public Price - incl. sales tax			

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Forecast Analysis

5. Sales Forecast

	Year 1	Year 2	Year 3	Year 4	Year 5
Units					
(per pack size/ form/strength)					
Value**					
(per pack size/ form/strength)					
Total Sales					
Mkt Share in Units					

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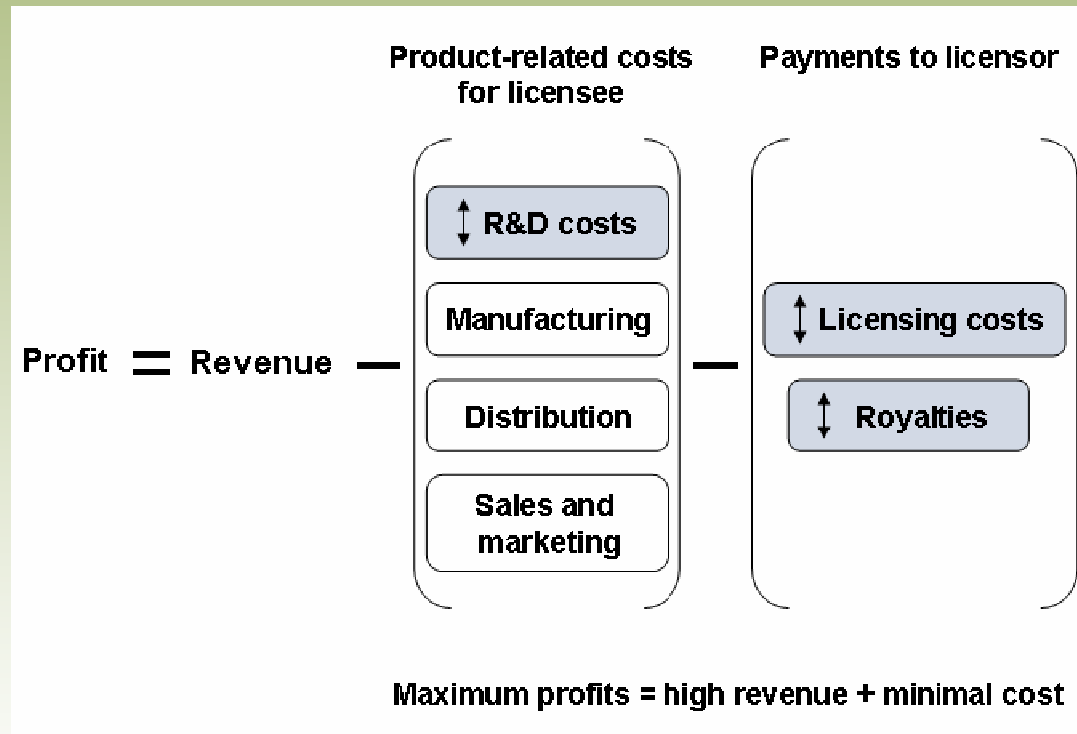
Forecast Analysis

6. P&L

	Year 1	Year 2	Year 3	Year 4	Year 5
<u>Net Sales:</u>					
-Cost of Goods					
Local Margin					
% of Sales					
<u>Marketing & Sales Expenses:</u>					
Advertising					
Direct Mail					
Brochures					
Samples					
Seminars					
Clinical Trials					
Sales Forces costs					
Other -specify					
<u>Total Sales & Marketing Expenses:</u>					
% of Sales					
Profit (Loss)					
Cumm. Profit					

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Putting a Value on a Deal



The valuation of a licensing deal is a critical phase of the process that determines the core reason for the licensing process

- how much money will each company stand to make out of the licensing agreement.

Parameters Influencing Deal Values

- Intellectual Property
- Stage of Development
- Competitive Profile
- Product fit
- Company profiles
- Deal Terms
 - Ownership of brand
 - Payment structure
 - Future developments
 - Options to change
 - Potential quid pro quos

Stage of Development Influence on Value

			<i>Probability of Achieving</i>		
End of Stage	Cumulative Development Cost (\$ million)	Time for activity (years)	Launch (%)	Major Sales (%)	Out-Licence (%)
Discovery		1 to 3	0,01		10
Preclinical	5 to 15	1 to 2	1		30
Phase I/II	10 to 30	1 to 2	10		50
Phase III	80 to 400	2 to 3	80		80
Registration		1 to 2	100		90
Launch				20	90

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Examples of Deal Values

Product Type	Total Stage Payments (\$)	Royalty Range (%)
<i>Launched Products</i>		
Already Established	0 or 1 to 3 years turnover	15 to 50 or 0
Marketed elsewhere	0	10 to 30
<i>Development Compounds</i>		
Discovery	1 to 20 million	2 to 8
Late Preclinical	1 to 30 million	2 to 10
Phase I/II	2 to 40 million	2 to 12
Phase III	5 to 50 million	8 to 16
Registration	20 to 60 million	8 to 20
<i>Other</i>		
Delivery System	1 to 15 million	1 to 10
Platform Technology	0,25 to 15 million	0,5 to 10
Assays	25.000 to 100.000	none

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Modeling

- Classical NPV models
- Option Theory and Tree Analysis
- Monte Carlo Simulation

Deal Structure

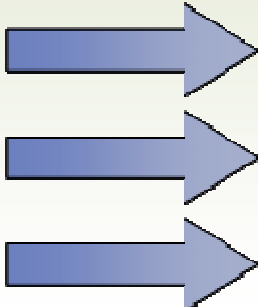
- Deal Types
 - Distribution Agreement
 - Product Acquisition
 - Licensing Agreement
- IP to be licensed
 - Patents
 - Data Exclusivity
 - Trademarks
 - Marketing Authorizations
 - Know How
- Levels of Exclusivity
 - Exclusive (only the licensee has rights to the product)
 - Sole (only licensee and licensor have rights)
 - Semi-exclusive
 - Non-exclusive
- Areas Covered by the Agreement
 - Geographical scope and Therapeutic sector, shared marketing
- Types of Income
 - Fixed Payments (up-front and milestone payments, option payments)
 - Variable Payments (royalties, supply price, % of sales)
- Duration

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Signing the deal & managing the alliance

- Once the final licensing agreement is secured, the proposed relationship between the two companies can begin in earnest.
- While entering into the agreement is a significant milestone in its own right, the true test for a licensing partnership is how efficiently the companies can work with each other to maximize the potential of the licensed product.

Poor deal management can have major detrimental effects on the alliance performance

- | | | |
|---------------------------------------------|--------------------------------------------------------------------------------------|----------------------------------------------------|
| ▪ Breakdown of trust |  | ▪ Poor innovation |
| ▪ Build up of negative partisan perceptions | | ▪ Project delays |
| ▪ Questioning partner's motives | | ▪ Dissatisfied partner performance |
| ▪ Niggling conflicts | | ▪ Missed milestones |
| ▪ Poor communal problem solving | | ▪ Unresponsiveness to market changes |
| ▪ Feelings of disrespect/coercion | | ▪ Perception that alliance is failing to add value |