



Business development at affiliates level

- Strategy & Methods -

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Business development at affiliates level

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1. Introduction

Business development opportunities being rare and complex, affiliates would be well-advised to adopt a systematic, rigorous and perfectly planned approach

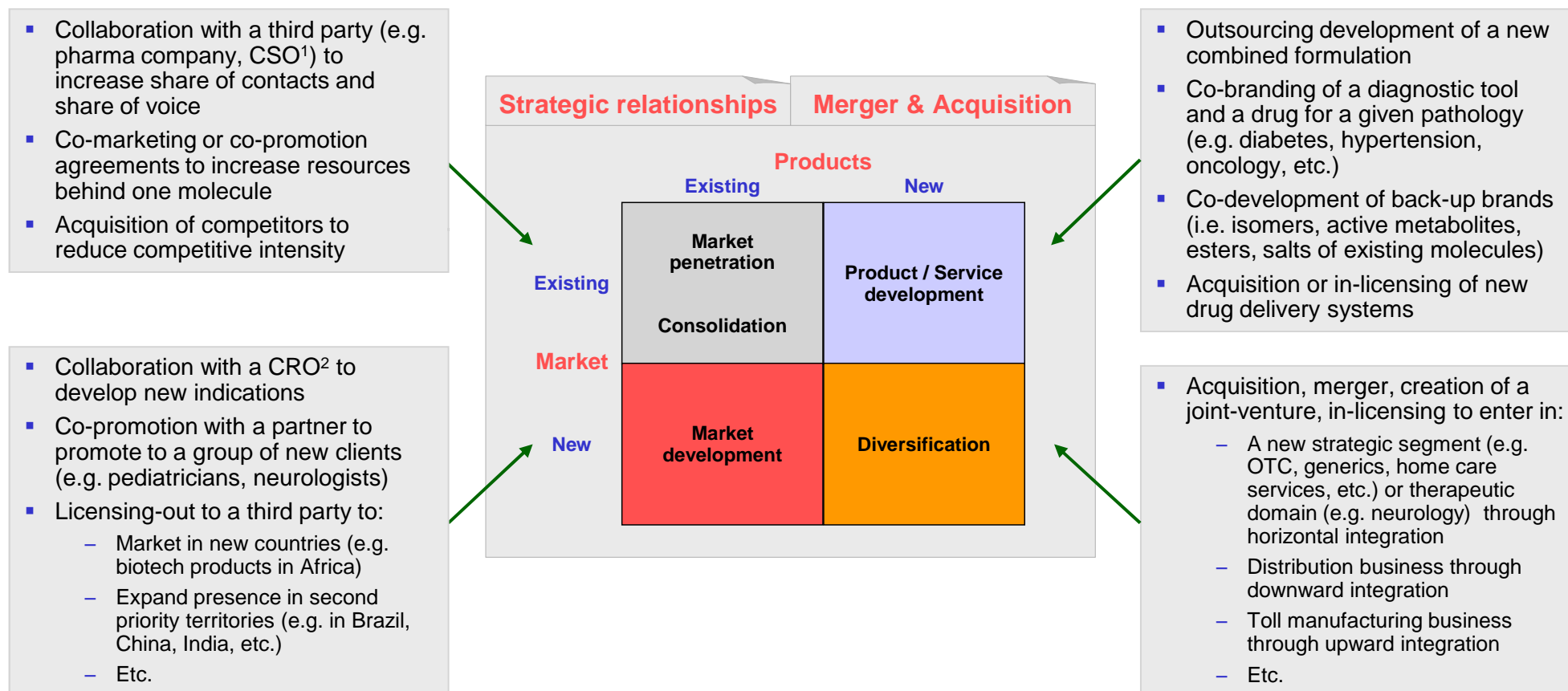
Key points addressed

- **What is the purpose of business development?**
- **What are the most common types of business development deals?**
 - **How to assess business development opportunities?**
 - **How to formalize a business development strategy?**
- **How to approach a target company for business opportunity?**
- **How to select a product eligible for business a development deal (application) ?**

2. Basic principles

Business development refers to strategic relationships or Merger & Acquisition deals which enable affiliates to grow and strengthen their competitive position

Definition of business development



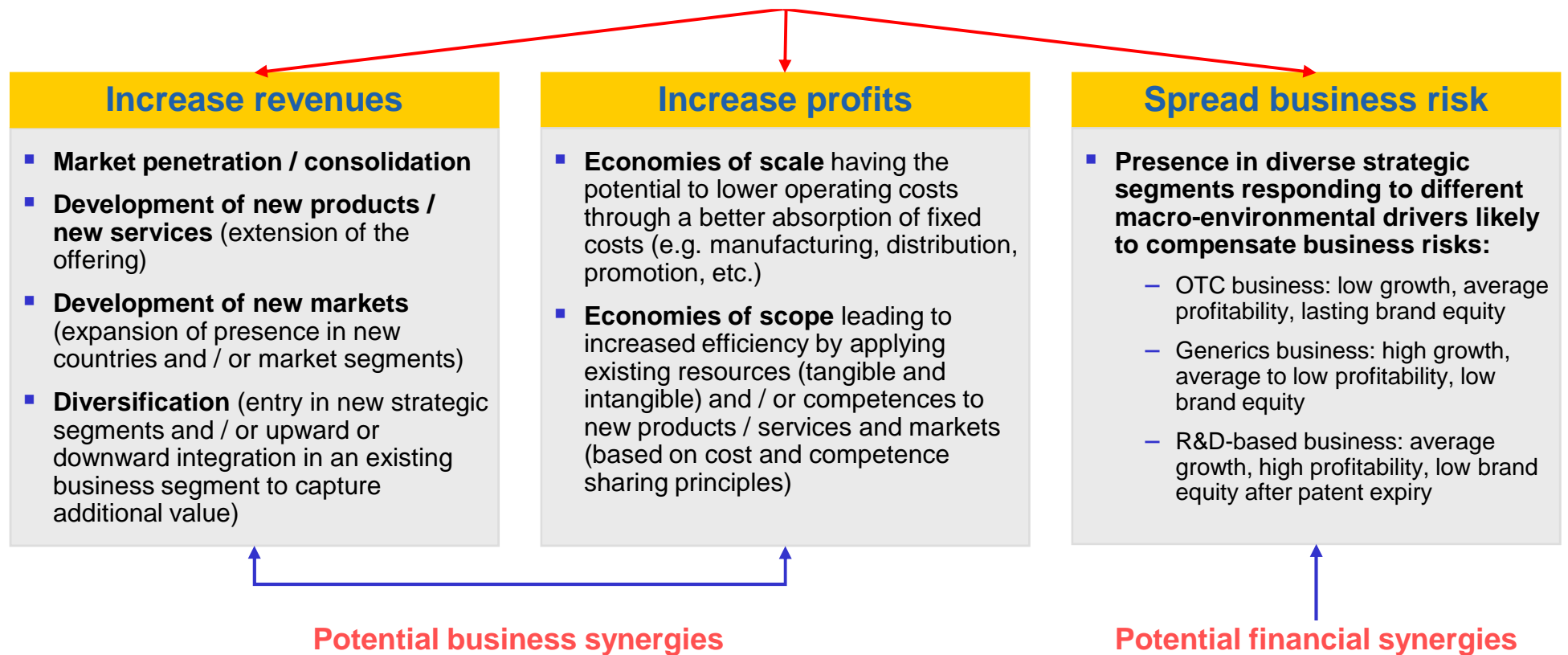
Source: Adapted by Smart Pharma Consulting from H. Ansoff

¹ Contract sales organization – ² Contract research organization

2. Basic principles

Business development initiatives are expected to generate extra revenues, increase profits and / or spread business risk, while leveraging potential synergies

Expected benefits of business development initiatives

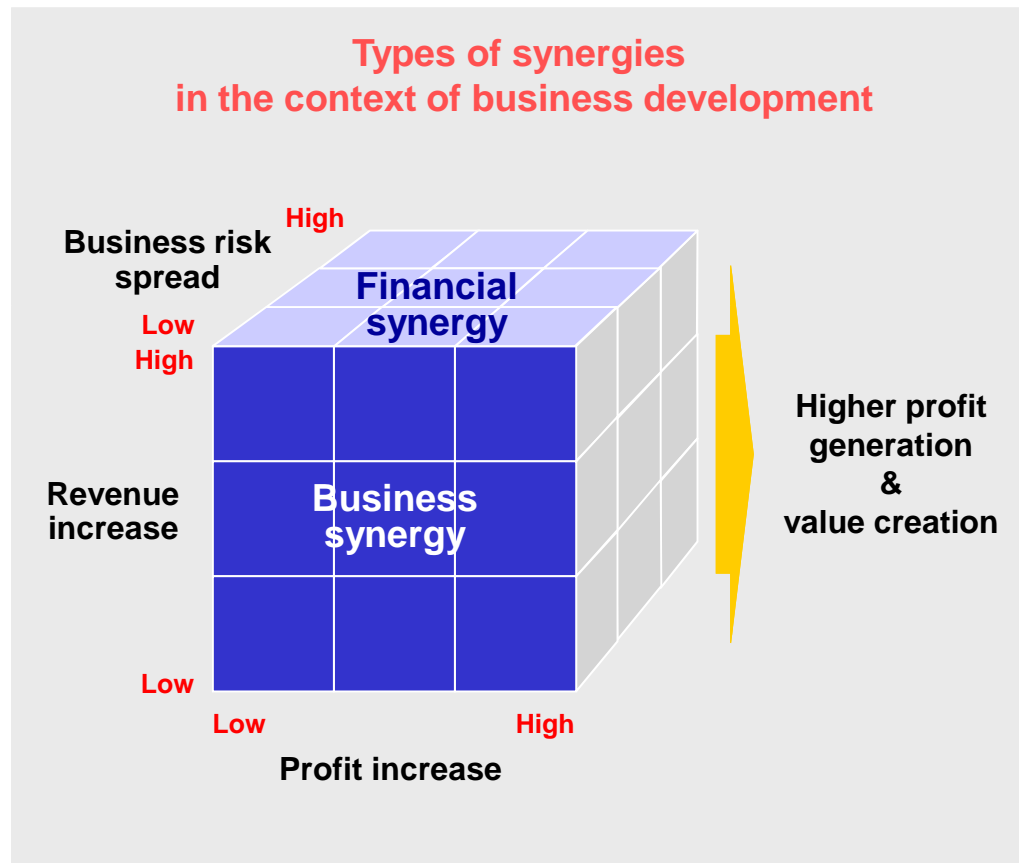


Source: Smart Pharma Consulting analysis

2. Basic principles

Synergies result from a better mixing and matching of capabilities, and are greatest when opportunities are in businesses similar to those in which affiliate competes

Concept of synergy applied to business development



Comments

- Synergy refers to the benefits gained where activities or assets complement each other so that their combined effect is greater than the sum of the parts
 - Synergies are supposed to generate higher profits and / or enhance value through:
 - Revenue increase with $1+1 \geq 2$
 - Cost reduction with $1+1 < 2$
 - There are two different types of synergies:
 - Business synergies due to cost reduction and / or revenue increase through combination of capabilities (i.e. tangible / intangible resources and competences)
 - Financial synergies related to possible spread of business risks if combined strategic segments are subject to different opportunities and threats
 - **Positive synergies are based on:**
 - Shared competences (economies of scope)
 - Shared costs (economies of scale)
 - **Negative synergies refer to lower profit generation and value destruction:**
 - Revenue decrease with $1+1 < 2$
 - Cost increase with $1+1 > 2$
- as a result of complexity, mismanagement, problems of integration, lower efficiency, brand cannibalization, etc.**

Source: Adapted by Smart Pharma Consulting from R Koch 2006 and from G. Johnson 2008

2. Basic principles

Strategic relationships and M&A may contribute to build capabilities and create business synergies, but not without difficulties and risks

Capability building through business development

Strategic relationships

- Strategic alliances involve the sharing of capabilities (resources + competences) in pursuit of common goals
- Outsourcing which is a form of subcontracting enables affiliates to access capabilities by borrowing them from other companies (e.g. deals with CSO¹)
- Accessing capabilities through alliances offer more targeted and cost effective means than acquisition
- Where both partners are trying to acquire one another's capabilities, results may be a "competition for competence" that ultimately destabilizes the relationship

Merger & Acquisition

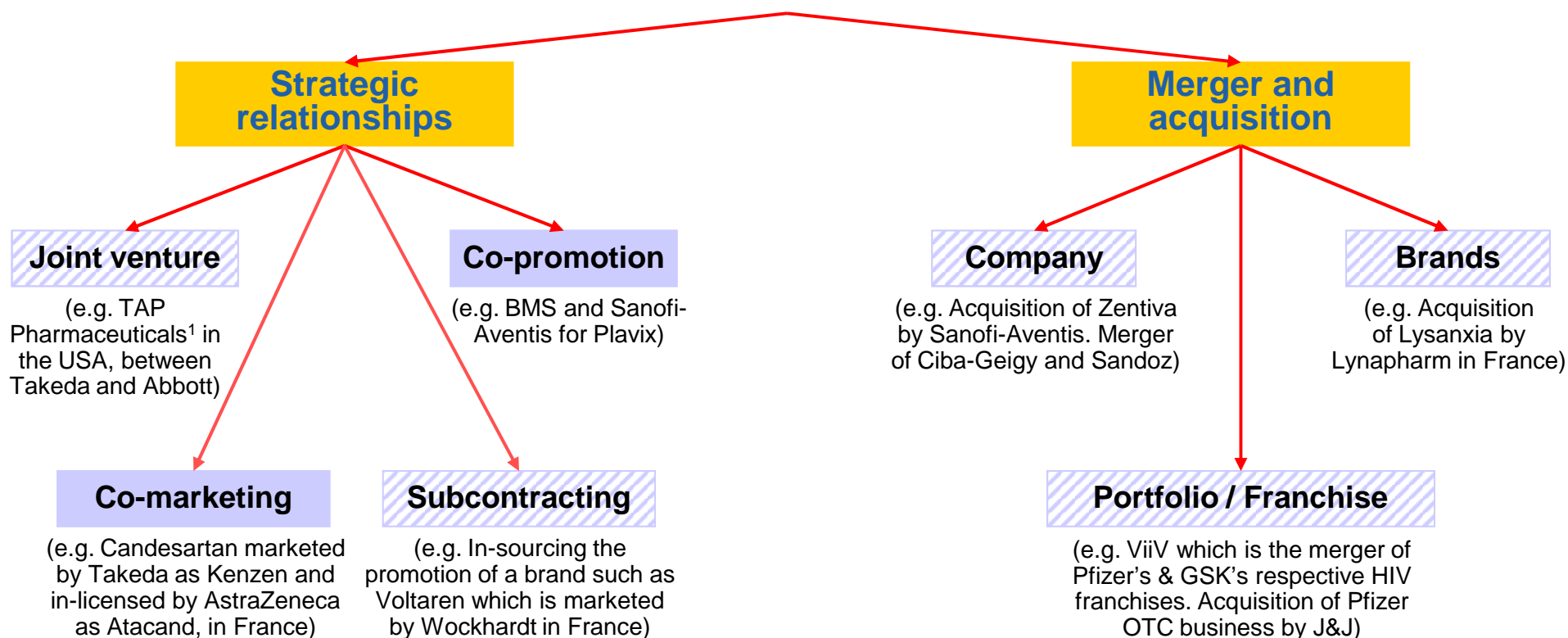
- Acquiring capabilities should be considered if desired capabilities can only be developed over long periods
- Integrating the acquiree's capabilities with the acquirer's ones involves major risks such as:
 - Culture clashes
 - Personality clashes
 - Incompatibility of management systemsresulting in degradation or destruction of the very capabilities that were sought

Note: Capabilities can grow internally by systematizing their replication through the formulation and the implementation of SOPs²

2. Basic principles

Co-promotion and co-marketing are the most common forms of business development deals in the pharmaceutical sector, at affiliate level

Typology of business development deals



Source: Adapted by Smart Pharma Consulting from R. Grant 2008 and D. Waters 2006

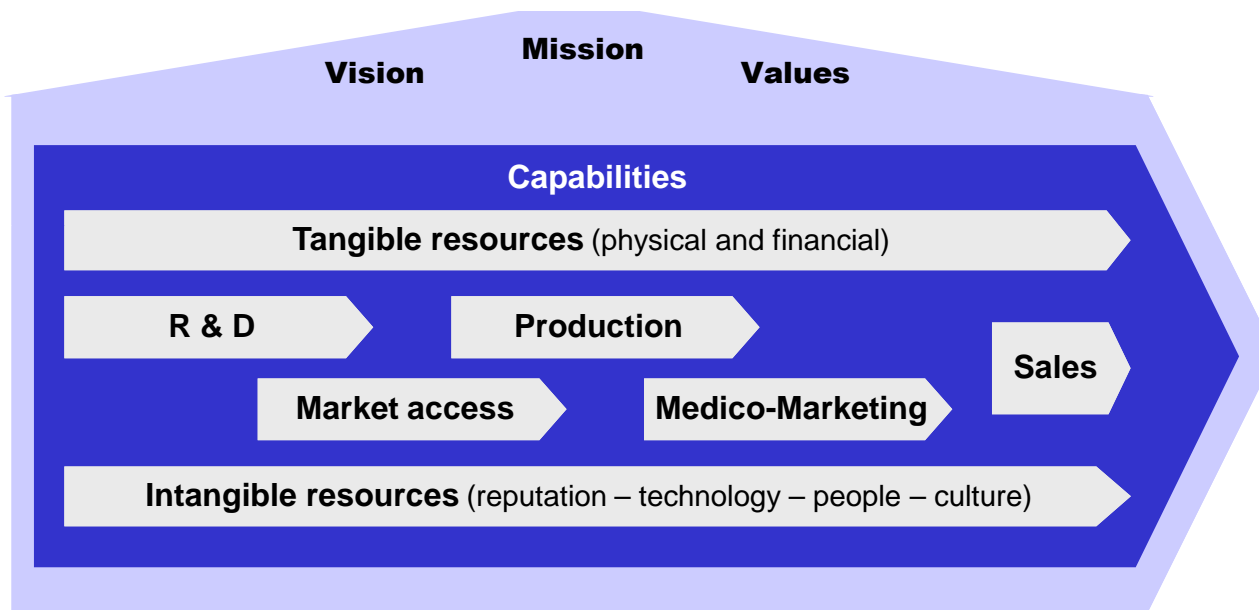
¹ Joint venture between Takeda and Abbott formed in the USA in 1977 and dissolved in 2008

3. Business opportunity assessment

Business opportunity assessment requires to analyze attractiveness / key success factors by strategic segment and affiliate's corresponding competitive advantage

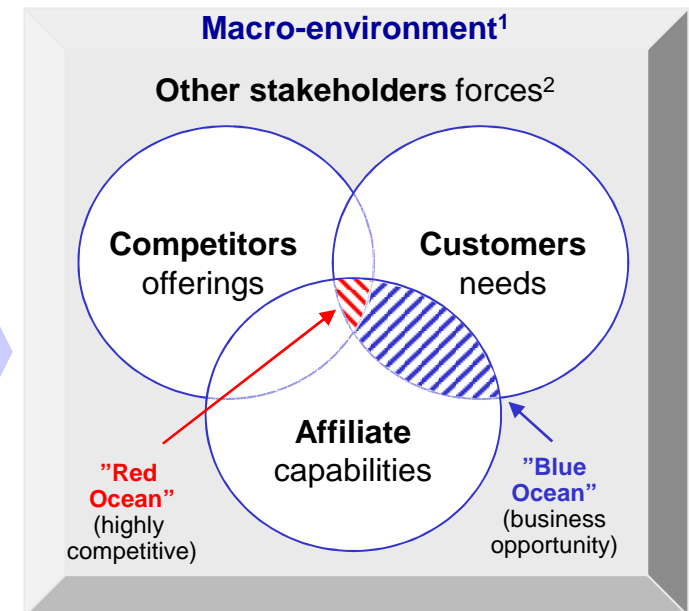
Methodology to assess business opportunities

The affiliate business model



Strengths & Weaknesses
(Competitive advantage)

Strategic segments (e.g. Rx-bound brands, generics, OTCs, devices, etc.)



Opportunities & Threats
(Attractiveness & Key success factors)

Ambition & Strategic priorities

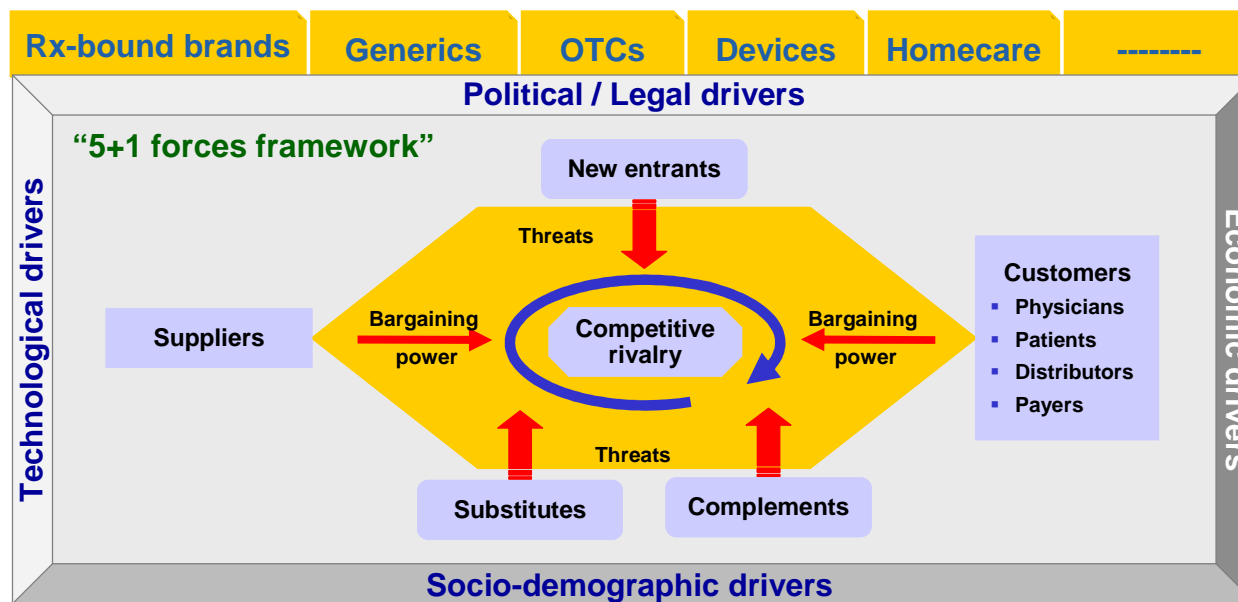
Source: Adapted by Smart Pharma Consulting from C. Kim et al. and from D.J. Collis, HBR April 2008

¹ Political / legal, economic, socio-demographic and technological factors –
² Including suppliers, new entrants, substitutes, complements

3. Business opportunity assessment

Business opportunities by strategic segment, such as Rx-bound brands, generics, OTCs, etc. can be assessed through PEST analysis and the “5+1 forces framework”

Attractiveness of strategic segments (1/3)



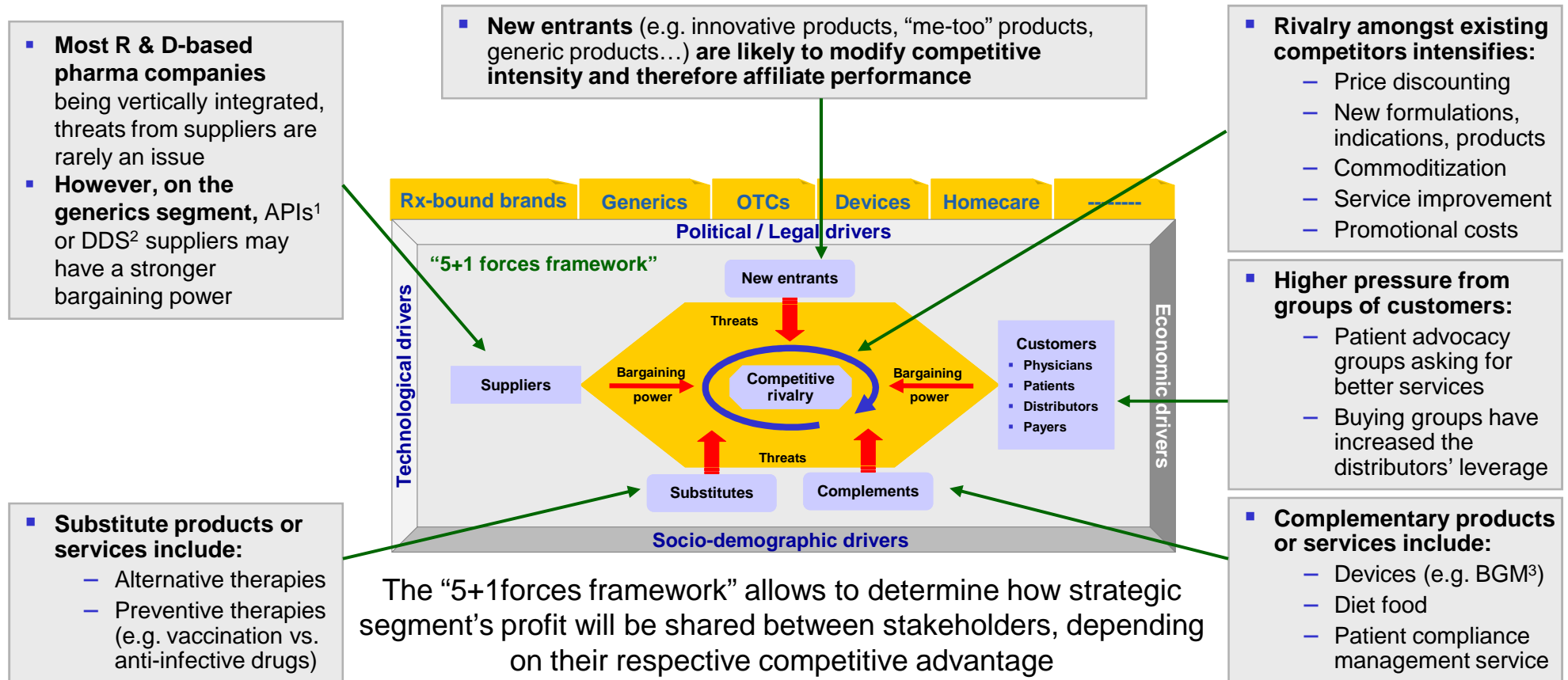
- The four key macro-environmental drivers:
 - Political / Legal
 - Economy
 - Socio-demography
 - Technology
 influence the attractiveness of a strategic group and impact the success or the failure of the Affiliates’ strategy per strategic group
- These key drivers for change can be used to construct scenarios of possible futures, especially by adopting the “what if” technique

Analysis of Political / Legal – Economic – Socio-demographic – Technological drivers, called PEST analysis, will help GMs set an appropriate strategic vision per strategic segment

3. Business opportunity assessment

The “5+1 forces framework” is particularly helpful to identify the key stakeholders that will influence the long-term structure and profitability of strategic segments

Attractiveness of strategic segments (2/3)



Source: Adapted by Smart Pharma Consulting from M. Porter 2008

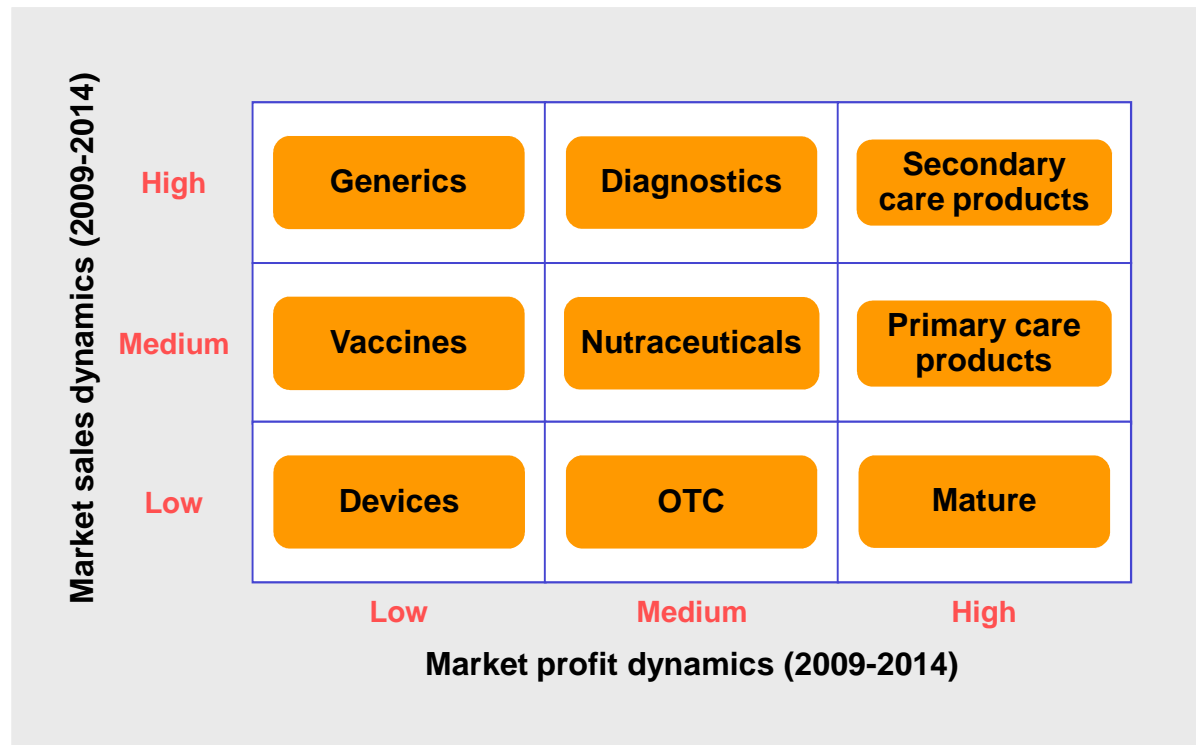
¹ Active pharmaceutical ingredients – ² Drug delivery system – ³ Blood glucose meter

3. Business opportunity assessment

Attractiveness of new strategic segments should be put into a dynamic perspective and potential synergies with affiliate's existing businesses also be considered

Attractiveness of strategic segments (3/3)

Illustrative



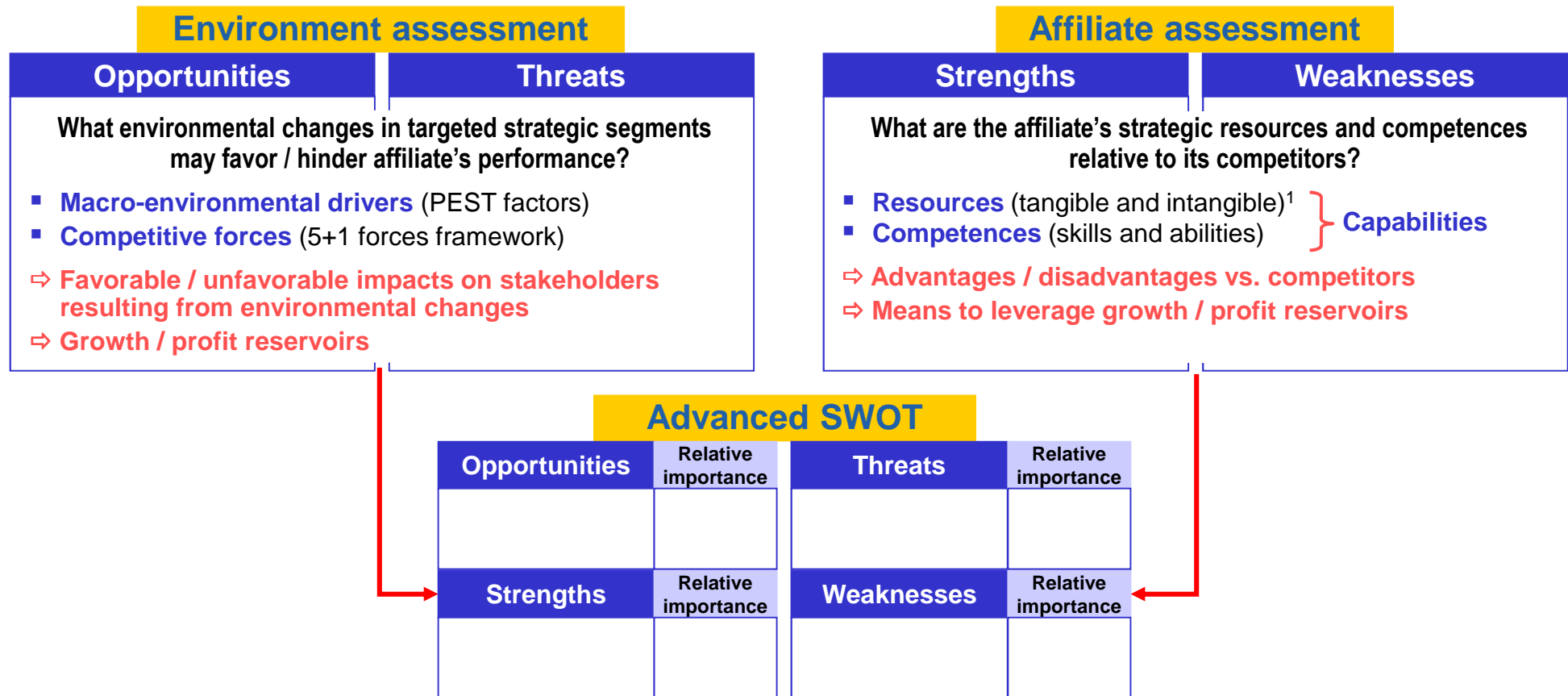
- The attractiveness of a strategic segment should be defined, based on the evolution of economic indicators such as sales and profits
- Additional parameters such as potential synergies with the existing business should also be considered, while evaluating attractiveness of new strategic segments

Source: Smart Pharma Consulting analysis

3. Business opportunity assessment

The “Advanced SWOT” is particularly appropriate to help the affiliate assess its potential competitive advantage per strategic segment and the possible synergies

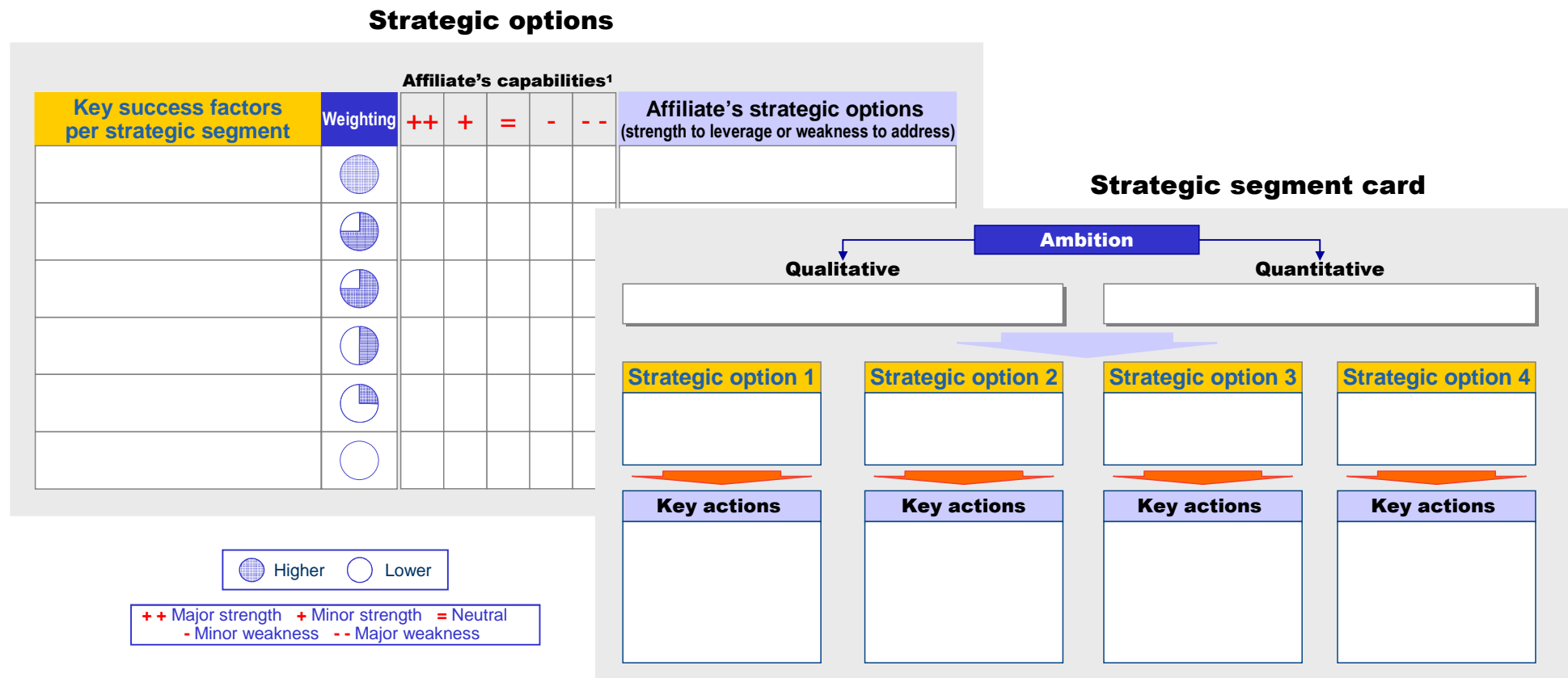
Advanced SWOT analysis



3. Business opportunity assessment

Affiliate's ambition and corresponding strategy regarding business opportunities in new strategic segments can be formalized with the following analytical tools

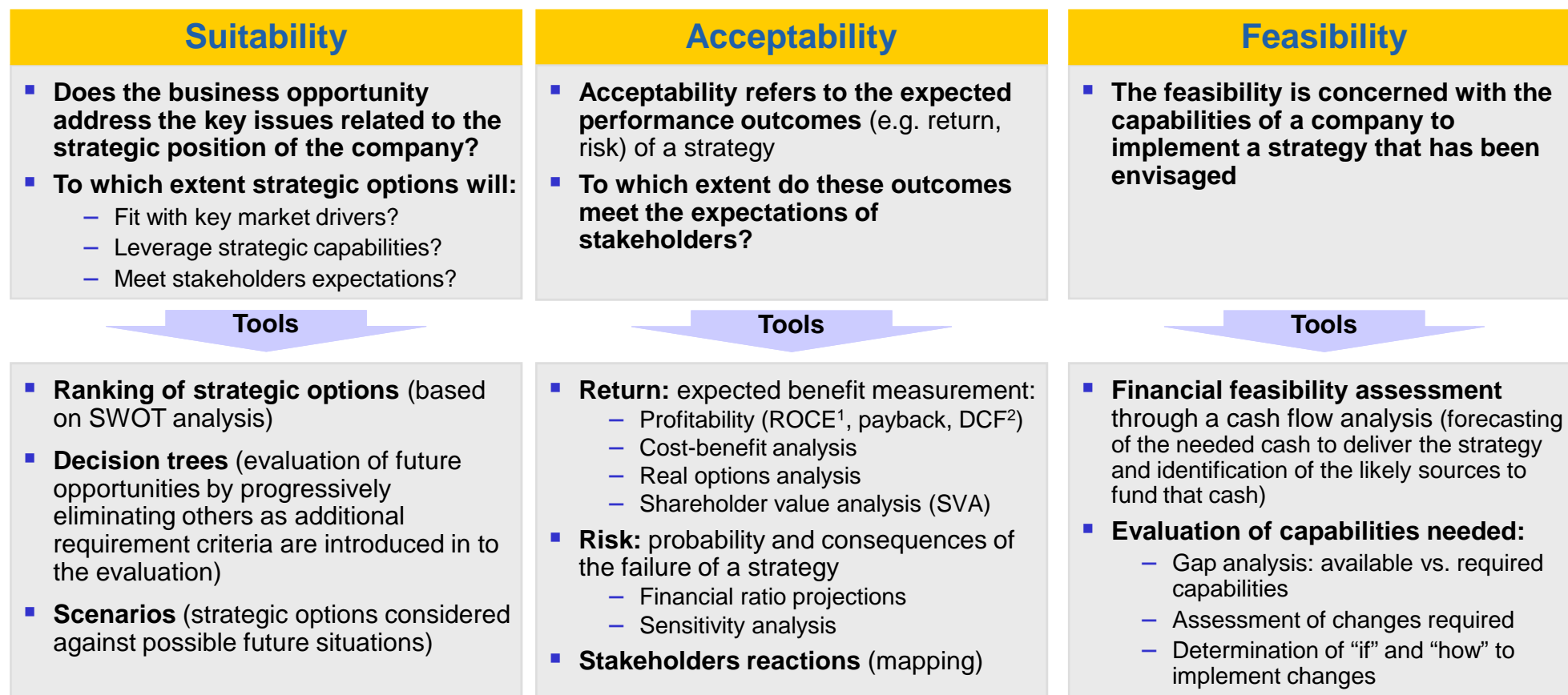
Strategic options and strategic segment card



4. Implementation guidelines

The evaluation of each business opportunity will be determined by its degree of suitability, acceptability and feasibility

Evaluation of business development opportunities (1/2)



Source: Adapted by Smart Pharma Consulting from G. Johnson 2008

¹ Return on capital employed – ² Discounted cash flows

4. Implementation guidelines

Discounted cash flows and sensitivity analysis are amongst the most frequently used techniques to assess business acceptability in the pharmaceutical sector

Evaluation of business development opportunities (2/2)

Illustrative

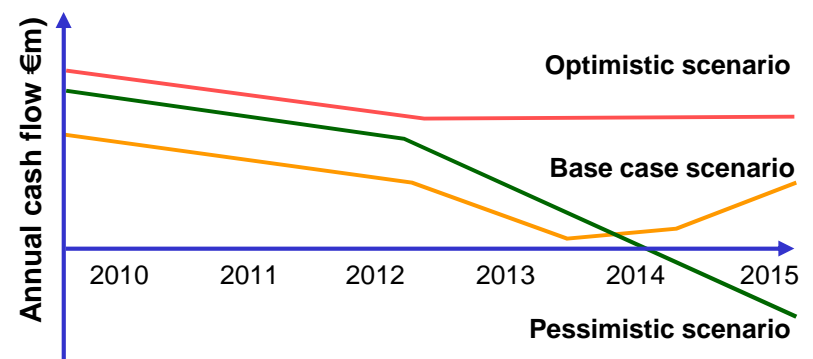
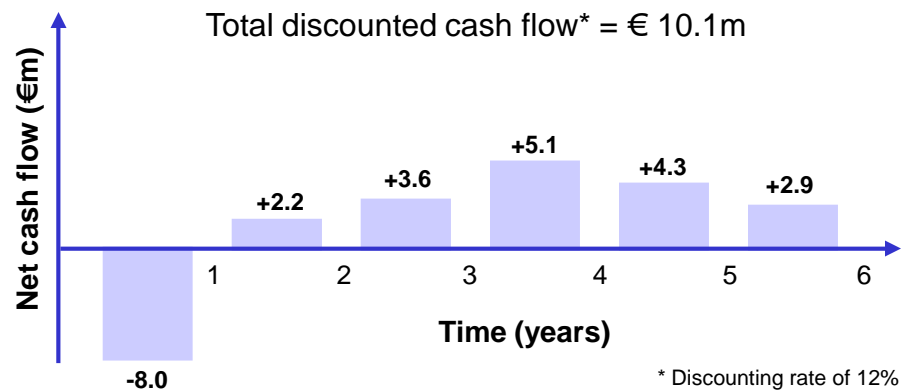
Examples of acceptability criteria

Return: Discounted cash flows (DCF)

- The DCF is an investment appraisal technique that can be used for business development opportunities (e.g. M&A, co-marketing, co-promotion, other strategic relationships)
- The total discounted cash flow or the net present value (NPV) is only as good as the assumptions on which it is based such as: sales forecasts, operating investment required, price changes, etc.

Risk: Sensitivity analysis

- Sensitivity or “what if” analysis is a useful technique for assessing the extent to which the success of a preferred business development opportunity is dependent on the key underlying assumptions, such as sales forecasts, price changes, investment requirements, new entrants, etc.
- This analysis helps estimate both the risk and the degree of confidence attached to an opportunity



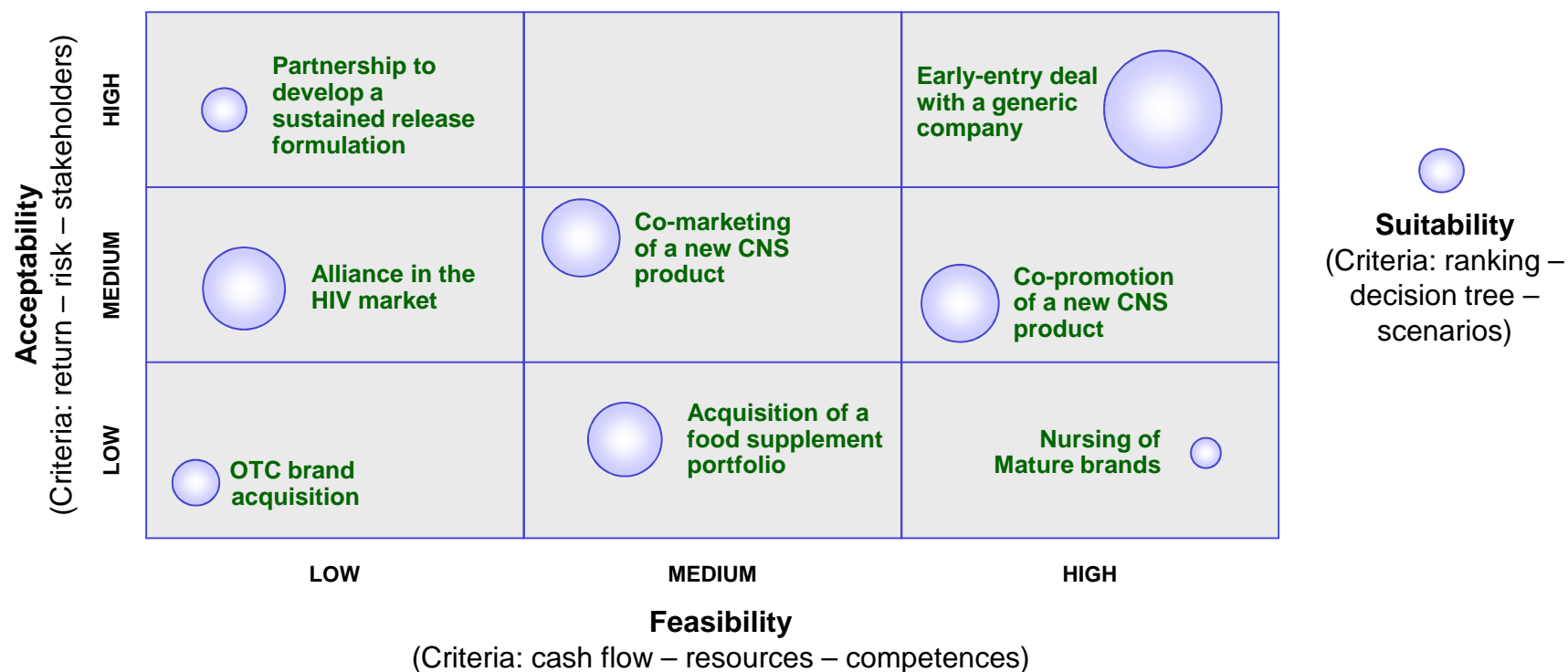
Source: Adapted by Smart Pharma Consulting from R. Grant 2008

4. Implementation guidelines

The strategic evaluation matrix represents a convenient means to put into perspective acceptability, feasibility and suitability of different business development projects

Business development evaluation matrix

Illustrative

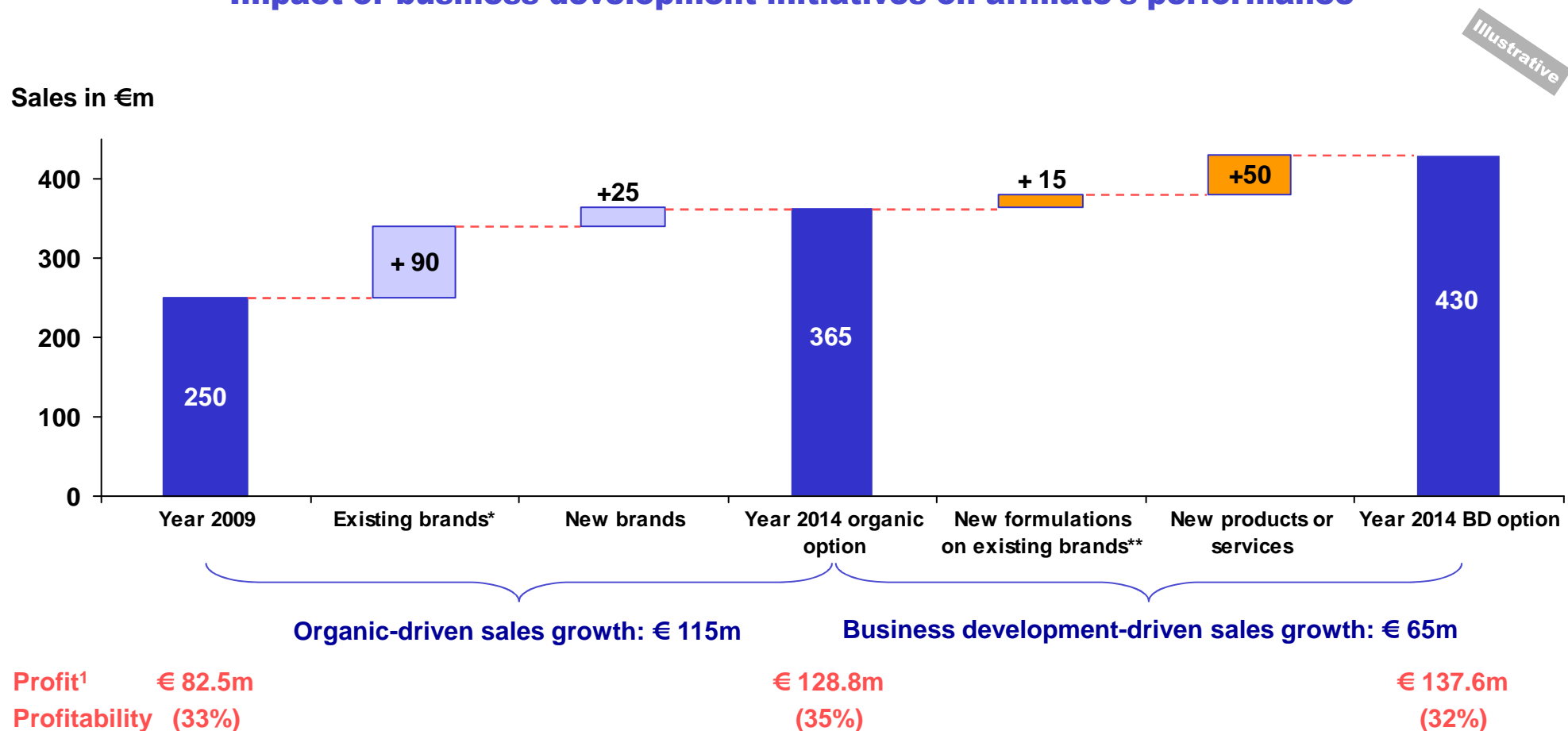


Source: Adapted by Smart Pharma Consulting from G. Johnson 2008

4. Implementation guidelines

In general, business development deals boost sales and profit growth, while altering profitability, due to profit sharing agreement and resulting organizational dysfunction

Impact of business development initiatives on affiliate's performance



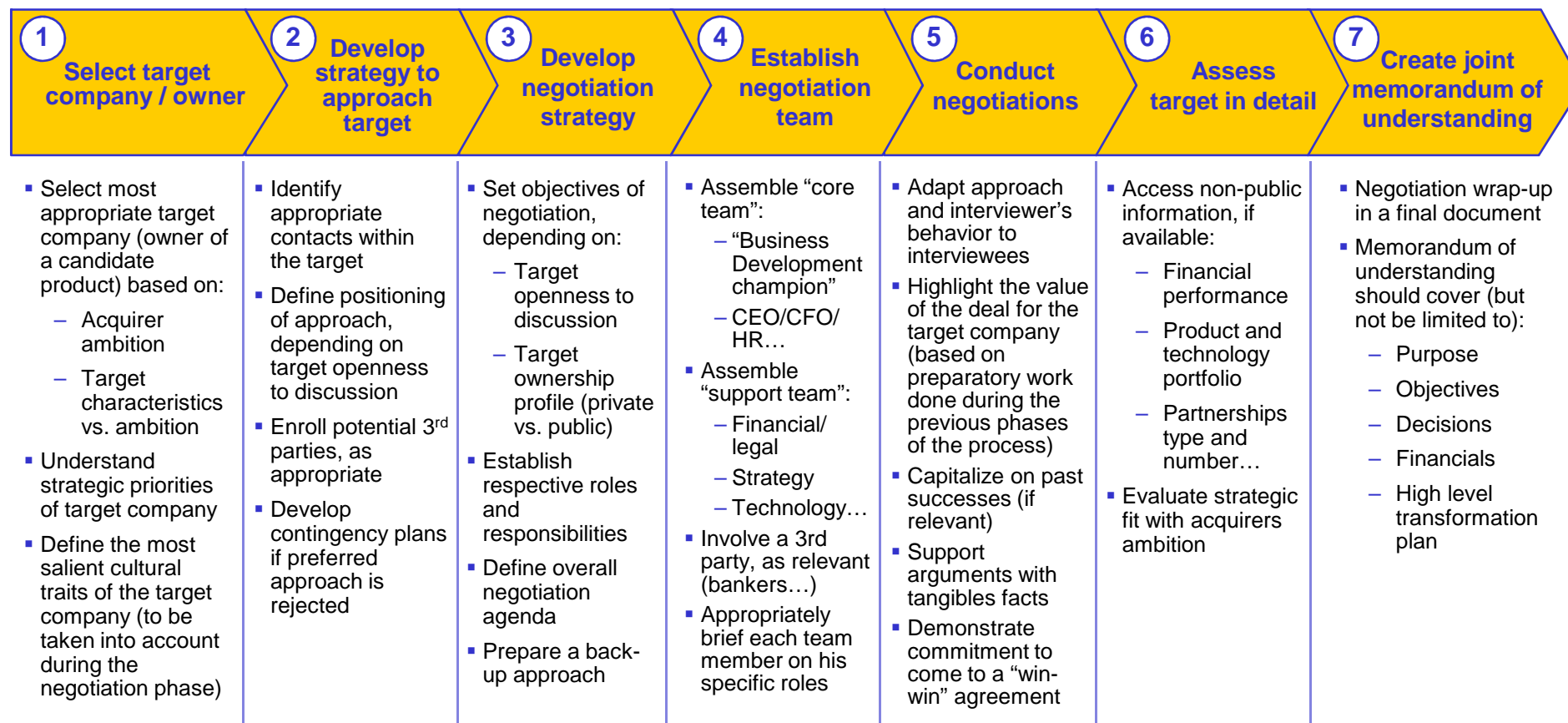
Source: Smart Pharma Consulting analysis

* Including new indications, dosages, formulations internally developed ** If externally developed – ¹ EBIT: Earnings before interest and tax

4. Implementation guidelines

Business developers should follow a well-defined process to approach target companies and raise their interest for strategic relationships or M&A opportunities

Process to approach target companies



Source: Smart Pharma Consulting analysis

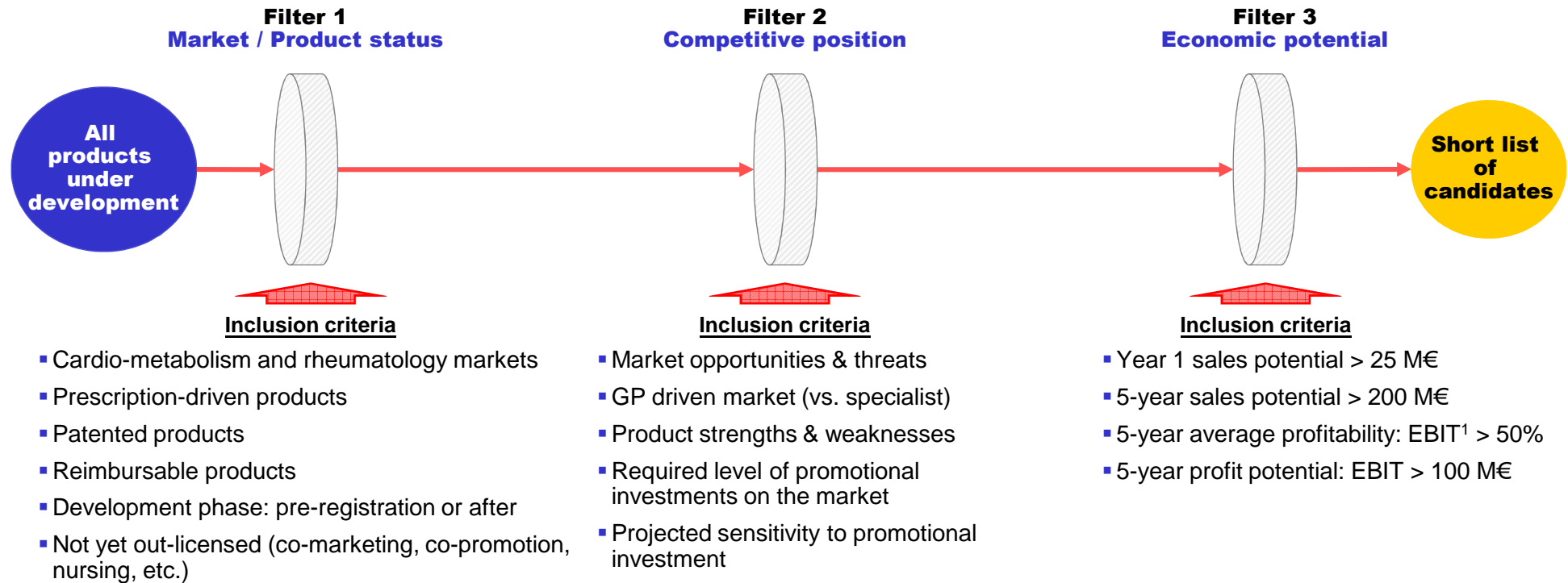
4. Implementation guidelines

Application

The selection of most attractive candidate products under development, within a defined strategic segment, can be established through the following methodology

Example of product screening (1/2)

Rx-bound products under development in France



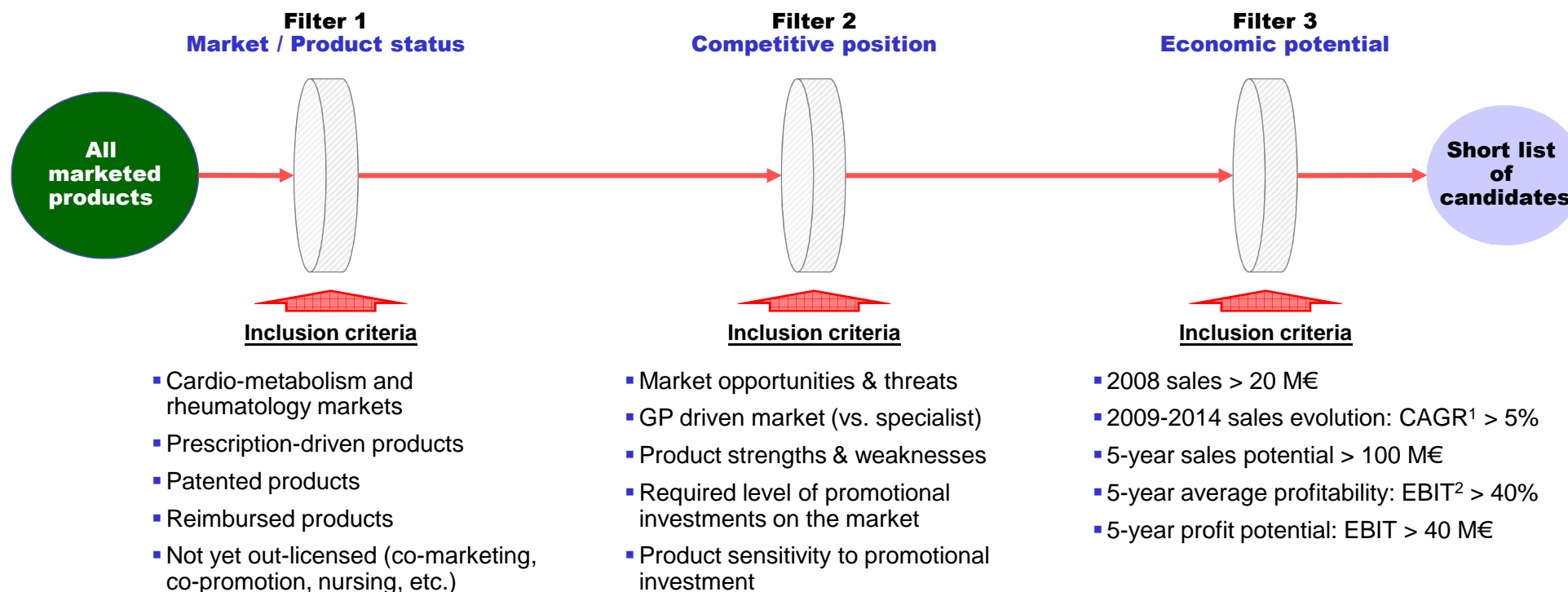
4. Implementation guidelines

Application

The selection of most attractive candidate products already marketed, within a defined strategic segment, can be established through the following methodology

Example of product screening (2/2)

Marketed Rx-bound products in France



Source: Smart Pharma Consulting

¹ Compounded annual growth rate – ² Earnings before interest and taxes

4. Implementation guidelines

Application

The results of the screening process, leading to the most attractive candidate products, can be summarized on simple charts to facilitate comparisons

Example of short listed candidate products

Under development products

Molecule	Brand name	Originator	Licensing agreement	Mode of action	Indications	EU status
Vildagliptin	GALVUS	Novartis	No	DPP IV antagonist	• Type 2	Registered
Saxagliptin	ONGLYZA	BMS	AZ (worldwide) Otsuka (Japan)	DPP IV antagonist	• Type 2	
Azimilide	STEDICOR	P&G US	Mitsubishi Tanabe - Asia	Potassium channel blocker	• Arrhyth	
Lercanidipine + enalapril	ZANERIL ZANITEK	Recordati	Meda (G), Solvay (Austria)	ACEI+ CCB	• Hyperte	
Olmesartan+ amlodipine	-	Daiichi-Sankyo	TBD	ARAI+CCB	• Hyperte	
Tolvaptan	SMASKA	Otsuka	No	Vasopressin 2 antagonist	• Corona failure	
Aliskiren	RASILEZ	Novartis	No	Renin inhibitor	• Hyperte	
Prednisone CR	LODOTRA	Nitec & SkyePharma	Merck-Serono	Immuno-depressant	• Rheum.	
Golimumab	-	Centocor (J&J)	Schering Plough (excl. US)	Anti-TNF alpha	• Spondy • Psorias • Rheum.	

Marketed products

Molecule	Brand name	Originator	Therapeutic class	Sales 2008	CAGR 2009-2014 ¹	Sales 2009-14	Promotional spend (2008)	Profits 2009-14
Rosuvastatin	CRESTOR	Astra Zeneca	C10A1	162 M€	25%	162 M€	20 M€	142 M€
Pravastatin + aspirin	PRAVADUAL	BMS	C10A1	21 M€	30%	21 M€	5 M€	16 M€
Ezetimib	EZETROL	Merck & Co	C10A9	75 M€	12%	75 M€	7 M€	68 M€
Ibandonate	BONVIVA	Roche	M05B3	32 M€	15%	32 M€	16 M€	16 M€
Eletriptan	RELPAZ	Pfizer	N02C1	26 M€	4%	26 M€	6 M€	20 M€
Hydroxyzine	ATARAX	UCB Pharma	N05C	20 M€	2%	20 M€	4 M€	16 M€
Mometasone furoate	NASONEX	Schering-Plough	R01A1	42 M€	5%	42 M€	9 M€	33 M€
Montelukast	SINGULAR	Merck & Co	R03J2	101 M€	4%	101 M€	9 M€	92 M€
levocetirizine	XYZALL	UCB Pharma	R06A	36 M€	-5%	36 M€	11 M€	25 M€

Source: Adisinsight, Septembre 2008 – GERS data 2008 – Analyses Smart Pharma Consulting

¹ Compounded annual growth rate

4. Implementation guidelines

Application

“ID” cards collecting key facts, figures and analyses related to each candidate product are particularly useful before approaching their respective owner

Example of identity card for short-listed candidate products

Molecule:-----	Brand name: -----	Originator: -----	Therapeutic class: -----
----------------	-------------------	-------------------	--------------------------

Product attributes				
Sales 2008 -----M€	CAGR 09-14 ¹ -----%	Sales 09-14 -----M€	Promo spent ² -----%	Profits 09-14 -----M€
Indications	Side effects	Status		
1. 2. 3.	1. 2. 3.	<ul style="list-style-type: none"> ▪ Patent expiry date: ----- ▪ Reimbursement level: -----% ▪ Price: a:----- b:----- ▪ Promotional sensitivity: 		

SWOT analysis																																	
<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #e6f2ff;">Market Opportunities</th> <th style="background-color: #e6f2ff;"></th> </tr> </thead> <tbody> <tr><td>-----</td><td></td></tr> <tr><td>-----</td><td></td></tr> <tr><td>-----</td><td></td></tr> </tbody> </table> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #e6f2ff;">Product strengths</th> <th style="background-color: #e6f2ff;"></th> </tr> </thead> <tbody> <tr><td>-----</td><td></td></tr> <tr><td>-----</td><td></td></tr> <tr><td>-----</td><td></td></tr> </tbody> </table>	Market Opportunities		-----		-----		-----		Product strengths		-----		-----		-----		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #e6f2ff;">Market threats</th> <th style="background-color: #e6f2ff;"></th> </tr> </thead> <tbody> <tr><td>-----</td><td></td></tr> <tr><td>-----</td><td></td></tr> <tr><td>-----</td><td></td></tr> </tbody> </table> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #e6f2ff;">Product weaknesses</th> <th style="background-color: #e6f2ff;"></th> </tr> </thead> <tbody> <tr><td>-----</td><td></td></tr> <tr><td>-----</td><td></td></tr> <tr><td>-----</td><td></td></tr> </tbody> </table>	Market threats		-----		-----		-----		Product weaknesses		-----		-----		-----	
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Product strengths																																	

Market threats																																	

Product weaknesses																																	

Value for the acquirer ----- ----- ----- ----- -----	Value for the owner ----- ----- ----- ----- -----	Recommandations <input checked="" type="checkbox"/> GO <input type="checkbox"/> NO GO
--	---	--

Preferred types of deals		
<input checked="" type="checkbox"/> Exclusive marketing license	<input checked="" type="checkbox"/> Co-marketing	<input type="checkbox"/> Co-promotion
<input type="checkbox"/> Non exclusive marketing license	<input type="checkbox"/> Nursing	<input type="checkbox"/> Acquisition
<input type="checkbox"/> Other:-----		

Source: Smart Pharma Consulting

Note: = high = medium = low

¹ Compounded annual growth rate – ² In 2008

5. Conclusions

Business development opportunities may play a key role in improving affiliates overall performance (top and bottom lines) while mitigating their business risk

Key learning (1/2)

- Business development refers to **strategic relationships** or **Merger & Acquisition** deals which enable affiliates to strengthen their competitive position
- Business development initiatives are expected to **generate extra revenues**, **increase profits** and / or **spread business risk**, while **leveraging potential synergies**
- **Synergies** result from a better **mixing and matching of capabilities**, and are greatest when opportunities are in businesses similar to that in which affiliates compete
- **Strategic relationships** and **M&A** may contribute to **build capabilities** and **create** business **synergies**, but not without **difficulties** and risks
- **Co-promotion** and **co-marketing** are the **most common forms** of business development **deals** in the pharmaceutical sector, at affiliate level
- Business opportunity **assessment** requires to analyze **attractiveness / key success factors** by strategic segment and affiliate's corresponding **competitive advantage**
- **Business opportunities** by strategic segment, such as Rx-bound brands, generics, OTCs, etc., can **be assessed** through **PEST analysis** and the **"5+1 forces framework"**

5. Conclusions

Business opportunities should be carefully assessed by affiliates through strategic analyses and with specific processes and tools to maximize their chance of success

Key learning (2/2)

- The “**5+1 forces framework**” is particularly helpful to **identify** the **key stakeholders** that will **influence the long-term structure** and **profitability** of strategic segments
- **Attractiveness** of new strategic segments should be put into a **dynamic perspective** and **potential synergies** with affiliate’s existing businesses also **be considered**
- The “**Advanced SWOT**” is particularly appropriate to help affiliates **assess** their potential **competitive advantage** per strategic segment and **possible synergies**
- The **evaluation** of each business opportunity will be determined by its degree of **suitability**, **acceptability** and **feasibility**
- **Discounted cash flows** and **sensitivity analysis** are amongst the most frequently used techniques **to assess business acceptability** in the pharmaceutical sector
- In general, business development **deals boost sales** and **profit growth** while **altering profitability**, due to profit sharing agreement and resulting organizational dysfunction
- **Business developers** should **follow** a well-defined **process to approach target companies** and raise their interest for strategic relationships or M&A opportunities