Best-in-Class Pharma BD&L

Concepts

Methods

Tools

- From Theory to Practice -

Key Guidelines

November 2017



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Sources: Smart Pharma Consulting

¹ Business Development & Licensing

A Smart Pharma Consulting

1. Introduction

BD&L opportunities being rare and complex, Pharma BD&L managers would be well-advised to adopt a systematic, rigorous and perfectly planned approach

Key points addressed

- What is the purpose of BD&L?
- What are the most common types of BD&L deals?
- How to assess BD&L opportunities?
- How to formalize a BD&L strategy?
- How to approach target companies for BD&L opportunity?
- How to assess and select a product eligible for BD&L deal (application)?

Four basic strategic directions can be pursued by affiliates of pharmaceutical companies to boost their strategic development

Alternative directions to ensure strategic development

- Increase market share by strengthening customer preference
- Defend existing market share by building customer loyalty and raising switching costs
- Enter new market segments (subset of patients such as children, new indications) and/or new geographical areas

Existing

Market

New

Existing	New	
Market penetration	Product / Service development	
Market consolidation		
Market development	Diversification	

Products

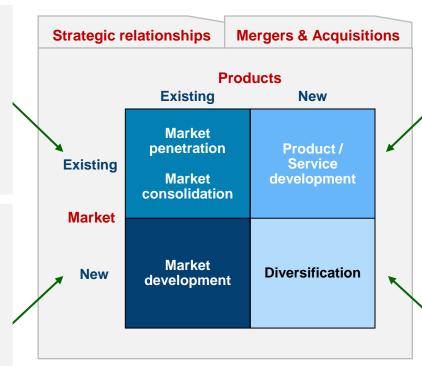
- Modify existing products
 (e.g. new dosage, form) or
 launch new products /
 services to further penetrate
 existing markets
- Diversify by entering in new strategic segments (e.g. OTCs, generics, medical devices, nutraceuticals)

Source: Adapted by Smart Pharma Consulting from H. Ansoff

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

Definition of BD&L

- Collaboration with a third party (e.g. pharma company, CSO¹) to increase share of contacts and/or share of voice
- Co-marketing or co-promotion agreements to increase resources behind one molecule
- Acquisition of competitors to reduce or better manage competitive intensity
- Collaboration with a CRO² to develop new indications
- Co-promotion with a partner to promote to a group of new clients (e.g. pediatricians, neurologists)
- Licensing-out to a third party to:
 - Market in new countries (e.g. biotech products in Africa)
 - Expand presence in second priority territories (e.g. in Mexico, South Africa, India)
 - Etc.



- Outsourcing development of a new combined formulation
- Co-branding of a diagnostic tool and of a drug for a given pathology (e.g. diabetes, hypertension, oncology, etc.)
- Co-development of back-up brands (i.e. isomers, active metabolites, esters, salts of existing molecules)
- Acquisition or in-licensing of new drug delivery systems
- Acquisition, merger, joint-venture or in-licensing deals to enter in:
 - A new strategic segment (e.g. OTC, generics, home care services, etc.) or therapeutic domain (e.g. neurology) through horizontal integration
 - Distribution business through downward integration
 - Toll manufacturing business through upward integration
 - Etc.

Source: Adapted by Smart Pharma Consulting from H. Ansoff

¹ Contract sales organization – ² Contract research organization

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

Expected benefits from BD&L initiatives

Increase revenues

- Market penetration / consolidation
- Development of new products / new services (extension of the offering)
- Development of new markets (expansion of presence in new countries and/or market segments)
- Diversification (entry in new strategic segments and/or upward or downward integration in an existing business segment to capture additional value)

Increase profits

- Economies of scale having the potential to lower operating costs through a better absorption of fixed costs (e.g. manufacturing, distribution, promotion)
- Economies of scope leading to increased efficiency by applying existing resources (tangible and intangible) and/or competences to new products / services and markets (based on cost and competence sharing principles)

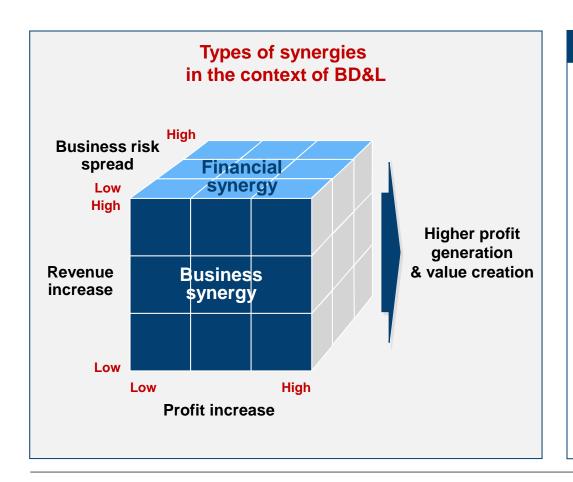
Spread business risk

- Presence in diverse strategic segments responding to different macro-environmental drivers likely to compensate business risks:
 - OTC business: low growth, average profitability, lasting brand equity
 - Generics business: high growth, average to low profitability, low brand equity
 - R&D-based business: average growth, high profitability, low brand equity after patent expiry

Source: Smart Pharma Consulting analysis

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

Concept of synergy applied to business development



Comments

- Synergy refers to the benefits gained when 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>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)
 - <u>Financial synergies</u> 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 increase (or even decrease) with 1+1<2
 - Cost increase with 1+1>2

resulting from 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

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 a CSO¹ or another pharma company)
- Accessing capabilities through alliances offers 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

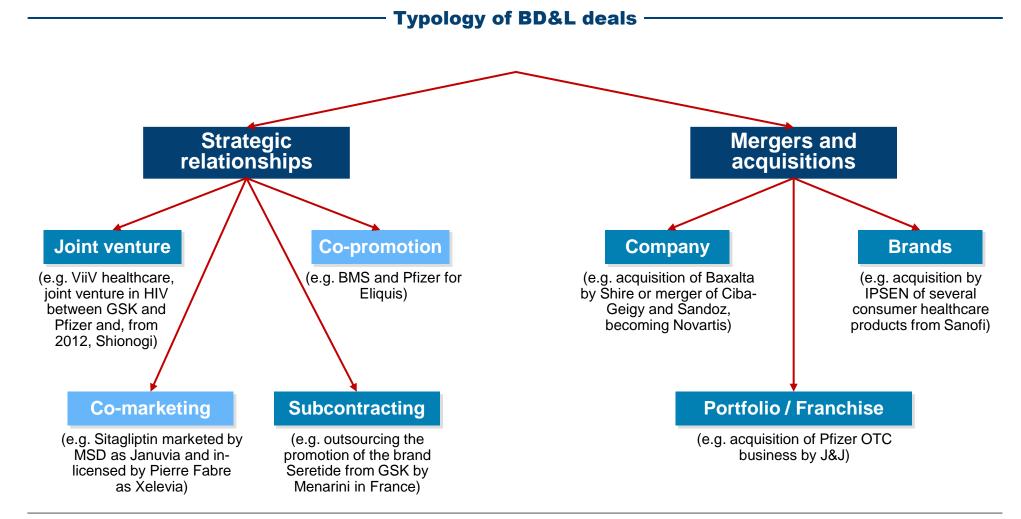
Mergers & Acquisitions

- 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 systems

resulting in degradation or destruction of the capabilities that were sought

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

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



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

The most important difficulty with co-promotion is to ensure an efficient collaboration between the two partners and a sufficient call pressure per physician

Pros and Cons of co-marketing and co-promotion agreements

Co-marketing

- Quick and easy to implement
- No shared decision-making
- Increased sales opportunities for the molecule which is promoted by two companies through a dual branding
- Possibilities to book sales
- Higher promotional spending (absence of shared costs)
- Competition between co-marketers (cannibalization)

Co-promotion

- Higher recognition as a result of resource concentration
- Cost-sharing with co-promoter
- Unique product positioning
- Leverage of partner's reputation

- Difficulty in ascertaining sales credits and reward criteria
- Increased management complexity
- Increasing number of physicians limiting call pressure per brand per annum

Pros

Cons

Source: Smart Pharma Consulting analysis

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

Methodology to assess business opportunities -

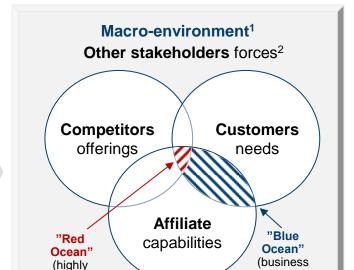
Mission Vision **Values Capabilities Tangible resources** (physical and financial) **R & D Production** Sales **Medico-Marketing** Market access **Intangible resources** (reputation – technology – people – culture)

Strengths & Weaknesses

(Competitive advantage)

Business model

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



opportunity)

Opportunities & Threats (Attractiveness & Key success factors)

competitive)

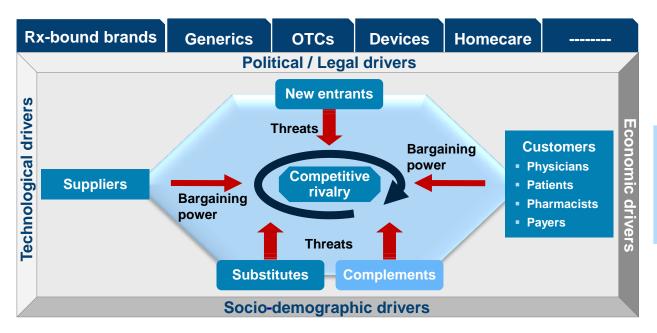
Ambition & Strategic priorities

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

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)



Analysis of Political / Legal – Economic – Socio-demographic – Technological drivers, called PEST analysis, and then the "5+1 forces Framework" after M. Porter will help pharma companies set an appropriate strategy per strategic segment

"Porter's five forces" "Additional force"

- The four key macro-environmental drivers:
 - Political / Legal
 - Economy
 - Socio-demography
 - Technology
- The five key micro-environment drivers:
 - Suppliers
 - Customers
 - New entrants
 - Substitutes
 - Competitive rivalry
- ... plus the "Complements" influence the attractiveness of each strategic segment and impact the success or the failure of pharma companies strategy
- These key drivers for change can be used to construct scenarios of possible futures, especially by adopting the "what if" technique

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

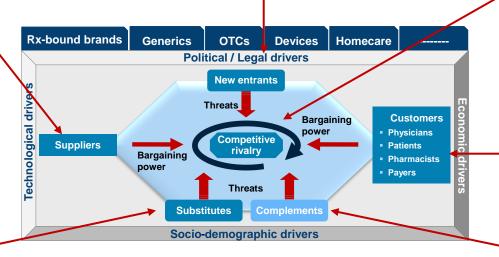
The "5+1 forces framework" is particularly helpful to identify the key stakeholders that will influence the long-term structure and profitability of strategic segments

Attractiveness of strategic segments (2/3)

- Most R&D-based pharma companies being vertically integrated, threats from suppliers are rarely an issue
- However, on the generics segment, API¹ or DDS² suppliers may have a stronger bargaining power

- Substitute products or services include:
 - Alternative therapies
 - Preventive therapies (e.g. vaccination vs. anti-infective drugs)

New entrants (e.g. innovative products, "me-too" products, generic products) are likely to modify competitive intensity and therefore pharma companies performance



The "5+1forces framework" allows to determine how strategic segment's profit will be shared between stakeholders, depending on their respective competitive advantage

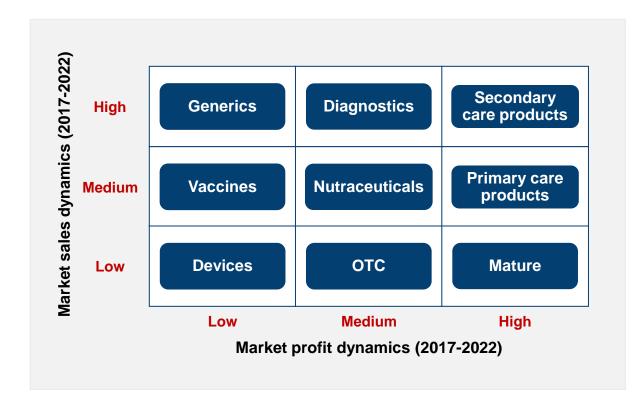
- Competitive rivalry intensifies with:
 - Price discounting
 - New formulations, indications, products
 - Commoditization
 - Service improvement
 - Promotional costs
- Higher pressure from groups of customers:
 - Patient advocacy groups asking for better services
 - Buying groups have increased the distributors' leverage
- Complementary products or services include:
 - Devices (e.g. BGM³)
 - Diet food
 - Patient compliance management services

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

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

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

Attractiveness of strategic segments (3/3) -



- 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

Key success factors by strategic segment where business opportunities have been identified are driven from competitive intensity and from customers wants

Key success factors by strategic segment -

How do affiliates survive competition?

Competitive analysis

- What drives competition?
- What are the main dimensions of competition?
- How intense is the competition?
- How can we obtain a superior competitive position?
- How can we create customer's preference?

What do customers want?

Demand analysis

- Who are our customers?
- What is their respective role?
 (prescribers, consumers, distributors, payers, influencers, "injectors", etc.)
- What do they want?
- What do they need?
- What are their available alternatives?
- What does create customers' preference?

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

Strategic priorities should be set after capabilities assessment to outperform competitors on key success factors inherent to each targeted strategic segment

Affiliate's competitive advantage and strategic priorities

Key success factors per strategic segment

 Exploiting pharma companies key strengths and addressing key weaknesses

Strategic priorities

- Deploying existing resources
- Filing resource gaps
- Building capabilities

Pharma companies competitive advantage

 Resources are the productive assets owned by pharma companies Competences condition deployment of resources through activities / processes to create advantage and superior performance

CAPABILITIES

Competences (skills & abilities)

Tangible resources

- Financial (cash flow, borrowing capacity, sources of capital, securities, capital, debtors and creditors, etc.)
- Physical (plant, equipment, facilities, locations, production capacity, access to raw material, etc.)

Intangible resources

- Reputation (brand equity, goodwill, corporate equity, relationships with stakeholders)
- Technology (products, patents, trademarks)
- Human (number and type of employees, skills, knowledge, loyalty, flexibility, motivation, etc.)
- Culture (values, traditions, social norms)

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

The "Advanced SWOT" is particularly appropriate to help pharma companies assess its potential competitive advantage per strategic segment and the possible synergies

Advanced SWOT analysis

Environment assessment

Opportunities

Threats

What environmental changes in targeted strategic segments may favor / hinder affiliate's performance?

- Macro-environmental drivers (PEST factors)
- Competitive forces (5+1 forces framework)
- ⇒ Favorable / unfavorable impacts on stakeholders resulting from environmental changes
- **⇒** Growth / profit reservoirs

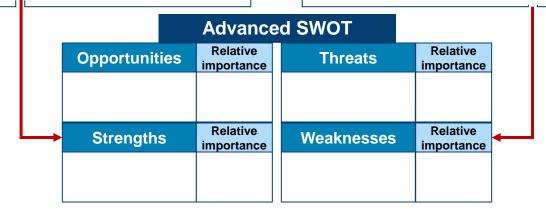
Affiliate assessment

Strengths

Weaknesses

What are the affiliate's strategic resources and competences relative to its competitors?

- Resources (tangible and intangible)¹
- Competences (skills and abilities)
- Capabilities
- **⇒** Advantages / disadvantages vs. competitors
- ⇒ Means to leverage growth / profit reservoirs

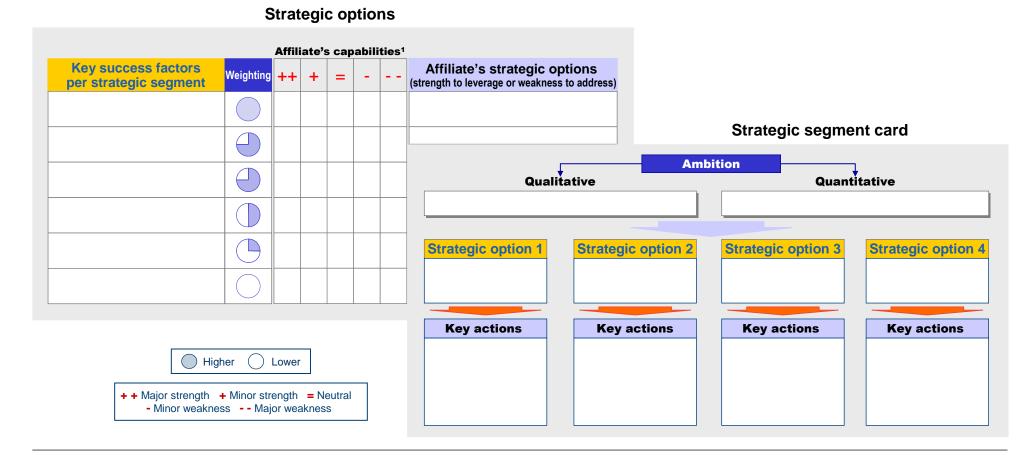


Source: Smart Pharma Consulting

¹ Including product and service offerings

Pharma companies' ambition and strategy to seize business opportunities in new strategic segments can be formalized with the following analytical tools

Strategic options and strategic segment card



Source: Smart Pharma Consulting

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

Evaluation of business development opportunities (1/2)

Suitability

- Does the business opportunity address the key issues related to the strategic position of the company?
- To what extent strategic options will:
 - Fit with key market drivers?
 - Leverage strategic capabilities?
 - Meet stakeholders expectations?

Acceptability

- Acceptability refers to the expected performance outcomes (e.g. return, risk) of a strategy
- To what extent do these outcomes meet the expectations of stakeholders?

Feasibility

 The feasibility is concerned with the capabilities of a company to implement a strategy that has been envisaged

Tools

- Ranking of strategic options (based on Advanced SWOT analysis)
- Decision trees (evaluation of future opportunities by progressively eliminating others as additional requirement criteria are introduced into the evaluation)
- Scenarios (strategic options considered against possible future situations)

Tools

- Return: expected benefit measurement:
 - Profitability (ROCE¹, payback, DCF²)
 - Cost-benefit analysis
 - Real options analysis
 - Shareholder value analysis (SVA)
- Risk: probability and consequences of the failure of a strategy:
 - Financial ratio projections
 - Sensitivity analysis
- Stakeholders reactions (mapping)

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Tools

- Financial feasibility assessment through a cash flow analysis (forecasting of the needed cash to deliver the strategy and identification of the likely sources to fund that cash)
- Evaluation of capabilities needed:
 - Gap analysis: available vs. required capabilities
 - Assessment of changes required
 - Determination of "if" and "how" to implement changes

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

¹ Return on capital employed – ² Discounted cash flows

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

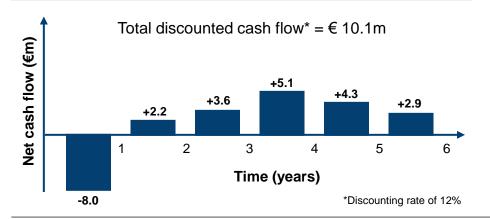
Evaluation of business development opportunities (2/2)

Examples of acceptability criteria



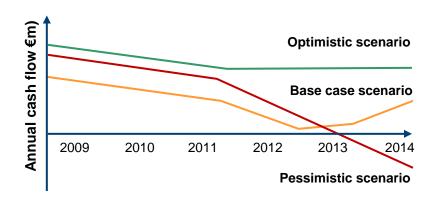
Return: Discounted cash flows (DCF)

- The DCF is an investment appraisal technique that can be used for business development opportunities (e.g. M&A, comarketing, 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

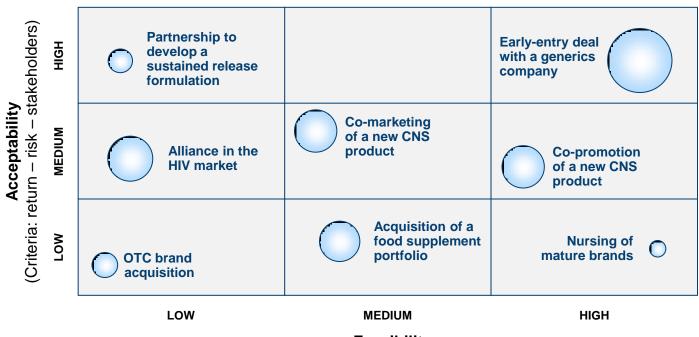


Source: Adapted by Smart Pharma Consulting from G. Johnson 2008

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





Bubble size



Suitability
(Criteria: ranking –
decision tree –
scenarios)

Feasibility

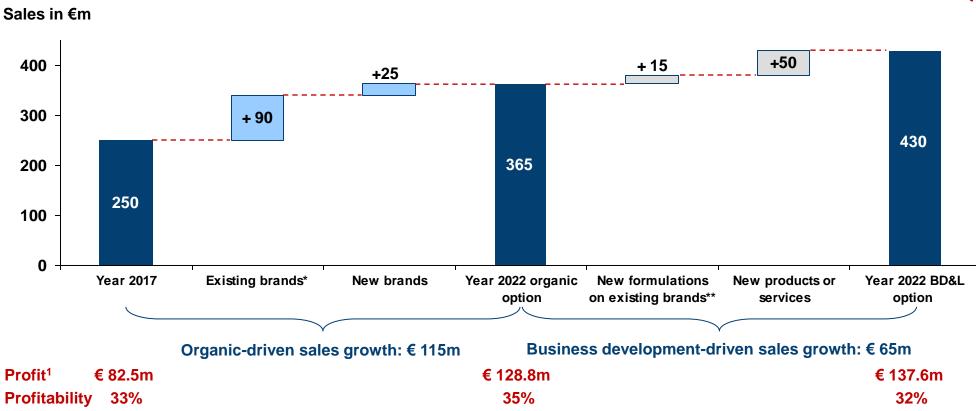
(Criteria: cash flow – resources – competences)

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

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







Source: Smart Pharma Consulting analysis

November 2017

^{*} Including new indications, dosages, formulations internally developed ** If externally developed – 1 EBIT: Earnings before interest and taxes

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

(5) (2) (3) (4) 6 (1)**Create joint** Develop Develop **Establish Assess** Select target strategy to Conduct memorandum negotiation negotiation targets company / owner approach negotiations of in detail strategy team targets understanding Select most Assemble a "core Adapt the Access non-public Identify Set objectives of Negotiation wrapappropriate target appropriate negotiation, team": approach to the information, if up in a final personality of the companies (owner contacts within depending on: available: document "Business target companies target companies of a candidate Development Target - Financial Memorandum of management product or portfolio) champion" openness to Define positioning performance understanding based on: Highlight the value - CEO, CFO discussion of approach, should cover (but Product and of the deal for the Acquirers depending on not be limited to): Target Assemble "support technology target companies ambition target openness to ownership team": portfolio (based on Purpose discussion profile (private Targets Strategy and preparatory work relationships Objectives characteristics vs. vs. public) done during the marketing Enroll potential 3rd type and Decisions ambition previous phases parties, as Establish roles and Medical number... of the process) - Financials appropriate Understand responsibilities at Production Evaluate strategic Capitalize on past corporate and/or - High level strategic priorities of Develop fit of target Financial, legal. successes transformation target companies affiliate level contingency plans companies with HR, etc. (if relevant) plan if preferred Define the most Define overall acquirers ambition Involve a 3rd party. Support approach is salient cultural traits negotiation as relevant Check the local arguments with rejected of target companies agenda (bankers...) tangibles facts reputation and (to be taken into Prepare a back-up reliability of target Appropriately brief Demonstrate account during the approach each team companies and commitment to negotiation phase) member on his brand come to a "winspecific role win" agreement

Source: Smart Pharma Consulting analysis

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

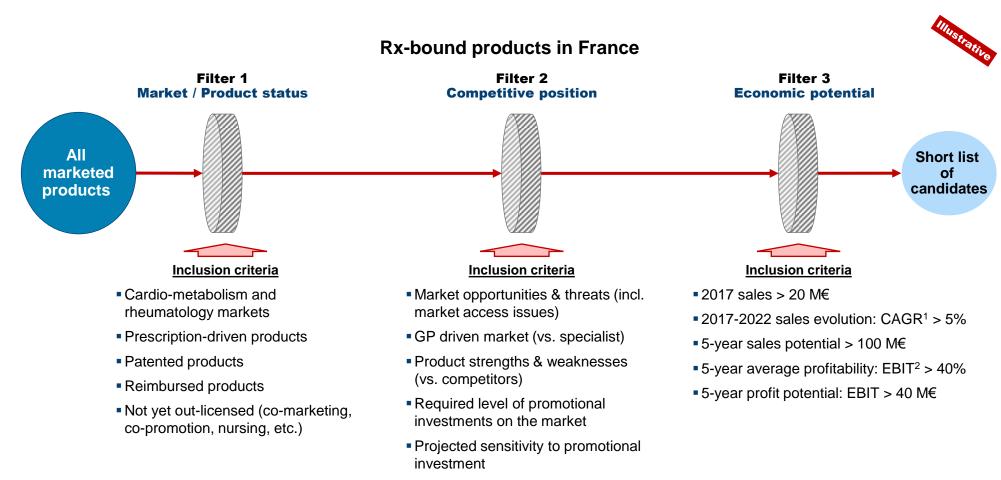
Under-development product screening

Rx-bound products in France Filter 2 Filter 1 Filter 3 **Competitive position Economic potential Market / Product status** AII **Short list** products of under candidates development Inclusion criteria Inclusion criteria Inclusion criteria Cardio-metabolism and rheumatology Market opportunities & threats (incl. Year 1 sales potential > 25 M€ market access issues) markets ■ 5-year sales potential > 200 M€ Prescription-driven products GP driven market (vs. specialist) ■ 5-year average profitability: EBIT¹ > 50% Patented products Product strengths & weaknesses • 5-year profit potential: EBIT > 100 M€ (vs. competitors) Reimbursable products Required level of promotional Development phase: pre-registration or after investments on the market Not yet out-licensed (co-marketing, co- Projected sensitivity to promotional promotion, nursing, etc.) investment

Source: Smart Pharma Consulting ¹ Earnings before interest and taxes

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

Marketed product screening



Source: Smart Pharma Consulting

 1 Compounded annual growth rate $-^{2}$ Earnings before interest and taxes

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

EU status

Registered

Under development products



Molecule	Brand name	Originator	Licensing agreement	Mode of action	Indications	
Vildagliptin	GALVUS	Novartis	No	DPP IV antagonist	Type 2 diab	etes
Saxagliptin	ONGLYZA	BMS	AZ (worldwide) Otsuka (Japan)	DPP IV antagonist	• Type 2 dia	М
Azimilide	STEDICOR	P&G US	Mitsubishi Tanabe- Asia	Potassium channel blocker	Arrhythmia	Ros
Lercanidipine + enalapril	ZANERIL ZANITEK	Recordati	Meda (G), Solvay (Austria	ACEI+ CCB	Hypertens	Pra +
Olmesartan amlodipine	-	Daiichi- Sankyo	TBD	ARAII+CCB	Hypertens	Ez
Tolvaptan	SMASKA	Otsuka	No	Vasopressin 2 antagonist	Coronary failure	lba
Aliskiren	RASILEZ	Novartis	No	Renin inhibitor	Hypertens	El
Prednisone CR	LODOTRA	Nitec & SkyePharma	Merck-Serono	Immuno- depressant	Rheumatc	Hyd
Golimumab	-	Centocor (J&J)	Schering Plough (excl. US)	Anti-TNF alpha	Spondylar Psoriasicr Rheumatc	Mon fu
						Mor

Marketed products

Molecule	Brand name	Originator	Therapeutic class	Sales 2017	CAGR 2017-2022 ¹	Sales 2017-22	Promotional spend (2017)	Profits 2017-22
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€
Ezetimibe	EZETROL	Merck&Co	C10A9	75 M€	12%	75 M€	7 M€	68 M€
Ibandronic acid	BONVIVA	Roche	M05B3	32 M€	15%	32 M€	16 M€	16 M€
Eletriptan	RELPAX	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	101M€	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

Source: Smart Pharma Consulting

¹ Compounded annual growth rate – ² In 2017

"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:	Origina Origina	ator: Therapeutic	class:		
Product a	attributes	SWOT analysis			
Sales 2017 CAGR¹ 12-17 Sales 12 M€ M M		Market Opportunities	Market threats		
Indications Side effects	Status	·	•		
1. 2. 2.	Patent expiry date:% Reimbursement level:%	Product strengths	Product weaknesses		
3.	Price: a: b:	•	•		
	Recommandations	•	•		
Value for the acquirer Value	for the owner	Preferred to	types of deals		
	X GO	X Exclusive marketing license	Co-marketing Co-promotion		
	NO GO	Non exclusive marketing license	Nursing Acquisition		
		Other:			

= medium

5. Conclusion

BD&L opportunities may play a key role in improving pharma companies overall performance (top and bottom lines) while mitigating their business risk

Key I	earnings	(1/2)
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- BD&L refers to strategic relationships or merger & acquisition deals which enable pharma companies to strengthen their competitive position
- BD&L 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 the greatest when opportunities are in businesses similar to that in which pharma companies operate
- 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, especially at affiliate level
- Business opportunity assessment requires to analyze attractiveness / key success factors by strategic segment and pharma companies 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"

Source: Smart Pharma Consulting analyses

5. Conclusion

Business opportunities should be carefully assessed through strategic analyses and with specific processes and tools to maximize the chances of success

· Key learnings (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 pharma companies existing businesses should also be considered
- The proposed "Advanced SWOT" is particularly appropriate to help pharma companies 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, BD&L deals boost sales and profit growth while altering profitability, due to profit sharing agreements and organizational dysfunctions
- Business developers should follow a well-defined process to approach target companies and raise their interest for strategic relationships or M&A opportunities

Source: Smart Pharma Consulting analyses

Smart Pharma Consulting has helped pharma companies and private equity companies assess business opportunities in various therapeutic areas

Experiences & competencies in BD&L and Strategic Due Diligences

- Smart Pharma Consulting has carried out several BD&L and Strategic Due Diligence projects for big and midsized pharma companies or for private equity firms:
 - Pharmaceutical companies such as:

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ALK – Amgen – Chiesi – Esteve – Ethypharm (CMO/Drug delivery company) – IPSEN – NextPharma (CMO) – Nordic Pharma – Polymedic (CMO) – Pierre Fabre – Roche – Schering-Plough – Servier – Synerlab (CMO) – Schwabe – UCB Pharma
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Private equity firms such as:

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Alma Capital – Astorg – Cinven – Exane – Keensight Capital – PAI – Rothschild – Sagard – Weinberg
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In various geographic areas:

Western and Eastern Europe – USA – Latin America – Middle East – Africa

For innovative and generic products belonging to many different therapeutic areas such as:

Oncology – Immunology – Ophthalmology – Allergy – Cardiology – Endocrinology & Diabetes – Pulmonology. etc.

Smart Pharma Consulting has carried out several business development projects & Strategic Due Diligences on numerous international markets

Examples of Business Development Projects & Strategic Due Diligences

- 2017 Value assessment of a new respiratory product in a co-promotion perspective
- 2017 Search of a worldwide pharma partner to market a dermatological product range
- **2016** Screening of target companies involved in the OTC business
- 2015 Evaluation of a "therapeutic" vaccine in HIV on EU5 and US markets
- 2015 Value assessment of a new product in osteoporosis in EU5 markets
- 2015 Preparation of a value dossier for "super-generics" and screening of mid pharma companies for licensing-in agreements
- **2015** Opportunity assessment of products to be acquired or in-licensed at the European level
- 2014 Evaluation of an existing brand in lipodystrophy
- 2014 Evaluation of the potential of a new treatment for psoriasis in the five largest European markets
- 2014 Evaluation of the potential of a new treatment for severe osteoporosis in seven European markets
- 2013 Identification of primary care developing and existing product candidates for the French market
- 2012 Identification of hospital and secondary care developing and existing product candidates for the French market
- 2010 Estimate of the sales potential of an oncology portfolio in: Iran, Iraq, Belorussia and Kazakhstan
- 2008 10-year sales forecasts for a leading anti-diabetic drug in ten countries, including the USA
- 2007 Sales potential estimate for an ophthalmology franchise in four major European countries
- 2007 Sales potential estimates for a biosimilar in six European countries
- 2007 5-year sales forecasts for a range of products in endocrinology in eight European countries
- 2006 Strategic Due Diligence estimating the potential of a 10-product portfolio in Spain, USA, France and UK

Source: Smart Pharma Consulting analyses

Smart Pharma Consulting's ambition is to provide participants with a unique experience during which they will boost their BD&L knowledge and thinking process

Masterclass¹: BD&L best practices

	Day 1
9:00	Introduction (objectives, organization of the day, specific requests from participants)
9:15	Lecture / discussion #1: BD&L objective and basic principles
10:00	Exercise #1 in plenary session: Would BD&L deals make sense at your affiliate / region level? And why?
10:40	Break
11:00	Exercise #2 in working groups: Draw the list of relevant information to be collected to evaluate BD&L opportunities, the corresponding sources and their level of reliability
11:50	Debrief of the exercise #2 and key takeaways
13:00	Lunch
14:00	Lecture & discussion #2: Market, product and company data analyses: best practices
15:00	Case study #1: Opportunity assessment
	 Group A: Rx-driven product
	Group B: OTC product
	 Group C: Medical device
16:15	Break
16:30	Debrief of the case study #1 and key takeaways
17:30	Conclusions of the day
17:45	End of the session

	Day 2
9:00	Lecture & discussion #3: Method and Tools to select most attractive opportunities (charts, ID cards, valuation techniques)
9:40	Case study #2: Best candidate(s) selection
	Groups A – B & C
11:00	Break
11:15	Debrief of the case study #2 and key takeaways
12:15	Lecture & discussion #4: Definition of the best deal structure (e.g. in-licensing, JV, acquisition)
12:35	Case study #3 in plenary session: Which deal structure to favor according to the situation?
13:00	Lunch
14:00	Lecture & discussion #5: How to approach and negotiate a BD&L opportunity?
14:45	Case study #4: Approach & Negotiation
	Groups A – B & C
15:45	Break
16:00	Debrief of the case study #4 and key takeaways
16:45	Lecture & discussion #6: Alliance management best practices
17:15	Conclusions of the session
17:45	End of the session

¹ Inter-company programs proposed both in English and in French. Smart Pharma Consulting proposes also ad hoc programs

November 2017

Smart Pharma Consulting proposes a 5-day seminar for high potential and seasoned marketers who want to reinforce their strategic and operational marketing skills

Seminar: Pharma Strategy & Marketing¹ -

Day 1: Strategic thinking applied to companies

- Worldwide Pharma and Biotech sectors
- Evolution of the Pharma business model by 2020
- Strategic management of pharma companies

Day 2: Marketing strategic thinking

- Optimization of brand value: Brand Preference Mix, etc.
- Dynamic prescribers segmentation: Behavioral Prescribers Segmentation (BPS) approach
- Sales forecasting and performance objectives setting
- Brand Planning: Advanced SWOT, Strategy Card, etc.

Day 3: Marketing tactical thinking

- Digital marketing and multi-channel approach
- Promotional resource allocation
- Definition of Key Execution Indicators (KEIs) and Key Performance Indicators (KPIs)
- Integration of new marketing tools: Integrated Promotional Strategy (IPS) approach

Day 4: Specialized market segment analysis

- Marketing of generics and biosimilar products
- Marketing of OTC products and Rx-to-OTC switches
- Management of mature products
- Marketing of niche and hospital products

Day 5: Development of managerial skills

- Sales force effectiveness
- Team leadership
- Corporate behavior
- Communication principles

Target Audience

- Marketing executive (e.g. marketing managers, group product managers, product managers)
- Market research executives
- BD&L managers

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- Strategic planners
- Medical executives (e.g. MSLs, medical managers)
- Sales forces executives (e.g. sales force managers, area managers)

Smart Pharma Consulting

¹ Inter-company program proposed both in English and in French. Since 2005, 137 experienced executives from 36 pharma companies have attended this seminar



Consulting firm dedicated to the pharmaceutical sector operating in the complementary domains of strategy, management and organization

The Best-in-Class Series

- This series intends to share concepts, methods and tools to boost the efficiency and efficacy of executives having operational responsibilities in the pharma business
- We have yet published three Best-in-Class issues:
 - The Medical Science Liaisons
 - The Pharma Marketers
 - The Medical Reps
 - The Hospital KAMs

Issue #5: Best-in-Class Pharma BD&L

- More than ever, BD&L (business development and licensing) operations have become a strategic lever to ensure longterm sustainability and performance of pharma companies
- However, BD&L activities are complex and require a high degree of expertise and experience
- This new booklet presents key concepts, methods and tools that we apply when we help pharma companies improve their BD&L excellence in the context of consulting projects or training courses

Smart Pharma Consulting Editions



- Besides our consulting activities which take 85% of our time, we are strongly engaged in sharing our knowledge and thoughts through:
 - Our teaching and training activities
 - The publication of articles, booklets, books and expert reports
- As of today, more than 100 publications in free access can be downloaded from our website
- In 2016, we have published more than 770 pages of documents covering Pharma market insights, strategic and marketing expert reports, as well as management concepts, methods and tools
- Our research activities in pharma business management and our consulting activities have shown to be highly synergistic
- We expect that this new publication will interest you and we remain at your disposal to carry out consulting projects or training seminars to help you improve your BD&L excellence Best regards

Jean-Michel Peny