

Understanding the Business Development Opportunity in Healthcare / Life Science

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Introduction

What do we mean and understand by the term, business development?

- General Definitions
- Business development (BD) comprises a number of tasks and processes generally aiming at developing and implementing growth opportunities between (multiple) organizations.
- It is a subset of the fields of business, commerce, and *organizational* theory. It fundamentally requires and involves all the sections that make up a business.
- Business development is the creation of long-term value for an organization from customers, markets, and relationships.

Is business development different for the Healthcare and Life Science sectors?

- For larger and well-established companies in healthcare-related industries, the term 'business development' often refers to setting up and managing *strategic relationships* and alliances with other, third-party companies.
- The companies may leverage each others' expertise, technologies or intellectual property to expand their capacities for identifying, researching, analyzing and bringing to market new businesses and new products.
- Business-development focuses on implementation of the strategic business plan through, e.g. equity financing, acquisition/divestiture of technologies, products, and companies, plus the establishment of strategic partnerships where appropriate.

Business Development for biotech & health sector start-ups & SMEs

- For biotech and other health sector start-ups & SMEs, without Business Development, there is no company...
- It is not only a matter of development and growth, but of survival.
- Therefore it is strategically essential and should be prioritized accordingly.
- BD is important and must be taken seriously, but it is not rocket-science. A simple approach is known as TDS:
 - **{Target Identification} + {Understanding of Drivers} + {Solution to Drivers} = BD Success**

Agua vitae...



Getting Started

- The science is fundamental, without it none of us we be here and there would be nothing to develop, but the business model does not start with the science, it starts with the customer. Without a customer there is no business model:
 - What is the market need? *If there is no market need, there is no business....*
 - How does your product, technology or service fill this market need
 - How is it better, what is its USP in relation not only to other products already on the market but also those in the pipeline?
 - Do you have IP to protect your technology and the Freedom to Operate to bring it to market?
 - Is there a customer willing to pay for it?

Market Need

- Very simply, what market are you addressing? Don't spend too much time on this in presentations, any VC or potential industry partner you present too will understand the size of the market for say CVD or Alzheimer's. You do however need to demonstrate that you understand the market you are targeting, and that there is indeed a real market need.
- How does your product, technology or service fill this market need: Basically what is your approach, and more importantly, how is it better; what is its USP (*versus solutions on the market, current standard of care, in pipeline, etc.*).

Intellectual Property & FTO

- Outside of the scope of this presentation except to note that if you do not have both sufficient IP to protect your approach and the Freedom to Operate to enable you to bring it to market, your options become very limited.

(unless for example you can do a licensing or cross-licensing agreement to secure FTO, or out-license your IP to the holder of the blocking patent, etc.). So do your due diligence and a thorough prior art and FTO search.

Your Customer

- Who is your customer? Most biotech companies will never bring a product to market themselves, so while the patient may be the end user, consumer or beneficiary, your “core customers” are the pharma, large biotech or device companies that might bring the product or technology to market.

Do your research!

- Market Landscape: Which pharma/biotech/health companies are the most likely core customers?
 - What exactly are they looking for? Not just “oncology,” but more general approach to, or biological area of, activity, stage, etc.

Learn as much as possible about your customer and then present a solution for one of their core drivers (**TDS**).



Your Customer cont.

- What exactly are they looking for? Not just “oncology,” but more general approach to, or biological area of, activity, stage, etc.

How?

- Check their websites (areas of interest, portfolio, deals)
- See their presentations (and ask questions)
- Engage early and learn while building relationships
- Not just indications/technologies, but are they wedded to competitive approaches, are they over exposed in a given space, how high is their need?

Relationships: Engage early & listen

- Business development is not just about the deal. Strategic business development starts early to build relationships, develop trust and organizational/cultural understanding, and learn exactly:
 - What your customer wants
 - At what inflection point
 - What is the development path they want to see, and why?
- Don't wait: you should be engaging actively well before the point at which you expect/need a deal.

Development Path

- **Development Strategy: Don't just guess!**
 - Must be informed not just by your own scientific and clinical teams plus KOLs, but also by what industry wants/needs in order to do a deal.
 - The Delta between where you are, and where you need to be to potentially real a deal with your customer, informs the required development path, as well as your overall strategy, financing needs and use of funds.
 - Do not do all the work (and burn your capital) and then show up to have industry tell you “that’s nice but it isn’t really what we need”.

Other Partners

- When you cannot (yet) do a good deal directly with a core *customer (or do not want to)*, who are your other potential partners/customers? e.g.
 - Sources of Funding (Angels, VC, CV, PE, Public funding)
 - Patient groups, charities, foundations, philanthropy
 - Academic institutions, TTOs
 - CROs, development companies
 - Pharma/biotech in non-core markets (ex US/EU: Japan, BRICS, etc.). Can provide revenue & “validation” without overly diluting core value.
- How do you prioritize?
 - Which customer is the best developmental fit and will support the most?
 - Which customer will be the easiest to reach?
 - Why do they need or want your product or service? Mutual benefit?

Resources

- Ex pharma & biotech executives, advisors & consultants
 - Notes:
 - Be clear what they can and cannot do. Many oversell. Some can open doors; others cannot. Some can advise on deal structure, others cannot. In all cases the CEO needs to directly understand the customer.
 - Do not over pay or underpay. Mix of cash and mutual risk share to ensure motivation and alignment with the company's objectives.
 - Possibility of board or advisory roles rather than pure consultancy.
 - Coaching/Mentoring via, e.g. FFH2 and similar European and national initiatives.

Core

- Understand your market
- Identify your customers(s)
- Establish your business *strategy* THEN seek the best fit...
- Ensure IP and FTO to enable strategy
- Engage, listen and adapt if needed (development path, financing & partnering strategy to cover delta to a deal)
- Be creative, find ways to get there
- Don't ever be tempted to try to fit an non-optimum target/platform/product/licence into the wrong space.

Deal Considerations

Licensors

- Need to raise funds
- Share cost of drug development
- Access to expertise and capabilities
- Cultural fit with licensee?
- Retention of control
- Agree press release etc
- Divest mature products for income
- Boost income by licensing marketed products

Licensee

- Determine ideal stage in lifecycle : Proof of Concept (PoC) or early stage, phase I-III, product portfolio licence
- Territorial fit
- Portfolio fit/filling pipeline holes
- Understand your own core –and realistic - competencies
- Make sure price is right
- Differentiate offering from competitor licensees
- Cultural fit with licensor?

General considerations:

Identify a range of suitable deals

- Critical to accept that this is a business of attrition, in a changing market
- Be transparent on licensing needs whilst ‘selling the opportunity’

IP due diligence

- Not just “do I own” but “can I use” ...
- **Freedom to Operate**
- Be prepared for the due diligence process, i.e. ensure you provide ALL information. Missing info can imply bad faith and kill the trust crucial to a deal.

Put together the ‘right’ team with sufficient resource.



Financial considerations:

- Valuation of IP is a challenge but there is enough material out there to create 'ball park figure'
- *Reduce ball park by at least 1/3 (or more!)
- Don't be greedy
- Don't 'over-egg' milestones
- Consider the priorities, i.e. upfront payments / milestones *versus* back-end
- Weight back-end potential, i.e. royalties but again be realistic...

Initiating the so-called *Roadmap* ... the business development plan.

- Consider the 'bedrock' – the potential 'pipeline' of opportunity. A pipeline refers to flow of potential clients which a company has started developing. **Networking** (early strategic business/relationship development)
- Resources: Fiscal and Personnel. Funding and its appropriate allocation
- Identify and understand rate limiting steps
- Use all available expertise (Really. Make your own decisions but get the input!)
- Subsequently develop plan to the next level, e.g. licensee with localised outposts internationally for sales (if appropriate) etc...
- **Manage expectations... and the relationships**

2. Flexibility

Or go with the flow...

Be prepared

- React to due diligence outcomes
- Look at the bigger picture
- There is never a necessity 'to do the deal we always do'... there are other opportunities out there
- Take some risks

Scope

- Determine and consider what the licensee really needs, e.g. an indication-specific licence? Exclusivity?
- The offer won't always be acceptable to the licensee even if its only intended to develop a product for a single indication. Be flexible...
- Consider development or sublicense clauses...

Territory (coverage)

- Even 'Big Pharma' do deals with each other, e.g. distribution. Few companies have genuine *global* marketing strength. Consider your *core competencies* thoroughly.
- Don't look to reinvent the wheel – factor in cost *versus* benefit etc.
- Consider deals for treatments / therapies that have major market need outside of the western world.
- Consider regional deals for Japan, Latin America, Russia, Eastern Europe etc. (*bring revenues without overly compromising value*)

Market development

- What is the size of the market?
- Does it require a large-scale marketing effort? (Preferred licensee?)
- Should revenues be shared in proportion to marketing spend?
- Alternatives: limit number of sales reps, share revenues after deducting marketing costs etc.
- Retaining some co-promotion rights is usually of interest to a Biotech and often helps to secure any deal...

Equity vs. Upfront & Milestone payments

Pharma

- Would prefer to have an asset to backend / royalties etc. Otherwise the deal is often considered too high a price to pay
- 'Positive' PR

Biotech

- Wants and needs(?) validation, e.g. to source further VC funding
- No obligation to reimburse if it all goes wrong.

Advantage of licensing to Big Pharma?

- Validation... Perceived 'rubber stamping' of the project / product within the industry sector
- Potentially critical if it's a General Practice / OTC product... market penetration requires a large sales force
- High(er) standard of product development, which should not necessarily be confused with fast(er) development

Advantage of licensing to Biotech SME / CRO?

- Ability to be more focused and move faster (again not always) on a specific project
- Less politics = faster decisions and greater transparency?
- Potential to retain some additional rights to licensor, e.g. permitting increased revenue generation / higher 'sell'. Obviously this is attractive to the licensor

Potential (and common) pitfalls.

- Poor understanding of market. Poor analyses. Poor utilisation of funds. Poor allocation of personnel (HR).
- Failure to understand 'bedrock' of business... will result in an inevitable poor return on expectations.
- Failure to fully understand and explain technical capability and opportunity.
- Failure to attract interested third parties and fully understand their needs.
- Failure to properly facilitate the creation of a critical mass of intellectual innovation and manage the IPR...
- Interest from **multinationals** will not materialise if there is not an environment that is conducive to creating collaborative mutual benefit and innovation.

Summary

- Critical understanding: i) know your favoured deal ii) be willing to negotiate.
- What flexibility is there in the value proposition?
- Piquing interest is great, but being flexible demonstrates a willingness to *maintain* interest and get the job done.
- Consider timeliness in closing the deal.
- Manage expectations – theirs and yours.
- Other considerations, e.g. press release, training, future product development, R&D funding, territory issues etc.

3. Realism

As opposed to romanticism...

Evolution of the biotech sector *per se* and business development in particular.

- New models are materialising out of necessity; both for VC and Pharma. BD is increasingly important and needs to be better focused...
- BD funding on the premise of potential alone is unlikely. Hard data is required. Proof of Concept (PoC), Phase 1 data etc.
- Pharma co-development funding will likely offer bare minimum in majority of cases, e.g. small upfront payments & milestones. Back-end to pay out.
- Pharma need innovation and are developing communication with academia, start-ups, Centers of Excellence etc to (re)build early stage relationships...
- Strategic Collaborations more sought after.

Business development checklist cont.

2. Operations and know-how – the “latter” issues*

- How will the product / service be produced? Manufacturing considerations (and quality control)*
- How will it be delivered?*
- How will the product be serviced and managed? Additional quality control considerations*
- How much is the product / service? Will pricing be staggered to size of customer etc?*
- Understanding the IP position implicitly, e.g. what license strategy has the company agreed?
- How flexible can you be regarding cost / licensing strategy?

Financial reality...

- Even though the sector is buoyant it remains very challenging to raise PE VC finance. Any finance! Always consider the financial markets in general. This example is 3 years old now but still very apt, especially as the capital markets are in deceleration ...
- Total PE VC raise in USA was \$3 *Trillion* in 2013.
- Biotech / healthcare accounted for \$4 Billion of that...
- Early stage? only \$250-300 Million.
- Majority of investment had moved 'downstream' i.e. later stage because of the lower risk.
- However, it is not all doom and gloom as funds for early-stage innovation have been reappearing...

Financial reality cont.

- Biotech finance in all its forms is continuing to change. Consider what is *being* financed? “Immuno” “Telehealth” “Diagnostic / biomarkers” etc.
- Pharma companies no longer have deep pockets unless you have a *game changer*. They increasingly recognise that they have developmental expertise and, e.g. databases / tools and that innovation is increasingly better achieved out-of-house...
- Having some data and a patent no longer means they will “come”.
- Key now are reimbursement and payor issues... Who will pay for your product? What is the true market potential?
- **Can you use H2020 funding to get to an inflection point...**
- *Collaborative and strategic* business development is critical.

Challenges.

- What are the potential risks in development? What is, and who are, the competition?
- Evolution – what additional growth has been contemplated? Horizontal and vertical markets.
- What other markets are there? Market change? Have new market analyses been undertaken...
- How will you measure current partner satisfaction? What more can you offer?
- What *other* core competencies can you leverage within the company?

Challenges cont.

- What have you learnt? What works? What do you need to grow further?
- What are your core competencies now? Who are your core customers? What more can you develop with and for them?
- If you were offered an increased BD budget of \$1MM, how and on what would you allocate it to further develop and increase business?
- What are your rate limiting steps and are you aware of them? What is preventing you achieving your business development plan?
- Failure to manage expectations and relationships is critical.

Model considerations

- There has been a lot of discussion of appropriate models over the years. From the “Integrated Company” model and the €1M per Employee valuation model (forget it 😊), to the purely virtual project/product development company.
- Frankly, preferred models are driven more by VC investors than by industry, who focus on what you have to offer them more than the model of the company.
- To some extent, investors have opinions on this, but they generally focus on ensuring that the core competencies are retained within the company (possibly geographically or otherwise close to the investors) and less crucial aspects are outsourced or partnered to ensure maximum expertise and minimal cost.
- What are your core competencies relative to your market, customer & development strategy?

Model considerations cont.

- From a strategic perspective (informed by BD), your model should be determined by your development strategy, which is determined by
 - 1. Where you are now
 - 2. What inflection point you need to reach to do a deal(s) with your customer(s),
 - 3. The most efficient structure, allocation of resources and use of funds needed to bridge that delta and get there.
- Examples (Drug Development, Digital Health, Services, Live Cell, Platform Technology)

Coda

- Brave new world which requires a better understanding of the **Core Competencies** of each stakeholder group
- Take the opportunity to learn from past industry histories and people, and harness core competencies and skills
- Innovative thought is the 'easy bit', the hard bit is commercialising it...
- Network, collaborate, network again, strategically position yourself and develop. And continue developing...
- **Manage the expectations and the relationship!**