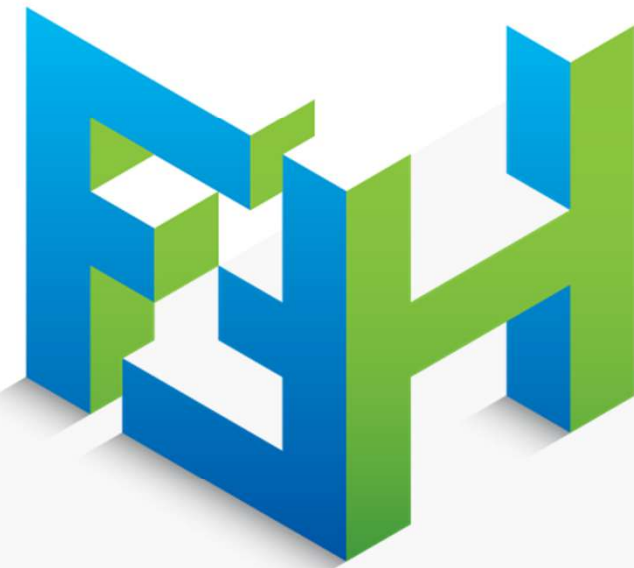


Fit for Health 2.0

Support to SMEs & Researchers in FP7 and Horizon 2020 health-oriented projects

Understanding the Business Development Opportunity in Biotechnology



www.fitforhealth.eu

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Introduction



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

- General Definitions (*wiki etc.*)
- 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 in the Biotech sector?

- 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 other's 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 bio 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, and that you are realistic about this.
- 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 approach 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 approach or biological area of activity, stage, etc.
 - Identify them
 - Meet them!
 - 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.
 - How?

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

- Plan B (C, D, E...) 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 like H2020 & SME Instrument)
 - 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? Mu
 - **FOCUS! Do they help get you where you need to be?**

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 under pay. Mix of cash and mutual risk share to ensure motivation and alignment with the company's objectives. Burn on the one hand, peanuts/monkeys on the other.
- Possibility of board or advisory roles rather than pure consultancy.
- Coaching/Mentoring via FFH2 and similar European and national initiatives.
- **COME TO THE TTS EUROPE IN 2 WEEKS!**

Core



- Understand your market
- Identify your customers(s)
- Establish your business *strategy* and 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.
- Don't do anything that takes you off your critical development path unless you have absolutely no choice. And create the choice!

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 while ‘selling the opportunity’

IP due diligence for the business case

- 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.

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...

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*)

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 (unless it is something they really want!)
- 'Positive' PR

Biotech

- Wants and needs(?) validation, e.g. to source further VC funding
- No obligation to reimburse if it all goes wrong.
- Higher royalties (back-end) mean more money, if the product gets to the market
- Can you get to the market, or survive, without a higher up-front? If not, trade off with royalties.

Advantage of licensing to Big Pharma?

- Validation... Perceived validation or '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

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.

Company Models



- 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 (Digital Health, Device, Diagnostic, Services, Live Cell, Platform Technology)

3. Realism

As opposed to romanticism...

Facing reality

- Pharma companies no longer have deep pockets unless you have a *game changer*. They do however increasingly recognize 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? Do your “pre-business development” and make sure your strategy is informed.
- *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.

- BASED ON ENGAGEMENT
- 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? Why? What will this achieve?
- 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.

RELATIONSHIPS

- Invest in your relationships
- LISTEN to your partners. What do they really want and really need?
- Their concerns? What are they most worried about? Address these (don't argue, help them overcome these concerns by providing real solutions or ways forward).
- Track Record: Build a track record and show consistent ability to deliver.
- Honor your commitments! Even the small ones.
- Follow up! Respond effectively.
- Demonstrate that you are a good partner they can

Coda



- Brave new world which requires a better understanding of the **Core Competencies and needs** of each stakeholder group
- Take the opportunity to learn from 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**

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Thank You

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