

# Understanding the Business Development Opportunity in Healthcare / Life Science

FFH2.0 – Prague, Czech Republic.  
10 May, 2017.

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# *Introduction...*

*“Technology transfer opportunities  
in healthcare / life science”*

# What do we understand by the term, technology transfer?

- Assignment of technological intellectual property, developed and generated in one place, to another through legal means such as technology licensing or franchising.
- Process of converting scientific and technological advances into marketable goods or services.
- In order to successfully develop technology transfer of a product, it must be ensured that the technology underlying the invention is appropriately protected e.g. Intellectual Property provisions. These can involve patents, trade marks, design rights and database rights as well as the non-registerable rights of copyright and know how.
- Ultimately it provides a good framework for assessing whether the technology developed during “research” has the potential to form the basis of a spin-out company.

# Is the technology suitable?

- Does the opportunity match your experience, skills and interests and do you have a sense of urgency to exploit the opportunity?
- Can you recruit and lead the team needed to exploit the opportunity? If you cannot, are you willing to accept external management input?
- Do the opportunity's resource needs (time, money, effort) shorten the odds of success?
- Is the timing of the opportunity right?
- Does the opportunity constitute a scaleable (and ultimately saleable) business?
- Does the opportunity offer good margin potential?
- Are you developing an opportunity or an idea?

# Licensing technologies?

- If licensing is chosen, the TTO will work with the inventors to identify potential licensees and lead the negotiations with the licensing partner.
- If spin-out is the preferred route, commercialisation usually begins with more detailed market assessment activities and the preparation of a business plan.
- If the business plan confirms that a spin-out company is a feasible proposition, then the technology transfer team works with the inventors and external advisors to raise funds and recruit a management team with skills and experience capable of exploiting the opportunity.

# Creating a spin-out company?

- Creating a spin-out company around a technology has the potential to generate significant wealth as a large share of any profits made are retained by the company, with the inventors being shareholders in that company.
- Creating a spin-out may also be an appropriate commercialisation route when there is a need to develop a technology further to extract its commercial value or when the team surrounding the technology are strongly entrepreneurial.

# Translating technology...?

- Translational research applies findings from basic science to enhance human health and well-being.
- In a medical research context, it aims to "translate" findings in fundamental research into medical practice and **meaningful health outcomes**.
- Translational research implements a "bench-to-bedside", from laboratory experiments through clinical trials to point-of-care patient applications, model, harnessing knowledge from basic sciences to produce new drugs, devices, and treatment options for patients.
- The end point of translational research is the production of a promising new treatment that can be used with practical applications, that can then be used clinically or are able to be commercialized.
- *You will need partners...*

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

- In healthcare-related industries, the term ‘business development’ often refers to setting up and managing *strategic relationships* and alliances with other, third-party companies.
- 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...



# Creating and implementing the business plan

- 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 understanding the business plan. Then you can source a 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?

# It's not only what you know, it's who you know, i.e. referral

- In any given year, a venture capitalist (VC) will see as many as 500 business deal opportunities, which is approximately 2 every working day.
- Whilst looking at your potential deal the VC will be working on due diligence for new deals, and actively participating in the business of the firm's existing portfolio companies. If they're not, then they are loosely termed as **dumb money**.
- You want **smart money**, i.e. expertise and active involvement not just investment. Other miscellaneous things in any given week will include attending board meetings; working with existing portfolio company's management; investor relations and preparing to raise, or raising, their next fund.
- Be clear and concise, be precise, have an *Executive Summary*.
- In summary, find a way to get a referral.

# The Executive Summary

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- How long do you think the VC / industry partner will spend on your proposition? Your immediate point of contact, i.e. your referral (if you have one) has put you in front of X and whilst he or she may read the full business plan (we can hope) it is more likely that senior colleagues will only skim-read the *Executive Summary*.
- As with a *curriculum vitae* you need to consider impact carefully. It is the key that unlocks the door to more in-depth discussions.
- The business plan must not be laborious to read – it must be concise and precise. Anything less will be considered as waffle and will dilute your chances of the invention on offer being viewed favorably.
- The Executive Summary is the “key”. The full business plan serves to support in greater detail the material with which the executive team will make a decision.

# Market need and *financial* modelling

- Very simply, what market are you addressing?
- Do not spend too much time on this in presentations. A potential partner (VC or industry) will understand the size of the market for, e.g. Alzheimer's. You do however need to demonstrate that you understand the market you are targeting, and that there is a real market need.
- What changes do you foresee? What milestones have you considered? What are your costs liable to be? Who are your paying customers? Who will reimburse you? How long before you reach profit? Ever?
- 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 Unique Selling Point (USP), i.e. versus solutions on the market, current standard of care, in pipeline, etc.

# Market need and *financial* modelling cont.

- How are you going to raise money throughout the course of your development? The VC / industry partner will need to see realistic financial projections.
- It is expected that you will have compared your financials to a comparable company, in a comparable sector, in a comparable market (use existing financial information in, e.g. Customs House for the UK, Googling etc). Such financial modeling and forecasting is essential.
- If you don't have all these factors covered... you don't have a business opportunity.
- Having a business plan, a great idea and a market opportunity is not the same as having a business - emphatically not.

# Continued Momentum

- So you've done the presentation and the potential partner declares "excellent presentation! Excellent business plan! What have you achieved since you first approached us with this business plan?"
- They want to know that you're multitasking and that while you're raising money, you're still conducting research / collaborative / licensing agreements etc. What new breakthroughs have been made? Who is showing interest now? What new partnership deals and / or collaborative proposals have you been made? News articles? Positive PR? Recent reports by research analysts can help validate further the business opportunity and build confidence in the management team.
- Consider that "the more arrows you have in your quiver, the greater the opportunity of hitting a bulls-eye".

# 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.*



# The Partner

- Who is your customer (partner!)? 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 partners” are pharma, large biotech or device companies that might bring the product or technology to market. Do your research.
- Finance – VCs are your potential partners first, investors *second*.
- Market Landscape: Which companies are the most likely core customers?
  - What exactly are they looking for? Not just “oncology,” but a more specific approach, biological area of activity, stage, etc.

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

## Your Partner: **\*\*A highlight\*\***

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

# Competitive advantage

- What about bigger players? Not just the multinational companies but other SMEs?
- Is your immediate business focus sustainable? Consider carefully that the large multinationals are probably already aware of you if you have something interesting; they have football pitches of patent analysts searching for competing products in their sectors or simply new products in new areas.
- Unfortunately many innovators fail to consider that these 'big' i.e. established companies usually have cash reserves, patent portfolios (blocking patents), research programs (temporarily shelved and / or ongoing), established distribution networks, and collaborative relationships that can swiftly kill off any competitive advantage that is not properly protected.
- Innovators need to consider how they will defend and indeed police their innovation. This is a key area of business strategy.

# 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
  - What inflection points are their drivers...
  - 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!**
  - This must be informed, i.e. not just by your own scientific and clinical teams. Find KOLs, but also align with what industry wants/needs in order to do a deal.
  - The Delta between where you are, and where you need to be, to potentially realise 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 Potential Partners

- When you cannot (*yet*) do a good deal directly with, e.g. a core corporate partner (*or do not want to*), who are your other potential partners?
  - 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 (Japan, BRICS, etc.). Can provide revenue and “validation” without overly diluting core value?
- How do you prioritize?
  - Which customer is the best developmental fit and will support your technology / development the most?
  - Which customer will be the easiest to reach?
  - Why do they need or want your product or service? Mutual benefit?

# “Informed” Resources

- Ex-pharma & biotech executives, advisors & consultants
  - 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 FFH2 and similar European and national initiatives.

# Core considerations

- Understand your market
- Understand your competitors; what is your advantage?
- Identify your partner(s)
- Establish your business plan, then agree your business *strategy* ... THEN seek the best fit.
- Ensure IP and FTO are in place to enable business strategy
- Engage, listen and adapt if needed (development path, financing and partnering strategy to cover *Delta* to a deal)
- Be creative - engineer referral etc.
- Be concise, be precise.
- Don't ever be tempted to try to fit an non-optimum target/platform/product/licence into the wrong space.



# *Deal Considerations*

# You – The “Company” / Licensors

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

# “Fit” with the partner / VC / Licensee

- Determine ideal stage in lifecycle: Proof of Concept (PoC) or early stage, phase I-III, product portfolio licence etc.
- Territorial fit
- Portfolio fit / filling pipeline holes
- Understand your own core - and realistic - competencies
- Make sure the price is right
- Differentiate offering from competitors
- Is there a cultural “fit”?

# 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.

**Manage the expectations... and the relationships!**

# Financial considerations

- Valuation of IP is a challenge but there is enough material out there to create 'ball park figure'
- \*Reduce ball park figure by 1/3 (or more!)
- Don't be greedy
- Unbelievably most potential partners are well aware that the likelihood of any deal is failure. VCs included...
- Be clear about what your achievable milestones are – **do not** 'over-egg' them...
- Consider the priorities, i.e. upfront payments / milestones *versus* back-end
- Weight back-end potential, i.e. royalties but again be realistic...

# Flexibility

*Or go with the flow...*

# Be prepared

- React to due diligence outcomes. Positive and negative. There will be a lot of negative outcomes. Learn from them.
- Adapt. You will make mistakes. You will not be able to answer all the questions – be honest. Don't bullshit.
- Look at the bigger picture of what others, e.g. advisors etc. tell you.
- Be flexible. If you hear “this is the deal we always do” ... STOP! Question that. Why? i.e. don't be bullied into accepting any sub-standard deal that will bite you on *la petit derriere* later.
- Don't ever be in a hurry. Take advice.
- Take some risks.

# Fit

- You'd think this was obvious but it is often overlooked. Don't waste time on the wrong type of partners / investors. Billion dollar funds that invest late stage are very unlikely to be interested in an early stage opportunity.
- Consider too that there is a reason VCs choose to invest in sector-specific areas; it is because they have the necessary expertise to do so.
- In addition don't send your biotech business plan to, e.g. a VC firm that specializes in Gaming Technology.
- Equally with Big Pharma or indeed Biotech– always take care in sending pitches to a “like-minded” partner.
- Fundamentally, don't waste any potential partners' time or indeed yours. Think clearly – remember that potential partners see multiple opportunities in a working day. Research your market to thoroughly include a set of *suitable* potential partners.



# Scope

- Determine and consider what the potential partner 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...

# Equity vs. Upfront & Milestone payments

## Pharma

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

## Biotech

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

# Advantage of partnering with 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

# 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.

# 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 well focused.
- Funding on the premise of potential alone is unlikely. Hard data is required. Proof of Concept (PoC) will only be enough in *exceptional circumstances*... unmet medical need.
- For therapeutics *per se*, Phase I data is increasingly critical, sometimes even Phase IIa.
- 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 sought after in areas of “difficult” expensive and high rate of attrition research...

# Models

- From a strategic perspective (informed), your business model should be determined by your development strategy, which is determined by:
  - Where are you now?
  - What inflection point do you need to reach to do deal(s) with your preferred partner?
  - What is the most efficient structure, allocation of resources and use of funds needed to bridge that *Delta* to achieve that goal?



# Financial reality

- 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 issues 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 the critical inflection point(s)...**
- *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.

# Presentability

- Be smart. Be presentable. Be courteous.
- Be concise. Be precise.
- Be fully prepared. You will make mistakes.
- Do not bombard your potential investors for feedback after a meeting.
- Think like a businessperson because alongside the innovation, the idea *per se*, fundamentally what your potential partner is investing in, is you. Investors need to see commitment and believe in a committed driver of the business.
- Clean your shoes! ;-)

# Coda

- What are your core competencies relative to your market, customer & development strategy?
- Take the opportunity to learn from past industry histories and people and use expertise and skills – informed expertise.
- Innovative research is the “easy bit”, the hard part is commercialising it...
- Network, collaborate, network again, strategically position yourself and develop. And continue developing...
- **Manage the expectations and the relationship**