



Building a Successful Business Development & Licensing Strategy

By Carlos N. Velez

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Before embarking on a business development process, it's important to consider that in-licensing and out-licensing has become more important for companies of all sizes and the atmosphere for attractive assets has become increasingly competitive. However, business development and licensing officials cannot go into "licensing mode" via partnering conferences blindly. It's important to have a good strategic framework for business development before any members of the company attempt to execute an in- or out-licensing plan.

This white paper discusses several topics to consider before investing in, planning, and executing a business development initiative.

Talk about Strategy

Mastering the Merger by David Harding and Sam Rovit speaks about a number of topics, but this insightful book touches on an important aspect when seen through a business development lens.

"Making mergers (business development and licensing) work is inseparable from strategy ... your corporate strategy must begin to guide your acquisitions (BD&L) long before they fully take shape."

Essentially, licensing executives have to understand the company's value and future plans before going through business development processes. There should be a meeting at the senior-most level in an organization where the following questions should be addressed.

- What is the company's vision and mission?
- What are the company's competencies?
- What are the company's incompetencies?
- How can business development fill the gaps?

The answers to these questions could have critical implications on a company's future and should be answered before executing a business development initiative.

In addition to the key questions, here is a group of secondary questions that should be addressed:

- What are the specific goals coming out of business development?
- What is the company's vision and mission?
- What are some must haves?
- How flexible are we?
- Can we pivot from one therapeutic category to another?
- Are we being realistic?
- Do we have the courage to capitalize on failure?

Having the answers to these questions will not only benefit the company's vision, but allow the business development team to make decisions and plans based on realistic goals.

Deal Makers and Breakers

After all these questions are answered, there should be a clear vision for the company, which will help members of the BD&L team make decisions efficiently on the road. For every licensing situation, there needs to be "must have," "nice to have" and "automatic no-go" criteria.

Must Have

This criteria is what a potential client or licensee must have in order for a project to move forward. These could be anything from data from a late phase of clinical development, or new patents.

Nice to Have

The criteria in this category is extra value you would like, but is not necessary to make or break a deal. For example, a company might want the global rights to sell because some companies want to be able to sublicense. However, this is not important to every company.

Automatic No Go

These are the deal breakers. If an asset doesn't have the type of data or information you need, or is not far enough in the process, you do not consider the project.

There are no right or wrong answers to these. These criteria stem from internal discussions and are filtered to the business development teams that make tactical plans.

Ask the tough questions, define a strategy, and organize the overall business development and licensing strategy before executing.

Telling a Story

Making a presentation is part of the process in many meetings. However, many presentations tend to be convoluted and don't tell a story to draw people in. Many presentations are also overly technical and complex – good for some audiences, but not the first one you are going to see.

You have to consider the audience. If this is the first meeting, don't give a presentation full of technical jargon, but instead provide insightful information to draw an audience into a deeper conversation.

Consider these when putting together a story:

- The presentation should be driven by market data, especially the financial opportunity for the other party, not the science or technical information. Technical information can wait until you're in front of the right audience further down the process.
- Use external independent data. Have external validation with support for statements you are making.
- Recognize current and future therapeutic alternatives. This information should be included and shows you have done your homework.
- Illustrate flaws, risks and uncertainties up front. For example, if there is regulatory issue, address it earlier than later. You don't want to surprise someone down the road.

Geography

Conferences are a key component to making business contacts and a great way to expand the geographic reach of the business development process. However, it's not the only way to find potential clients or licensees.

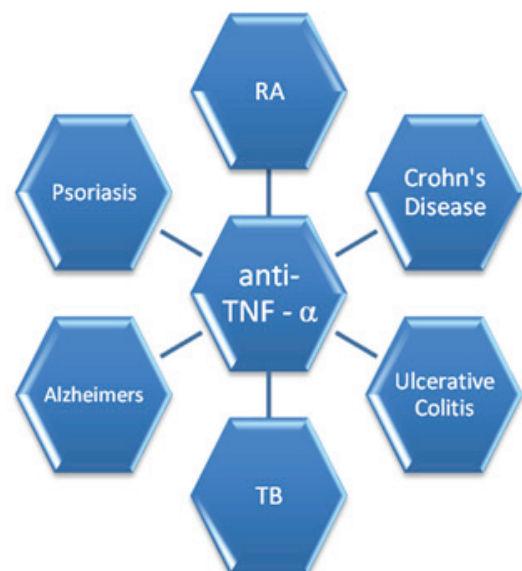
There are many companies looking for in- and out-licensing opportunities that cannot or do not go to conferences. In fact, some companies have a no-conference policy. Relying on conferences as the sole solution to expanding the reach of the business development process is not an ideal strategy.

A way to work around this is having local representation to augment the overall BD&L process. For instance, if your BD&L team is focused on the United States, perhaps you can find an individual or outside consultant to run a parallel process in Europe.

Conferences are great, but not the only way to build relationships. Having local relationships is critical to expand geographical reach.

Adjacencies

To understand adjacencies, let's consider the anti-TNF- α pathway. It does a number of things for a wide variety of diseases including Psoriasis, Crohn's Disease, Alzheimer's and Ulcerative Colitis. If your asset has a very broad mechanism of action, it's imperative that your company take a look at each opportunity and extract the maximum value from the asset.



Now although this sounds trivial, the research behind assessing each opportunity and assigning a possible value takes an extreme amount of work.

As with local representation, adjacencies can be a good series of tasks to have outsourced to an external firm. This analysis can run in parallel of other BD&L activities being performed internally.

Enhancing Corporate Sensitivity to Opportunity

If you look at a classic corporate value chain, business development tends to sit on the right and internal pre-clinical and clinical departments on the left. Although traditionally, those on the left of the chain are never involved in developing business opportunities, the whole chain should be involved in developing key relationships. Even if those on the left side of the chain don't attend these meetings, they are often going to conferences and networking, so they should be aware of the opportunities the company is looking to acquire or divest.



All employees should be made aware of company goals through training and internal seminars. Everyone should walk away with an understanding of the goals and vision, and be able to identify the type of opportunities being sought.

Anonymity

When meeting with companies, you may find that they don't qualify for your "must-have" criteria and you decide to not move forward. One challenge for BD&L teams is that interesting opportunities may be too early or are off-strategy. Additionally, the opportunity requires further research, but the team does not have time.

Balancing the need to stick to the criteria and looking for opportunities is important; try not to lose focus. Therefore, having an extra resource such as a consultant or firm can help to uncover opportunities that don't fit the strict criteria.

In addition, the use of external firms allows for anonymity. Names of clients do not have to be used until a specific time. This shields the client from the need to review an excessive number of opportunities.

Using external firms can be a great way to anonymously funnel potential clients.

Outsourcing Business Development and Licensing

Companies should not outsource the entire BD&L effort. There should be some internal function: someone taking charge of business development. Internal business development teams need to focus on areas of expertise and competence while overseeing and managing the external staff.

Summary & Recommendations

Ask the following questions:

- Is the strategy working?
- Are you generating leads that fit your criteria?
- Are you criteria correct?
- Are there process issues?
- Is the assessment process taking too long?
- Are there issues that were looked over during due diligence?

Consider the following key takeaways:

- Compose a market-based story for a presentation, or find someone who can help. Do not get technical and into a lot of detail on the first presentation. Presentations in the initial set of meetings should be market driven and financially focused.
- Seek local advice to uncover opportunities. Big companies can afford to have business development representatives all over the world, identifying local opportunities. If you can't afford to have an internal, global business development team, consider seeking outside help from a consultant.
- BD&L may require different approaches and skills. Building across the value chain will help. Take advantage of getting everyone involved because the next transaction can transform the entire company.
- Consider using a virtual data room. Good ones require users to agree to a confidentiality notice upon entry, access is controlled, functions can be blocked and everything is monitored.

About Carlos N. Velez

Carlos N. Velez, Ph.D., MBA has 20 years of experience in pharmaceutical research, consulting, venture capital, entrepreneurship, and business development. He is currently the co-founder and Managing Partner at Lacerta Bio, a business development and licensing consultancy. (www.lacertabio.com) Prior to co-founding Lacerta Bio, Carlos was the Director of Business Development and Licensing for Penwest Pharmaceuticals, a leading oral controlled release drug delivery company. His previous consulting clients span from startup biotechnology companies to large companies such as Forest Laboratories and Pfizer, plus venture capital and private equity firms. He holds an MBA from the Rochester Institute of Technology, a Ph.D. from the University of North Carolina at Chapel Hill and a BS from the Albany College of Pharmacy.

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