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Getting Ready for a Bio-Pharma Partnering Deal

By Linda Pullan

Introduction

In order to thrive, biotechnology firms must successfully develop and commercialize their discoveries or, as is increasingly more common these days, partner with large pharmaceutical firms to complete the development and commercialize their product. Deciding when and with whom to partner can be a daunting task, but breaking it down into the major elements that need to be considered will help you to develop a plan.

When considering a biotech-pharma partnering deal, the first question is whether partnering at this time is in your best interest. On the one hand, partnering can be a great way to raise non-dilutive funds, off-load expenses, bring in additional expertise from the partnering company, and increase your credibility. Statistically, big pharmaceutical partners also increase your chances of getting to an approval.

On the other hand, there can be drawbacks. Your company's long-term business vision could be compromised by giving up control of your asset to a partner. Nobody else has the passion that you have for your asset, so you have to ask yourself whether this partner the right fit for you and whether now the time for a partnership?

To evaluate whether now is the best time to partner, ask yourself some key questions. What is your vision for the future of your company and how would a partnering deal mesh with that vision? What scenario is best for the product? Will a partnership increase the probability of technical and commercial success? Does the potential partner have the resources to speed up or maximize the development of your product? Are there alternative funding options that make more sense than a partnership? Consider whether the early deal terms with a partner will be sufficient to offset the loss of later possible profits.

Assuming you've decided that pursuing a partnering deal is in your product's and your company's best interest, then what's next? Before going any further you'll want to determine what your product is worth, but how do you do that?

Valuation Drivers

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How your asset will be valued depends on numerous things. The data you've collected will, of course, be of paramount interest to a potential partner. Advanced and robust data will significantly drive value. Today partners are increasingly looking for small companies to tell them how their drug will get to market. So, having the ability to demonstrate a drug's efficacy on a target, showing you know how to set the dose in clinical trials and displaying an understanding of patient populations is increasingly important, even at very early deal stages.

Being ahead of your competition is always an advantage and will help drive value. It's also advantageous to have either a back up or follow up drug candidate or, better still, to have a flow of drug candidates in your pipeline.

Already having a partnering relationship with another company, especially a large pharmaceutical company, will serve to validate your credentials to a potential new partner. Having multiple companies interested in your product is the best-case scenario. If a potential partner sees that there is competition for your asset, the value will be increased and they will move faster to make decisions.

Creating competition for your asset is a process that you should actively manage. Be aggressive, and line up multiple potential parties who are in the position to act. Part of being ready for multiple bidders is getting prepared for the due diligence process before diligence begins. Having a virtual data room prepared well in advance of any partnering consideration will accelerate the due diligence process and may make it clear that you are professional and ready to solicit relationships with multiple worldwide partners, all while keeping your intellectual property secure.

Calculating Value

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Knowing the drivers of value, now let's look at some of the ways in which value is calculated. Unfortunately, value of an asset can be very subjective and, although there are multiple factors that can help estimate value, none of them are perfect.

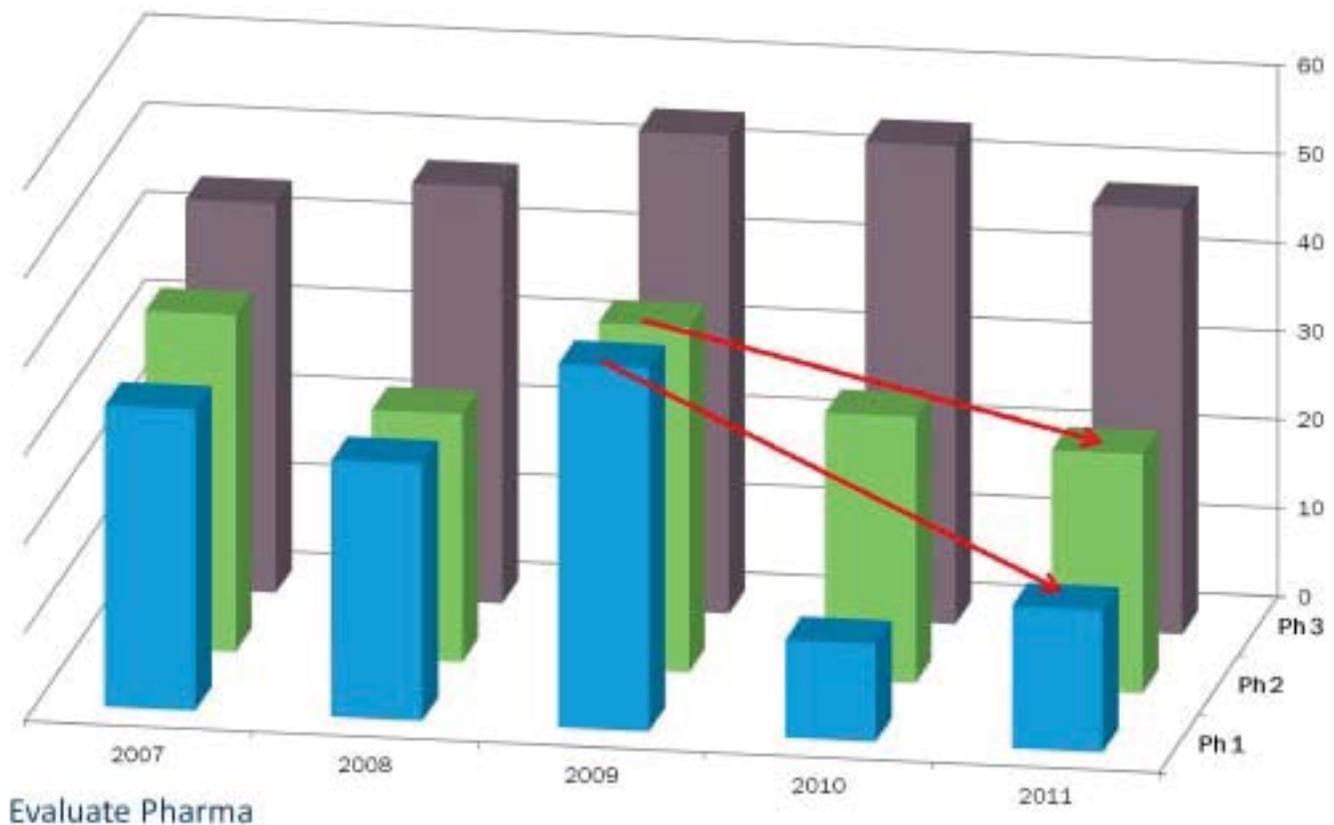
- Sunk costs, or what you've spent, can be a starting point, although sunk costs could be irrelevant to a partner if they think you've spent too much or spent unwisely.
- A partner's ability to replicate your asset and the resulting gain of lead time is valuable, but judging how much lead time you have is subjective.
- It's always instructive to look at comparable deals, but every deal has its own nuances, so it's unlikely that you'll find a deal that is exactly the same as yours.
- You can look at companies that are similar to yours and look at their valuations, but they are unlikely to be exactly the same.
- You can calculate risk adjusted discounted cash flows and time value of future sales, but these models are only as good as the assumptions you make in terms of cost of capital, peak sales and time to launch.
- Industry deal averages can be a useful way to assess the value of your opportunity, but it's important to remember that these are primarily averages of only the deals that have disclosed terms. Published deals tend to be either large "material" deals with public companies or deals everyone wants to tout because they're big, so there's generally a bias toward the larger deals. There are many more deals done that have not issued press releases or have press releases that don't disclose the dollar amount of the deal and therefore won't factor into industry deal averages.
- Although upfront payments and deal totals are often published, royalties are much harder to find. If the product is successful, royalties can be the biggest dollar amount in the typical deal. So, when assessing value it's important to factor in future royalties. Typically royalty rates have a tiered structure, meaning that as sales increase, so does the royalty rate.

Ultimately, putting a value on a company or one of its assets is like putting value on art. Imagine buying a painting to hang over your sofa. The decision to buy it or not is often driven by whether you like it, and whether it fits with your décor, rather than by what the market might say it's worth. It's not necessarily a rational process.

What if someone else wants the same painting? Have you ever been to an auction? When multiple bidders are present, parties can get excited and the price can get driven up. So, again, competition to buy your asset can be a major driver of increased value.

The bar graph below shows some recent trends in product license upfront payments over the past five years.

In-licensors want Ph 3 Ph 1 & 2 Upfronts down



You'll see that in recent years, during a soft economy, large pharmaceutical companies facing the patent expiration cliffs were looking for late-stage opportunities, and were able to bargain down Phase 1 and Phase 2 upfront payments. This means that, at least today, early deals may fetch lower values than in the past.

The Long Road to a Deal

If you've decided you want to do a deal and you now have some idea as to what your product might be worth, what can you expect in the process?

Unfortunately you may have to kiss a lot of frogs in order to find your prince. Large pharmaceutical companies are looking at lots and lots of opportunities to find their deals.

The graphic below shows a typical breakdown of the stages a large pharmaceutical company goes through to find their deals.

Partner's Triage



A typical large pharmaceutical might see 500 to 1000 opportunities in a given therapeutic area. Only 100 or so of those will go on to non-confidential meetings and only 50 or so of those will end up going to Confidential Disclosure Agreements (CDAs) and confidential meetings.

Moving onto the due diligence phase for the large pharmaceutical companies is a big and costly step, so here there's a further reduction of opportunities that stay in the process. Only some of the opportunities undergoing diligence will go on to having terms sheets and even fewer will move on to drafting a full agreement. Even after the drafting of a full agreement there can be attrition. In other words, not every agreement that gets drafted gets signed. So it's not uncommon for a large pharmaceutical company to begin with 500 opportunities and to end up signing only 2 or 3 deals.

These somewhat harsh numbers show the importance of having alternatives to your deal even when you're in the process of negotiating a final agreement. Alternatives are your negotiating power and insurance against no deal.

Understanding Deal Timelines

Unfortunately, getting a deal done can take a long time. After initial talks, getting a CDA can take a month or more. It might take another month for the other side to assemble appropriate team members and schedule team meetings. It can then easily take another month for them to evaluate all the information and to decide that they will indeed go forward with the formal due diligence process. From the point when the other party has decided to go forward with term sheet negotiations, it can take another six to twelve months to get to a signature on a full agreement.

Despite the inevitability of time elapsing, it's important to remember that the faster a deal progresses the more likely it is to come to a successful conclusion. You can't always control how long it takes the other side to make a decision, but you can make sure that you aren't the cause of slowing things down. Having a well-organized virtual data room is a critical step in making sure that potential partners have everything they need to make an informed decision and to help the process move along as quickly as possible.

The Importance of a Good Virtual Data Room

When a potential partner begins the due diligence process, they're trying to get to know you and your asset in greater detail, and they're attempting to verify what they've been told. They're also attempting to understand the potential of your asset and all the risks and obligations associated with it.

The best way to present this information is in a well-organized virtual data room. A modern-day virtual data room is ideally suited for due diligence needs of the bio-pharmaceutical industry including bio-pharma partnering, technology licensing, clinical study management or any other application that requires secure sharing of documents with third parties.

Having a virtual data room up and ready in advance increases deal momentum, makes you look professional and can even create the possibility in the participant's mind that they have competition.

A good virtual data room is secure and customizable so that all your non-confidential and confidential presentations, your publications, IP and contracts are easily accessible by the individuals you want to grant access to on the terms that you determine. Documents can be organized so that there's information for the pre-clinical expert, the toxicology expert, the regulatory expert, the lawyers, and you remain completely in control of who sees what.

You can also stage the sharing of the most sensitive information (such as unpublished patent filings or chemical structures or manufacturing processes) until it becomes clear that the parties involved need and are serious enough to see that information.

Remember, your partner is trying to learn in weeks everything that it took you years to create. They might not always get it right, so in addition to having a well-organized data room at their disposal, it may also be very helpful to guide them through the learning curve. It's difficult to appreciate all the nuances of an asset if you're not an expert in the field. So, if your asset is outside their area of expertise or something that's a new approach, you want to make sure they have what they need. Give them access to your experts, provide overview presentations, and answer questions. In short, spend the time it takes to make sure they really understand it.

Preparing for Negotiations

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Let's assume the due diligence process has been completed and negotiations are about to begin. Are you ready? Remember, you only get what you ask for. If you're very clear about what you want and you're very consistent in pursuing that goal, you're more likely to achieve it.

How do you prepare yourself for negotiations so that you're in the best position to achieve what you want?

Have a Clearly-Stated Goal

Ask yourself *"What is the goal of this deal?"* Make sure you can state that goal succinctly. This goal statement will be very useful as the deal moves forward as a check on how the deal is progressing and whether it's staying on track and continues to be the solution that best meets your purposes. Make sure your whole team has consensus on the goal statement and can state it clearly. Getting what you want is achieved by being unified and consistent, not by sending mixed messages.

Have a BATNA Plan

BATNA stands for **B**est **A**lternative **T**o a **N**egotiated **A**greement. In other words, what will you do if the deal falls through? Ideally, you'll have deal alternatives because you've pursued other partners or you have plans for your own development. You need to have a clear alternative to the deal against which you can weigh a particular set of deal terms.

Differentiate Between Wants and Needs

Needs are those things you must have to do a deal. Wants are things you'd like to have, but might be willing to trade away to ensure the deal happens. Make sure everyone on your team is clear what might be negotiable and what you're going to be unwilling to bend on. When presenting your needs, try to avoid stating them as positions, but rather be prepared to clearly communicate the rationale for those needs. For example, "I must have 140 million dollars," could be better stated as, "To maximize the value of this asset, we are going to need 140 million dollars to spend on the next set of clinical trials that will move us into Phase 3." A rationale is much more effective at justifying the cost to the partner or investor.

Profile Your Partner

Often it's beneficial to get the partner to sell you on why they would make a good partner. Ask them for a capabilities presentation. Ask them how they're going to maximize the value of your asset. Understand their pipeline and how your asset will fit into it. For example, if you have an asset that has multiple indications, it's very important to have a discussion about how they're going to develop multiple indications. Do they see the priority the same way you do?

Look at the history of your partner's deals. Whatever they've done in the past will be much easier for them to do again. If they've done an option in the past, they probably would at least consider one again. The kinds of terms and structures they've used in the past will be much easier to get approved again.

Consider their strengths and weaknesses. Why do they want your asset and what can they bring to the table? What does their pipeline look like? What are their competitive pressures? All of these things can help at the bargaining table.

You've considered your wants and needs, and your BATNA; now put yourself in the shoes of the partner. What are their wants and needs? What is their best alternative if the deal falls through? Do their wants and needs mesh with yours? By turning the tables a little and evaluating them as a potential partner, you can see if there is a good fit for your partnership. Deals get done when there's a good strategic fit between the parties. As a result, the success of your asset will be maximized when there's a shared vision of how to go forward.

Moving Forward with Negotiations

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Okay, you've prepared your team for negotiations and you've done your best to understand your partner's position. How do you begin negotiations? Most negotiations start (perhaps before it is recognized that it is a negotiation) with a discussion about what the goals of the negotiation will be. Now is the time to state your general "wants and needs". Start with big items as concepts and avoid getting too specific. At this point in the negotiation you're merely exploring whether the partnership will be a good fit for both of you.

When you start talking numbers, start higher than where you want to end up, but don't be unreasonable. A partner will not appreciate unjustifiable numbers and you'll risk losing credibility. Remember, you've done your homework, so you can present your position in the framework of its value and how it benefits both parties.

Defining Team Member Roles

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It pays to take some time to specifically define the roles each of your team members will play while sitting around the negotiating table.

Team Leader

Ideally, it's advantageous to have one leader who will do most of the speaking and who will ask other team members for input when needed. This negotiator should have the authority to make decisions within some ranges without deferring to a higher power. However, it may be best not to have the CEO in the room because sometimes it's better to be able to defer decisions rather than be put on the spot to make them instantly.

Practical Expert

It's important to have someone on the team who understands the consequences of the deal, someone with hands-on experience in drug development, so that they can assess the practicality of the decisions in the negotiations.

Note Taker

Make sure someone is taking detailed notes. A lot can go on in a negotiating session and it is invaluable to have a record of who said what and where you ended up. It can also be a good practice to provide a summary of your notes to the other side. Documenting decisions that were made can be a powerful tool for making sure action items don't slide. Comprehensive notes are also useful for when negotiations become very complex and it becomes necessary to go back and show that a specific item was indeed agreed on.

Pharmaceutical Lawyer

Should a lawyer be present? Definitely, but maybe not until after some basics have been ironed out in simple term sheets. Although lawyers are expensive, the earlier a lawyer is involved in negotiations, the better he'll be able to understand your aims and goals and the more up to speed he'll be before a full agreement is drafted.

Term Sheets

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Negotiations are typically started with a high-level discussion of the goals and purposes of the deal, and who's going to be responsible for what. Once those conceptual items are agreed on, it's time for someone to draft a term sheet. Term sheets can take a lot of different forms, but essentially they are aimed at defining the most essential terms and conditions of the business relationship. Term sheets are almost always non-binding because, by their very nature, they are relatively short and therefore incomplete. However, as negotiations progress, term sheets can evolve and become more comprehensive. Often there are multiple drafts of terms sheets, each one adding more detail as the participants in the negotiation understand more and more about what the deal will look like. At some point, the term sheet becomes detailed enough that it becomes time to draft the full agreement.

It's important to note that either side can provide the first term sheet, but generally the party with the most concrete ideas will write the term sheet, and then either side can redraft it as needed throughout the negotiations.

The Full Agreement

The full agreement takes the content from the term sheet and adds additional legal language as well as additional terms that may not be in the term sheet, such as how information will be shared, ownership and prosecution of IP, and the ownership of new inventions. If a lawyer hasn't been involved up to this point, this is where a good lawyer with experience in pharmaceutical licensing transactions is absolutely essential.

These processes to a deal are generally true but every negotiation is unique and signing the full agreement leads to a unique relationship. Hopefully, your deal is successful.

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ShareVault provides a secure document sharing solution for life sciences organizations and is ideally suited for the due diligence required during bio-pharma partnering, business development, technology licensing, fundraising, M&A, clinical study management or any other application that requires secure sharing of documents with third parties. More and more, the leading pharmaceutical companies, clinical research organizations, biotech companies, medical device firms and CROs rely on ShareVault to safeguard their critical information, to reduce due diligence costs and streamline third party document collaboration.

About Linda

Linda Pullan



Linda M. Pullan, Ph.D. offers biotech and pharmaceutical companies consulting in all aspects of partnering through Pullan Consulting (www.pullanconsulting.com). Linda has a Ph.D. in Biochemistry and a B.S. in Chemistry. Linda has more than 20 years of drug industry experience, beginning in drug discovery at Monsanto/Searle/now Pfizer and ICI/Zeneca/now AstraZeneca. After doing licensing at what is now AstraZeneca, Dr. Pullan continued as head of oncology and hematology licensing for Amgen. She then joined Kosan Biosciences as VP of Business Development and experienced all the tasks of out-

licensing and business development in a small company. For several years, she has been providing companies help in identification, evaluation, valuation, negotiation and strategy for partnering in or out. She has an extensive deal sheet ranging from company acquisitions to Phase III compounds and from preclinical candidates to technologies, with both in- and out-licensing. She writes a free monthly newsletter, Pullan's Pieces, with tidbits of science and business for about 3,800 readers. Interested readers may sign up by sending an email to lpullan@msn.com.

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