

SUCCESSFUL BIOTECH LICENSING NEGOTIATIONS

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Whitepaper

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Negotiate, have clearly stated goals for the deal,
organize your documentation so that it's easily
accessible by potential partners.

Background

In today's complex biotechnology world, finding the right partner for your drug candidate and successfully negotiating the terms of that partnership can be a daunting task, especially for small companies. However, there are many concrete ways to make the process easier and maximize its chances for success.

Achieving the best outcome depends on preparing well in advance of the negotiation process, having clearly stated goals for the deal, organizing your documentation so that it's easily accessible by potential partners, and realizing that non-financial terms are just as important as financial ones.

The Negotiating Process can be broken down into five distinct areas:

- Getting Ready
- Defining Needs & Wants
- Term Sheets
- The Full Agreement
- Implementation

AREA #1

GETTING READY.

Perhaps the most important step in preparing for a deal is clearly stating your goal for the deal. What is the desired outcome? Is it the ability to run more than one clinical trial? To raise cash for other projects? Validation?

Whatever it is, ensure that there is consensus among your team, and then write it down. Remember, you only get what you ask for. This goal statement will be very useful as the deal moves forward as a watermark of 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 not only believes in the goal statement, but can state it clearly. Getting what you want is achieved by being unified and consistent, not by sending mixed messages.

AREA #2

DEFINING NEEDS AND WANTS.

Once you've established your general goal for the deal, go a step further and define your needs and wants for the deal. Needs are specific conditions that if not met will cause you to walk away from the deal.

Your needs will likely vary from deal to deal and across the different companies you seek to partner with, but may include very general things such as an evaluation of whether the partner is someone you can comfortably work with and whether they hold credibility with investors, to more specific criteria such as whether you will retain U.S. copromote rights.

Wants are the things you'd like to get but are willing to trade away in order to get the things that are most important to you. An example would be a willingness to compromise on higher initial payments in trade for higher royalties later on, or perhaps relinquishing control over development in exchange for a higher initial payment.

Again, these needs and wants should be written down so that your whole team is

on board.

MONEY NOW OR MONEY LATER

- Do you need money immediately or does it make more sense to maximize royalties later?

RESOURCES

- Who will provide resources? You? The partner?
- Does it make sense to bring in a third party such as a CRO to maximize resources?

IMAGE, VALIDATION, PUBLICITY

- What's more important?

OPTIONS & FLEXIBILITY

- Sometimes smaller companies do not fully recognize the value of options and flexibility.
- Remember, there's a long road ahead, and the path may be unclear. Be careful not to cut off paths of future growth.

DEAL TIMING

- What kind of timeline is important to you?
- Do you want progress immediately, or is waiting for an optimal deal possible?

RISK AVOIDANCE

- Is bringing in marketing muscle important to you?
- Perhaps getting commitment for more than one clinical trial?

CONTROL

- How much are you willing to give up?
- How much do you want to retain?

QUALITY OF RELATIONSHIPS

- Will you be able to work well with this partner?
- Are your visions aligned?

As you define needs and wants also consider alternatives to the deal. 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. A clear alternative to a deal enables you to weigh a particular set of terms for a deal against your best alternative.

Having alternatives also gives you more power at the negotiating table.

Evaluating Potential Partners

Before reaching the negotiating table you'll want to assess whether the partner you're approaching is a good one.

Unfortunately, this process isn't always easy. One thing to avoid is the temptation to judge your potential partner based on the CDA process.

CDAs are often difficult to achieve and this process doesn't necessarily reflect how a company will deal with you as a partner. This is also true of the negotiation process. Sometimes negotiations are extremely painful, but once completed can result in a very amiable and profitable relationship. The quality of the diligence team can reflect the quality of the partner, but remember that the diligence team that is evaluating your asset may not be the same team that runs the program.

One easy way to evaluate a partner is to talk to other companies they've partnered with and determine if those other partners are happy with the relationship. Perhaps the most valuable way to judge whether your partner is a good fit is determining whether the two of you share a similar vision for the product's development. Take time to discuss the development path of the product for

the short and long term. If you and your partner's vision for product development are aligned, chances are that partner is a good one.

It can also be helpful to review what a potential partner has done in the past.

Having knowledge of a partner's past activity can often provide solutions to issues that arise with your deal. You can say, "You've done this before, so this should work."

The Importance of a Good Virtual Data Room

As you identify a partner that looks like a good fit for you, they will simultaneously be evaluating whether you and your asset are in turn a good fit for them. When a potential partner begins the due diligence process they're not only trying to get to know you and your asset in greater detail, but they're attempting to verify what they've been told and confirm that your data is accurate. They're also attempting to understand all the relevant issues and potential associated with your asset as well as its obligations and risks and the best path to maximal return.

The best way to present your information is in a well-organized virtual data room. A modern-day virtual data room is ideally

suited for the due diligence needs of the biopharmaceutical industry including partnering or licensing, clinical study management or any other application that requires secure sharing of documents with other parties.

Being prepared for the due diligence process well in advance of when that process begins is crucial to deal success. Having a virtual data room up and ready 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 wholly 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.

And, because access is completely customizable, you can stage the sharing of the most sensitive information (perhaps patent applications or manufacturing processes) until it becomes clear that the parties involved need and are serious enough to see that information.

Data rooms are also ideal for dividing up information to make it easy for the right diligence expert to see it. For instance, documents can be divided up so that there's information for the preclinical expert, the toxicology expert, the regulatory expert, the lawyers, and you control who sees what. If the deal does not go through you can later revoke rights to documents or "virtually shred" documents, even after they've been downloaded.

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 can also be 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 is a new approach, you want to ensure they have what they need to fully recognize value. Give them access to your experts, provide overview presentations, answer questions. In short, spend the time it takes to ensure they're getting it.

AREA #3

TERM SHEETS.

Term sheets are dynamic documents that evolve as the deal evolves. A term sheet will typically start out with large conceptual items and progress with increasing detail until it is almost the full agreement.

The goal of the first term sheet is simply to get consensus between you and your partner on the basics. Who are the parties involved? What is the goal of the deal? What will be involved?

Will the deal involve a license, option or purchase? Is the agreement exclusive or non exclusive? Who will be responsible for what? It's important at this stage to keep things conceptual, leave room for compromise and to listen to what the other party wants. Early term sheets should define a mutual understanding of the deal shape in easy to grasp terms. One thing that should probably not be discussed at this stage is pricing.

Better to wait until after the basic shape of the deal is defined. Once both parties are aligned on these basics, more specifics—financials, control, dispute resolutions, sublicenses, etc.—can be incrementally added. Remember, if it's

important to you, it needs to be in the term sheet.

Who puts out the first term sheet with numbers? Sometimes young companies are hesitant to suggest pricing first because they worry that they could have done better. But first numbers represent a stake in the ground. Once established it is difficult to adjust that number significantly. So, if you know what you want, it's good to suggest pricing first.

What about getting paid for exclusive negotiations? On the one hand, exclusive negotiations are a sign of seriousness. But consider: Is the compensation enough to justify your asset being off the market? Exclusive negotiations can enable your partner to drag their feet and slow the negotiation process down. It can also cost you both negotiating and closing power since there is no competing party.

NEGOTIATING TIPS

PREPARE:

- You only get what you ask for.
- Negotiations begin at the first meeting.
- Know what you want.
- Imagine alternative outcomes and how to deal with them.
- Have alternatives in case the deal fails.

PERSUADE:

- Write things down.
- Ask questions.
- Have your team aligned.
- Move fast.

DEAL WITH DISPUTES:

- Preserve optionality.
- Use contingency terms when the two sides differ in beliefs.
- Don't assign motives to their actions—just deal with their actions.
- Step to the balcony and view the process with the calm of a spectator.

When do you need a good lawyer?

Typically lawyers need not be invited in until it's understood generally what the deal involves, but don't make the mistake of waiting too long. Once mistakes are made they can be difficult to reverse. Remember, it's much easier, and cheaper, to change a term sheet than it is to change a final agreement.

A lawyer should always be consulted any time you don't understand the language of the negotiation. And remember that terms you think you understand may have different meanings in the context of prior court cases or in different territories.

Certainly a lawyer should be involved no later than during the first draft of the final agreement.

AREA #4

UNDERSTANDING THE FULL AGREEMENT.

Once the term sheet has progressed through several (or many) iterations, it will become clear that it's time to draft the full agreement. Remember, at this time an experienced lawyer should be involved. The full agreement will be unique to your asset and your partnership, but will generally address four major categories.

THE ASSET

Scope and Exclusivity

When we talk about scope we're talking about what exactly you're giving the other party the right to do with your asset.

This can include a license or option to research, develop, make, use, sell, or offer to sell your asset. The scope of the agreement might also include licensed products, specific compounds, backups and derivatives.

Patents and patent applications will most likely be included, but be careful to be specific. Are all your patents included or only the ones necessary to make and use the asset? If you include rights to derivatives, derivatives will also need to be well defined; often a difficult task. Think ahead and do your best to define what a derivative might encompass.

What else? How about improvements you make to the asset? Are they

included? If so, for how long? How will know-how be transferred? Is it all at once at the beginning or is there an ongoing obligation? If there's an ongoing obligation, is compensation included?

The full agreement may also include rights for affiliates, wholly-owned subsidiaries and contractors.

When you license your asset, your partner will obtain either exclusive or nonexclusive rights, but perhaps more important for you are the rights that you retain. Do you want to be able to continue to do research with your molecule as a tool? Do you want the right to develop the next generation of that molecule? Do you want to do clinical development and offer those indications for your partner to option?

Think about what you want to do in the future and ensure that those rights are retained.

Field of Use

The Full Agreement will generally contain a field-of-use limitation. Field of use is a provision that limits the scope of what you authorize a partner to do with your asset by specifying a defined field of permissible operation by the licensee. In addition to affirmatively specifying the field of use, the agreement may specify a field or fields from which the licensee is excluded. For example, an agreement might authorize a licensee to develop a drug for oral administration, but not for topical administration, or to market a drug for therapeutic use in humans, but not in animals.

Sublicensing

Sublicensing can be a difficult arena to navigate because often it requires a renegotiation of a prior university license. Universities often put a lot of restrictions on sublicenses, but pharma companies want sublicenses in order to be able to maximally develop a compound, perhaps for development or marketing in another territory or to fund bigger trials. Consider the purposes of sublicensing for your partner and how you will pass through the obligations.

Will you hold your partner responsible for paying the milestones and royalties or will they pass those on? Or, will they

pass on obligations no less stringent? Also consider if you want to share in revenues upon a sublicense, perhaps a percentage of the upfront or the cash at the time of upfront. This sublicensing share often goes down as time passes and the partner's relative contribution to the asset value is larger.

Territories

Territories can be partnered separately to create extra value, for instance, a deal for the U.S. and a deal for Europe.

However, remember that territorial splits require a lot of coordination.

Each partner will have concerns about the other partner hurting their product with different development studies and marketing messages.

Information will need to be shared, including manufacturing processes, regulatory information, and adverse events. This type of coordination will be greatly facilitated if your virtual data room is organized and comprehensive. Territorial limited deals are also an area where an experienced lawyer is essential.

COMPENSATION

The next step after defining the parameters of what your partner can do with your asset is to define what you're

going to get paid for it. Negotiating price might seem like one of the most arduous components of the negotiating process, but in reality it tends to be simpler than many of the other areas the full agreement must address. There will certainly be some give and take over value, but it's generally fairly easy to specify. A place where compensation negotiations can get a little murky is in how things are defined. That's often true regarding milestones, because milestone payments are often triggered by the "successful completion" of something and "successful" can sometimes be ambiguous. One way to avoid this ambiguity is to use the start of the next phase as the trigger rather than trying to define what success is. It's also important to think about whether these milestones are paid one time or one time per indication. Does a backup molecule get to substitute for a failed first molecule and not pay the prior milestones?

There are, of course, different ways to get compensated for your asset including upfront payments, equity, profit share, payments based on development of sales milestones, royalty payments and a combination of these. Small companies sometimes underestimate the value

of royalties because they're perceived as a long way off and may never come to fruition, but they can amount to the largest part of a deal when assets become successful.

Royalties are commonly tiered up meaning that as sales increase so does the royalty percentage. When negotiating royalties two things are important. First, royalties will be based on a percentage of net sales, so it's imperative to clearly define what net sales are. See the sidebar on the next page for things that can affect net sales. Secondly, the agreement must state how long royalties will be paid. Ten years? Indefinitely? Last to expire valid claim? Until a generic takes 25% market share?

DEFINING NET SALES:

- Import, Export, Excise & Sales Taxes
- Custom Duties
- Insurance Premiums
- Cost of Transportation from Manufacturing to Customer's Premise or Point of Installation
- Cost of Installation at the Point of Use
- Credit for Returns, Allowances or Trades

CONTROL AND DILIGENCE

Control is the definition of how you and your partner will work together. This part of the agreement defines who gets to make decisions and who is responsible for doing what. Often this part of the agreement will specify divisions of labor. For instance, you manufacture; we market and sell. These divisions can be based on expertise and capabilities, or sometimes according to indication or formulation, or often combinations thereof. Sometimes the bigger company simply takes full control when the transaction is complete.

Diligence requirements in the full agreement should be clear, objective, specific and reportable. These requirements for diligence can include a timetable for the progress of a compound against developmental stages; timelines are common in university licenses, but not in partnerships with global pharma companies. If milestone timelines are not met, sometimes the agreement will allow for the responsible party to pay the cash associated with that milestone or to buy an extension to that milestone's deadline. Diligence requirements can also limit periods of inactivity, specify minimum

annual spending and minimum annual royalties, and can require "commercially reasonable efforts." In order to know if diligence requirements are being adhered to, you can require annual or semi-annual reporting of plans and progress and it's rarely bad to have a seat on a joint steering committee.

DISPUTES AND TERMINATION

Disputes and termination provisions define courses of actions if things don't go well. Disputes can be handled in a variety of ways including by committee, by veto of one party, by CEOs, by mediation, by arbitration or by courts. Sometimes a combination of methods is used and often they can be organized in a hierarchy. For example, if a committee fails to resolve the dispute it then goes on to arbitration.

It's also important to clearly define termination provisions. Many deals will be terminated so it's important that the full agreement specifies who can terminate and under what circumstances. It may be possible to require steps for an orderly transfer, dealing with information sharing, supply and other things that make it easier to start up development or sales again. Remember that a high

percentage of drugs that get terminated eventually move on to approval. The full agreement should guarantee that if a drug is terminated your rights and obligations are returned to you. The agreement should specify who can terminate and under what circumstances. The road to finding a good partner for your drug candidate can seem like a

long and winding one, but preparing in advance, knowing what you want, clearly defining the terms of the agreement, and having all relevant documentation available and organized in a good virtual data room can not only expedite the journey, but can go a long way in ensuring its success.

ABOUT THE AUTHOR

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Linda offers biotech and pharmaceutical companies consulting in all aspects of partnering. Linda has a Ph.D. in Biochemistry, a B.S. in Chemistry and more than twenty years of drug industry experience. Linda has worked in many deals, from in-licensing to out-licensing and a few acquisitions. Linda publishes a free monthly newsletter, Pullan's Pieces.

As the lead consultant at Pullan Consulting, Linda M. Pullan, PhD, has been advising biotechs on the most effective ways to partner for many years. Prior to consulting, Linda worked for many years in licensing, BD, and research at small (Kosan) and big (Amgen, AstraZeneca, Monsanto/Searle) companies.



Services that Linda provides include any or all of the following:

- creating business plans
- seeking new opportunities to in-license
- making contacts
- setting up meetings
- pitching out-licensing opportunities
- structuring presentations & communications
- evaluating opportunities & competition
- preliminary market assessments
- managing the diligence process
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