ADDA Lecture Series: Business Development

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Knowledge that will change your world
“Business Development” Means Different Things to Different Segments of Pharma

- Small biotechnology companies (and the ADDA)
- Big (Branded) Pharma
- Generic Pharma
“Business Development”: A Bit of a Black Box

Some Really Cool, Innovative Research Results

Some Stuff Happens Here . . .

You get a TON of money from a pharma, big biotech or VC!!
“Business Development”: Working Definition

• All of our programs are very early in the drug development arc

• We (ADDA) can only take programs to a certain point: IND, maybe Phase I

Business Development:
Finding industry partners that are willing and able to take our programs forward through clinical development and to the market
Peeking Inside the Black Box . . .

On paper, licensing a program to a pharma or biotech company is pretty straightforward:
Peeking Inside the Black Box . . .

But in practice, the process looks a bit more like this:
Remember the Fairy Tale . . .

. . . About the princess who goes around kissing frogs to find the one that becomes her Prince Charming?

There’s a LOT of that in Business Development . . . .
So if you have to kiss frogs . . .

. . . it’s important to reduce the “Frog:Prince Ratio” as much as possible!

It is important to understand:
• The potential therapeutic indication
• The competition
• Our program (good and bad)

• Who is in this therapeutic area?
• Who has a competing program?
• Who is open to (very) early-stage assets?
• Is there any interest in our specific programs?
Reducing the Frog/Prince Ratio

Even with all of the filters applied, we talk with many different types of potential partners

- Big Pharma – includes Big Biotech
- Regional Pharma – EU, JP, KR, etc.
- Specialty Pharma
- Classic Biotechs
- “In Betweeners”
- Investors

And all of the discussions start the same way . . .
“So tell me about your program”
Standard Questions from Companies

• “How far along is the program?”

• “What is your IP status?”

• “Do you have any *in vivo* proof-of-concept?”

• “Is there any clinical or genetic correlation for the mechanism?”

• “How long before you get to IND?”
It All Comes Down to the Data

• Without good science, business development has nothing to do

• Basic science
  – Novel insight into disease
  – Clear understanding of mechanism
  – Linkages to clinical samples or genetic studies
  – *In vivo* proof-of-concept

• Applied science
  – Chemistry
  – Pharmacokinetics (including oral bioavailability)
  – Toxicity
  – Intellectual Property
“This program sounds interesting. I would like to find out more.”
“So the first meeting went well – Now what?”

“You are here”
More Science!

• It is important to get scientific “buy-in” from the potential partner on a program

• If their scientists aren’t excited, or if they have concerns . . .

• Important to have their experts talk to our experts – dive deep into the science

“There is no such thing as too much data.”
Material Transfer Agreement (MTA)

- Often part of the scientific deep dive
- Also referred to as “Trust Yet Verify”

- We provide the potential partner with our compound
- They test it to see if they can reproduce our data
- They might also test it in other systems or models that we don’t have

Sounds pretty simple, doesn’t it?
Example: Global Pharma

• “The studies are delayed a bit – the technician who does these experiments left the company”

• “OK – we have a new person to do the studies. But the core assay isn’t working . . . We’re not sure why. We’ll get back to you.”

• “Now the studies seem to be working”

• “We decided not to move forward with this program. We couldn’t reproduce your data.”
Example: Chinese Pharma Company

• “We’ve signed the agreement and finalized the studies. But we would like to add one more . . . “

• “Could you send us that one cell line? It would be faster than if we order it ourselves.”

• “Please send us some of that other compound – it would be good to have a positive control. Just in case.”

• “Don’t send anything yet. We just found out that we need to get an import permit from the government . . . We’ll get back to you.”
Coming to Terms

• **Term Sheet**: A summary of each side’s roles and responsibilities in the partnership

• Who pays what and when?
• What is the territory and indication(s)?
• Who makes decisions?
• Who is responsible for
  – Further development steps
  – Patent applications/persecutions
  – Regulatory filings
• What happens if the partner changes their mind?
• How are potential conflicts resolved?
Diligence: Where EVERYTHING is Shared

• Scientific
  – Experiment-by-experiment
  – Notebook-by-notebook
  – Animal-by-animal

• Clinical
  – Dose-by-dose
  – Patient-by-patient
  – All lab values

• Intellectual Property
  – Patents Issued
  – Patent Applications
  – “Freedom To Operate”

• Manufacturing
  – Yields
  – Batch-to-Batch Comparisons
  – Stability
Definitive Agreement

- All agreed-upon terms, wrapped in legalese
- Also includes extensive representations and warranties
  - “Yes, we do have the right to enter into this deal . . . “
  - “We guarantee to use our best efforts . . . “
  - “We won’t sue you if our people mess up . . . “
- Lots of billable hours for the lawyers
- Legal contract, signed by appropriate officers from both sides
Closing the Deal

• Getting final signatures (Hint: Avoid holidays)

• HSR: “Hart – Scott – Rodino”, or “There’s no deal until the government weighs in”

• Cashing the check

• Hitting the bar – hopefully with your new partners!
And then the next morning . . . .

• Alliance management
  – “Now that we’re working together, how do we keep track of things?”
  – Meetings, agendas, budgets, reports to senior management, etc.

• Hitting milestones
  – What resources do we have to commit to hit the goals that we committed to?
  – What can we do to help our partner hit their goals?
Deal Timeline

In Theory

• Six months

• Discussions with one or two companies (assuming a good Frog:Prince ratio!)

In Reality

• 18 – 24+ months

• Discussions with up to 40 companies (we hear “No” in many different forms!)
Why Companies Say “Yes”

• They have a gap in their pipeline

• They are invested in the therapeutic area

• A program clearly shows value
  – Scientifically
  – Commercially/Financially

• “Keeping up with the pack”
Why Companies Say “No”

• Program is too early

• They are looking at multiple programs for this indication – and pick another one

• They are simply gathering a little competitive intelligence

• Unresolved scientific questions/concerns

• Financials are too risky or don’t add up
Things Change: “Frog” ↔ “Prince”

- “There’s been a change in our strategy”
- “We’re getting bought”
- “We need to raise money”
- “The team is being relocated”
- “We’re going through a reorganization”
- “We’re buying someone”
- “Our program failed”
- “We have a new CSO”

Some of these can be good news, some not so good
A Virtuous Cycle

Present programs to companies

Collect company feedback

Provide information to researchers on gaps & drivers

Research teams use input to refine program
A Virtuous Cycle

Present programs to companies

Collect company feedback

ADDA Programs

Pharma & Biotech Companies

Completed Licensing Deals

Research teams use input to refine program

Provide information to researchers on gaps & drivers

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Knowledge that will change your world