“Business Development”: A Bit of a Black Box

Some Really Cool, Innovative Research Results

Some Other Stuff Happens Here . . .

You get a TON of money from a pharma, 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

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**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?”
• “How long before you get to IND?”

• Plus a number of questions that are specific to the indication, target and/or mechanism
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
  – *In vivo* proof-of-concept

• Applied science
  – Chemistry
  – Pharmacokinetics (including oral bioavailability)
  – Toxicity
  – Intellectual Property
“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.”
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

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

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

• All agreed-upon terms, wrapped in legalese
• Also includes extensive representations and warranties
  – “Yes, we really 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

**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
• They want to broaden their pipeline
• 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
• Questions/concerns about:
  – Target and/or mechanism
  – Chemistry
  – Pharmacokinetics
  – Toxicology
• Financials are too risky or don’t add up
Things Change: “Frog” ↔ “Prince”

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

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