Business Concepts for Life Scientists: Business Development

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Business Concepts for Basic Scientists

Strategy
Finance
Business Development
BD course objectives

By the end of the workshop, you will be able to:

1. Define Business Development
2. Understand how Business Development contributes to a business’ vision and goals
3. Describe different vehicles that Business Development can leverage to accomplish their objectives
4. Describe successful deal structures
Business Development is one of the components of a business’ strategy

Vision: The North Star, The Aspiration

Mission: Key problem(s) that will be solved or minimized

Objectives: The key milestones and actions required to achieve the Mission & Vision

Strategy: How you will achieve the Objectives
  ➢ Product / Therapeutic Area: Where to focus?
  ➢ Marketing: Who, how and where to target?

These key components provide structure to an organization and its operations
What is Business Development?

- **Business development** drives growth and expansion for an organization, product and/or brand.

- The purpose is to identify and execute on opportunities that can drive revenue, profit and/or brand growth.

<table>
<thead>
<tr>
<th>In biotechnology...</th>
<th>How the company will fill its pipeline, bring products to market and serve its stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>In academia...</td>
<td>How the lab will fill the project pipeline and execute opportunities to publish, fund and grow the lab</td>
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</table>
Need for Business Development

There are many ways to drive growth

+6% for all externally sourced assets

+20% for breakthrough assets

+54% for orphan drugs
Overview of BD process

1. Identify the Gap
2. Determine the Vehicle to Fill the Gap
3. Execute the Deal
4. Measure Success
The BD process – Identify the Gap

1. Identify the Gap
2. Determine the Vehicle to Fill the Gap
3. Execute the Deal
4. Measure Success
Identify the Gap

• What types of gaps are in-scope?
• How are gaps identified?
What types of gaps are in-scope

A diverse set of gaps can be in-scope

**FINANCIAL**
- Revenue
- Profit
- Access to capital

**MARKET**
- Market Share
- Geographic footprint
- Access to markets

**STAKEHOLDERS**
- Product adoption
- Expertise gaps
Example Gaps

Revenue Gap

Novartis Earnings Fall on Slide in Cancer-Drug Sales
Novartis is leaning heavily on new drugs to offset declining revenue from Gleevec - WSJ

Pipeline Gaps

Stakeholder Adoption Gap

Market Penetration Gap
Example Gaps

Revenue Gap

Stakeholder Adoption Gap

Pipeline Gaps

Market Penetration Gap

Eli Lilly has long raised concerns among investors about the future of its drug pipeline...due to expiration of patents [of its] blockbuster treatments - The Motley Fool
Example Gaps

Revenue Gap

Pipeline Gaps

Stakeholder Adoption Gap

Market Penetration Gap

Novartis Heart-Failure Pill Hits Hurdles With Doctors
Drug maker is having a problem in getting physicians to prescribe Entresto
- WSJ
Example Gaps

Revenue Gap

Pipeline Gaps

Stakeholder Adoption Gap

Market Penetration Gap

J&J Global Market Strategy
… a common choke point for the company in [expansion] lies in delivery of services & [expansion into] local markets.

- DevEx
How are gaps identified

Current Business Model Gaps are identified through measuring progress towards Goals.

Future Growth Gaps can be identified through market assessments.

Source: www.learnmarketing.net
How are gaps identified in the pipeline

Example Pipeline View

<table>
<thead>
<tr>
<th>Product</th>
<th>Indication</th>
<th>Stage</th>
<th>Partnership Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tacrolimus IR¹</td>
<td>Transplant</td>
<td>Preclinical</td>
<td>Canadian promotional activity¹</td>
</tr>
<tr>
<td>Vistitan™ (bimatoprost 0.03% w/v)¹</td>
<td>Glaucoma</td>
<td>Clinical</td>
<td>Canadian promotional activity¹</td>
</tr>
<tr>
<td>AQS1301 (ariprazole-TDS)</td>
<td>Psychiatric disorders</td>
<td>Approval</td>
<td>Global rights available</td>
</tr>
<tr>
<td>AQS1302 (clobazam-TDS)</td>
<td>Epilepsy</td>
<td>Marketed</td>
<td>Global rights available</td>
</tr>
<tr>
<td>AQS1303 (pyridoxine/doxylamine-TDS)</td>
<td>Anti-nausea</td>
<td></td>
<td>Global rights available</td>
</tr>
</tbody>
</table>

Source: www.aequuspharma.ca
How are gaps identified in the market

Example: Commercial Gaps

Source: MediSafe via www.slideshare.net
Advanced topics

Identification of gaps also can include:

• Understanding of metrics vs. success indicators
  o leading and lagging
• Financial Analysis
• Market Assessment, including Competitor Analysis
• Stakeholder Behavior Analysis
• Root Cause Analysis
Parallels to Academia: Q&A with Anatol

- How does an academic lab utilize BD?
- How do you identify gaps the lab could fill?
  - Gaps in the field?
  - Gaps in the lab?
  - Financial gaps?
The BD process – Fill the Gap

1. Identify the Gap
2. Determine the Vehicle to Fill the Gap
3. Execute
4. Measure Success
“Deals” to Fill the Gap

• What deal types and structures are used?
• What deal structures will address a gap or opportunity?
• Which agreements will help achieve goals and align with internal values?
## An Overview of Some Common Deal Types

<table>
<thead>
<tr>
<th>Deal Type</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Research Collaboration (Large company “hires” a smaller company to evaluate a technology)</td>
<td>• Often the fastest deals to execute  &lt;br&gt; • Allows licensor to evaluate high-risk technologies and get to know the smaller company  &lt;br&gt; • Lowest size monetary deal  &lt;br&gt; • Low/no long-term payments</td>
</tr>
<tr>
<td>2. License or License Option</td>
<td>• Licensor gains revenue and recognition for an asset or share of an asset  &lt;br&gt; Sometimes includes only time-limited payments and/or development assistance but could extend through approvals and sales</td>
</tr>
<tr>
<td>3. Development Agreement</td>
<td>• Leverages complementary partner capabilities  &lt;br&gt; • Can increase the overall asset value through expanded and/or focused development  &lt;br&gt; • Can sometimes slow development through collaborative decision making</td>
</tr>
<tr>
<td>4. Commercialization Agreement</td>
<td>• Can leverages capabilities of a larger partner  &lt;br&gt; • Can gain significant commercial value from established infrastructure  &lt;br&gt; • Can include resources / milestone payments during development phases  &lt;br&gt; • Can limit upside for the licensor</td>
</tr>
<tr>
<td>5. Acquisition Option</td>
<td>• Can gain a payment and potential for a buyout  &lt;br&gt; • Can limit competitive bids</td>
</tr>
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Research Collaboration

**Benefits**
- Establish technology feasibility with a partner
- Build trust, understanding, and lead to a larger deal in the future
- Can help defray early research costs for both partners

**Funding**
- Range from a few hundred thousand dollars for a short in-vitro proof-of-concept study to tens or hundreds of millions for clinical stage assets

**Structure**
- Usually benefits from a clear delineation of defined success criteria and what a next step of a partnership would be

**Risks**
- Low risk for the licensee
- Easiest to terminate or abandon
- Easiest deals to do and get approved internally

**Key Questions**
- Data ownership, publication rights, termination rights, option rights
## License or License Option

### Benefits
- Can have the most varied of the deal structures – provides lots of room for creativity or solve multiple issues and concerns

### Funding
- Options to license products at specific phases of development. These can include milestone payments to scale as a product moves through development

### Structure
- Commercial rights globally or in a specific territory
- For all indications or for a one or a subset of specific indications
- For all customers or for specific customer segments (field limited rights)

### Risks
- Licenses can potentially limit upside from licensors
- …But could also raise the value of later deals

### Key Questions
- Licenses can potentially limit upside from licensors or alternatively, increase the value of later deals
License Examples: Onyx & Pharmacyclics

Licenses can potentially limit upside from licensors (for example a potential acquirer may no longer be interested because rights to a key asset are now owned by a different company) or raise the value of later deals

- Potentially limiting: Onyx’s license to Bayer was cited as a reason why companies did not purchase the company for years

- Potentially facilitating: J&J essentially purchased half of Pharmacyclics and Abbvie purchased the other half at a significant premium
# Development Agreement

## Benefits
- Can benefit small companies because they leverage resources from larger companies such as clinical expertise, samples, vendor relationships, international infrastructure and entities, regulatory experience.

## Funding
- Funding usually comes from the larger company but can be split in cases of territory exclusive licenses or co-development agreements.

## Structure
- Commercial rights globally or in a specific territory
- For all indications or for a one or a subset of specific indications
- For all customers or for specific customer segments (field limited rights)

## Risks
- Do you have the right partner?
- Partner priorities
- Partner changes

## Key Questions
- Speed of trials, initiation of research, legal review time, evaluation / approval delays, go/no go timing
# Commercial Agreement

<table>
<thead>
<tr>
<th>Benefits</th>
<th>• For more developed products and platforms, commercial agreements can be quite advantageous for each party</th>
</tr>
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<tbody>
<tr>
<td>Funding</td>
<td>• Mechanisms can be used that are unique to the product such as various sales royalties, milestones, revenue guarantees, sales &amp; marketing funding, manufacturing agreements, and equity agreements, etc.</td>
</tr>
<tr>
<td>Structure</td>
<td>• Agreements can span or divide territories, indications, or customer types</td>
</tr>
<tr>
<td></td>
<td>• Licensors can thereby realize value from one area of an asset to fund value in another area</td>
</tr>
<tr>
<td>Risks</td>
<td>• Market changes</td>
</tr>
<tr>
<td></td>
<td>• Partner changes</td>
</tr>
<tr>
<td></td>
<td>• Co-opetition</td>
</tr>
<tr>
<td>Key Questions</td>
<td>• Who are the partners that can add the greatest value?</td>
</tr>
<tr>
<td></td>
<td>• What will be the right partnership to maximize the value of the asset?</td>
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</table>
Example: J&J’s (Ortho) Commercial “Agreement” with Amgen

The first approved erythropoietin product was epoetin alfa (Epo), from Amgen under the proprietary name EPOGEN. Ortho Biotech, a subsidiary of Johnson & Johnson, licensed the product to sell it under the proprietary name PROCRIT. EPOGEN/PROCRIT was approved with the following indication:

“treatment of anemia associated with chronic renal failure, including patients on dialysis (end stage renal disease) and patients not on dialysis.”

Under the contract, Ortho gained rights to development and marketing for any indication other than for the treatment of anemia associated with chronic renal failure. Epogen and Procrit had identical labeling information for all approved indications based on development programs conducted by Amgen or Ortho.

At the time, Amgen’s commercial department was small and according to many insiders, learned a great deal from Ortho’s experience, sales, commercial best practices…and legal.
# Acquisition Options

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Funds, stock, or combinations from the acquirer</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Perhaps the most nuanced deal for the licensor can be an acquisition or option for acquisition… “When do we sell the company?”</td>
<td></td>
</tr>
<tr>
<td>Structure</td>
<td></td>
</tr>
<tr>
<td>• Purchase prices can be based on development or commercial milestones</td>
<td></td>
</tr>
<tr>
<td>• Purchasing the company or just a lead asset?</td>
<td></td>
</tr>
<tr>
<td>Risks</td>
<td></td>
</tr>
<tr>
<td>• Balancing of risk and return with various risk-mitigations</td>
<td></td>
</tr>
<tr>
<td>• Purchase price can be calculated on an equation that can benefit the larger company</td>
<td></td>
</tr>
<tr>
<td>Key Questions</td>
<td></td>
</tr>
<tr>
<td>• “Locking up” the acquisition target company</td>
<td></td>
</tr>
<tr>
<td>• Can limit a smaller company’s ability to raise additional capital because it can limit the upside of new investors</td>
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Example: Myriad purchasing Crescendo

- Myriad Genetics made a $25 million debt investment with an interest rate of 6% into Crescendo Bioscience and secured a three-year option to purchase the developer of molecular diagnostics targeting autoimmune diseases.

- Separate from Myriad's investment, Crescendo said that it had completed its $31 million in Series C equity financing.

- The acquisition of Crescendo would expand Myriad's portfolio of tests as a sixth disease specialty.

- Myriad's option to purchase Crescendo may be exercised if it attains minimum revenue milestones during the three-year option period. *If those milestones were achieved, the sales price would be based on a predetermined multiple of revenue based on the growth rate of Crescendo at the time of the option exercise.* If the milestones are not met, Myriad will have a one-time right to acquire Crescendo for a fixed purchase price in lieu of the formula.
Some advanced topics…

- Non-binding term sheets: when they are useful.
- Managing diligence and liabilities: reps and warranties.
- When things go wrong: indemnities can be helpful but are limited.
- Strategic Alliances: multi-party deals or “coopetition.”
- Competitive protections: how to protect against competitive intel
- Legal experience: there’s a reason why big pharma can be slow to review legal documents
- Getting the best deal: does not usually mean negotiating for the maximal value share.
The BD process – Execute the deal and Measure success

1. Identify the Gap
2. Determine the Vehicle to Fill the Gap
3. Execute
4. Measure Success
Executing the Deal

- How do individuals work with stakeholders to structure a deal?
- How do you finalize and “get a deal over the finish line?”
- How do you measure success?
- How can companies maximize success after deal completion?
Processing a Deal...get to know your legal council

Internal Alignment  Partner Integration  Scope & Structure  Legal/Contracting

Signatures, Press releases, Finance, etc.

Corporate approvals

Finance Sign-off

Priority Integration

execute

Business Development for Basic Scientists

06/08/2016
How can one maximize success? Deals take all forms but it starts with communication

Feedback loops create transparency and accountability:

- **Weekly**: Calls with team leads
- **Monthly**: Project management updates, Update points-of-contact
- **Quarterly**: Financial reviews
- **Annually**: Deal evaluation, Project updates
How can one maximize success? Deals take all forms but it starts with communication.

Feedback loops create transparency and accountability:

- **Weekly**
  - Calls with team leads

- **Monthly**
  - Project management updates
  - Update points-of-contact

- **Quarterly**
  - Financial reviews

- **Annually**
  - Deal evaluation
  - Project updates

Point-of-contacts for contracts, finance, R&D, commercial, etc.

Clear mechanisms for dispute resolution
Key Understandings

- Realizing that completing a multi-year project by signing a deal is the completion...

  ...Of starting the relationship and not even the first chapter in the book

- Deals (~30%) get clarified, renegotiated, and “revised”
Example: Renegotiating / Updating a Deal

12 Years of Regeneron / Sanofi Deal Evolution. Highlights:

- 2003. Aventis (acquired by Sanofi) signs an agreement to do drug development with the VEGF-Trap technology. Aventis/Sanofi takes a 4% equity stake.

- 2007. Sanofi collaborates on new antibody discovery and development, pays $85M upfront and up to $475M R&D, $250M in sales milestones. Sanofi increases ownership to 19%.


- 2013. Sanofi increases its ownership stake in Regeneron.

- 2013. Regeneron pays Sanofi $20M upfront plus milestones for ophthalmology compounds previously included in the collaboration.

- 2015. Companies launch new collaboration in immunotherapy. Regeneron will be responsible for discovery, antibody generation and development through POC, Sanofi has the ability to opt-in. The companies will alternate serving as the lead development and commercialization organization after Sanofi opts-in to an antibody program, also alternating leads worldwide. Companies share profits equally.
Formulas for Disastrous Business Development

Put personal interests first:

- Individuals on either side that seek to advance their careers rather than the interests of their company
- Negotiators who are trying to squeeze the other side for the absolute best deal
- Individuals that are inflexible (i.e., are overly set on specific deal terms or deal types)

Poor communicators or planners:

- Individuals that don’t listen (e.g., to the other sides’ needs)
- Individuals that don’t anticipate issues (anything that could go wrong…)
- Individuals that don’t “listen to the science.”
A Few Hallmarks of Outstanding Business Development

**Relationship Building:**

- Individuals that establish fundamental trust – when things go well and when they go poorly
- Individuals that listen not only to what is said, but to what isn’t shared verbally
- Individuals that find creative solutions to not only their internal company issues but their partners’ constraints and challenges
- Individuals that know that the relationship is only beginning once the “deal is done” (the contracts are signed)
The BD timeline reflects both the long term and short term organizational goals

**Search & Evaluation**
Finding the technology, company, and team

**Discussions and Diligence**
Vetting teams, technologies, and deal structures

**Negotiation and Contracting**
Term sheets, contracts, and deal points
Advanced Topics: Developing BD Requires

Analysis of the following areas:

- Scientific: discovery, dev, lead op, CMC, ADME, pre-clinical
- Therapeutic: clinical trials, guidelines, integration of care
- Commercial: clinical use, TPP, TAM, PAM, Regional uses
- Finance: reimbursement, global payments, royalties, stacking

Use of the following skills sets:

- Curiosity
- Patience
- Clear verbal and written communication
- Working with people!
Parallels to Academia: Q&A with Anatol

- What vehicles could the lab bring to meet its goals?
- How do you establish collaborations?
- How do you structure collaborations?
- What do you negotiate in a collaboration?
- Can you share an example of a deal gone bad?
Case study

Break-out groups for discussion

- Choose 1: large company licensing a technology, small company looking to license OR academia
- Choose a note taker and a presenter.
BD course objectives

You should now be able to:

1. Define Business Development
2. Identify steps in the BD process
3. Understand how Business Development contributes to a business’ vision and goals
4. Describe different vehicles that Business Development can leverage to accomplish their objectives
5. Describe successful deal structures
Wrap Up

Resources to learn business development

- UCSF courses
- Coursera or iTunes University
- Harvard Business Review (HBR)
- FierceBiotech daily newsletter (or sister publications)
- Earnings calls from public companies of interest