



iJobs Workshop: Business Development Case Study

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About Me

- Professional with over 16 years of experience in the life science regulated industry, spanning from pharmaceuticals, biotechnology, medical device, and cell & gene therapy.
- Co-Founder and President of a Tech Start-up Company – Software Solution Service Provider (B2B)

About Business Development

Management team recruitment

Phasing in or out of markets or products

Arranging strategic alliances

Identifying and acquiring companies

Securing corporate financing

Divesting of assets or divisions

Management of intellectual property

01

Vision

02

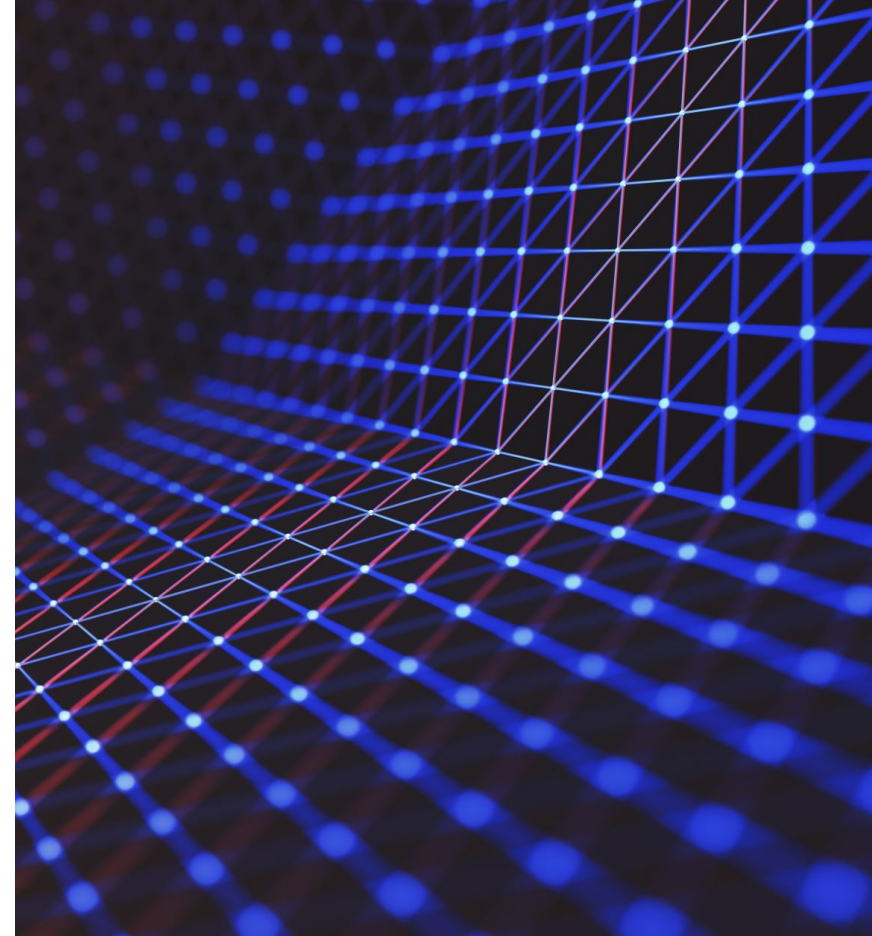
Strategy and
Execution

03

Commerciali-
-zation

Stages of Business Development

Disclaimer: This was a BD model used by a generic commercial pharmaceutical company.



Accounting and Finance Overview



Balance Sheet

Assets = Liabilities + Equity



Income Statement

Also known as “Profit or Loss”



Cash Flow Statement

Cash inflow / outflow

Simulation

A Case Study

- A Business Development Analyst in a pharmaceutical company in New Jersey
- Lost market share due to various factors
- Excessive pharmaceutical finished goods inventory that are nearing expiration date
- Operating income is less than 50% of the target for the given fiscal year

Scenario

What would you do?
What would be your
“Creative Solution”?





Potential Market

The global animal health market size is expected to reach 64.6 billion USD by 2025.

Source: Grand View Research, Inc.

\$1M Question

Can the marketed human pharmaceutical drug products be sold to the veterinary market?

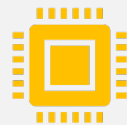
Required Tools



Access to Company Portfolio (e.g., List of NDA / ANDA)



Access to the Marketing Research Platform (e.g., IQVIA, etc.)



Access to Competitive Analysis Tool (e.g., Oracle ERP Business Intelligence Platform)



Internet (e.g., FDA Website)

Groups

(3-4 Members / Group)

- Group 1 – Bethamethasone Dipropionate
- Group 2 – Clindamycin Hydrochloride
- Group 3 – Doxycycline Hyclate
- Group 4 – Fluocinolone Acetonide
- Group 5 – Gentamicin Sulfate

Business Development Planning

Example: Nystatin Topical Cream

- 1) Assess existing inventory pipeline
- 2) Gather information from the FDA “Green” Book (e.g., drug information, exclusivity, competitors labeling, etc.)
- 3) Conduct Competitor Analysis (e.g., SWOT Analysis, Market Share Analysis)
- 4) Research the regulatory requirements (e.g., FDA, Regulatory Affairs)
- 5) Perform Financial Analysis (e.g., Net Present Value (NPV))

Step 1

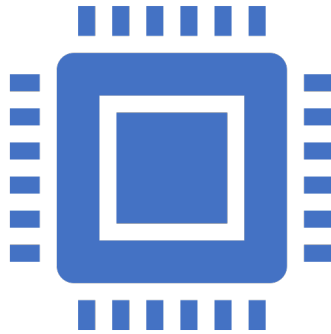


- 1) Prepare a list of active, approved NDA / ANDA
 - ✓ Excessive inventory
 - ✓ Near expiring

Step 2

- 1) Compare the list of active, approved NDA / ANDA against the list of FDA's Approved Animal Drug Products (Green Book)
- 1) Identify the API in the Green Book against the active, approved NDA / ANDA list.

Step 3



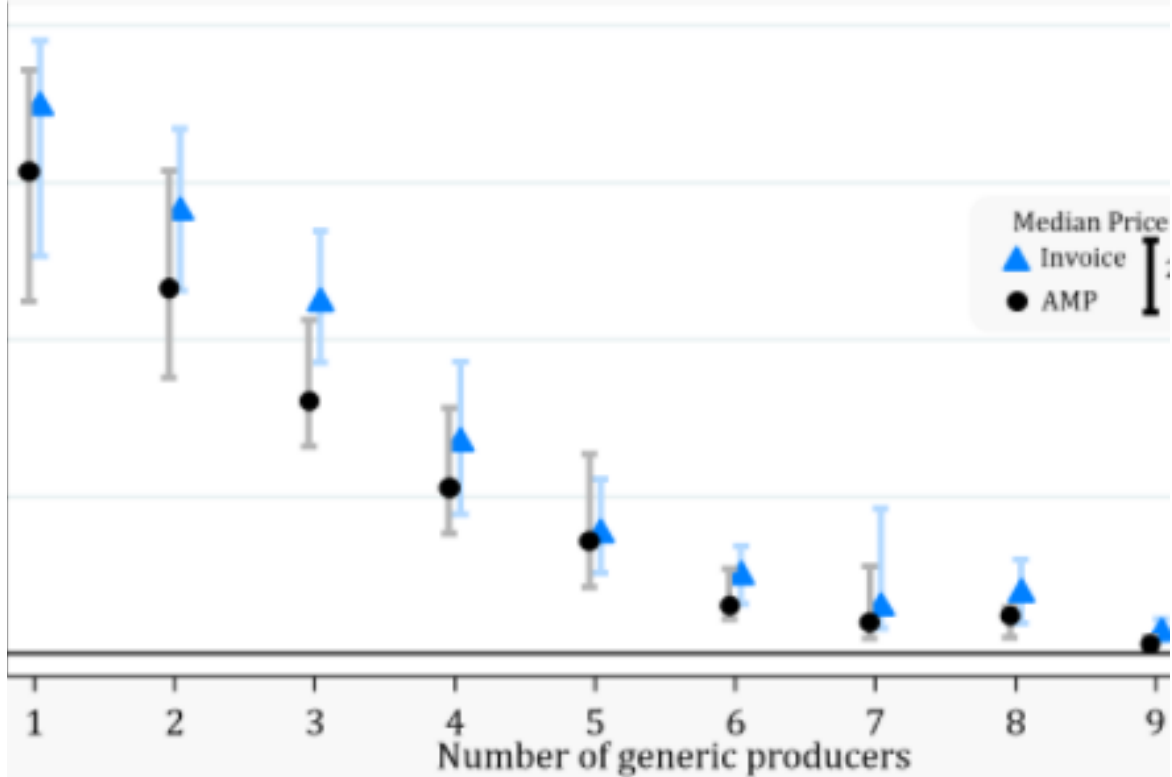
Identify potential competitors or drug sponsor from the Green Book (include API that matches your firm's API)



Identify the market share via application / subscription

Generic Competition and Drug Prices

Median generic prices relative to brand price before generic



Generic drug products with initial generic entry from 2015-2017.
Based on IQVIA NSP invoice-based sales and units sold to pharmacies (▲) and average manufacturer prices (AMP) reported to CMS (●).

Price per dosage form is important

Source: FDA Website: Generic Competition and Drug Prices

Step 4

1) Understand Regulatory requirements

- Requirements to proceed to manufacturing and marketing products

Regulatory Requirements

The information in the ANADA must show that the generic copy has the same quality, performance, and intended use as the approved brand name drug.

The drug sponsor must prove to CVM that the generic copy is the same as the approved brand name animal drug in:

- Active Ingredient
- Strength
- Dosage form
- Dosage regiment, including route of administration

Regulatory Requirements (Cont'd)

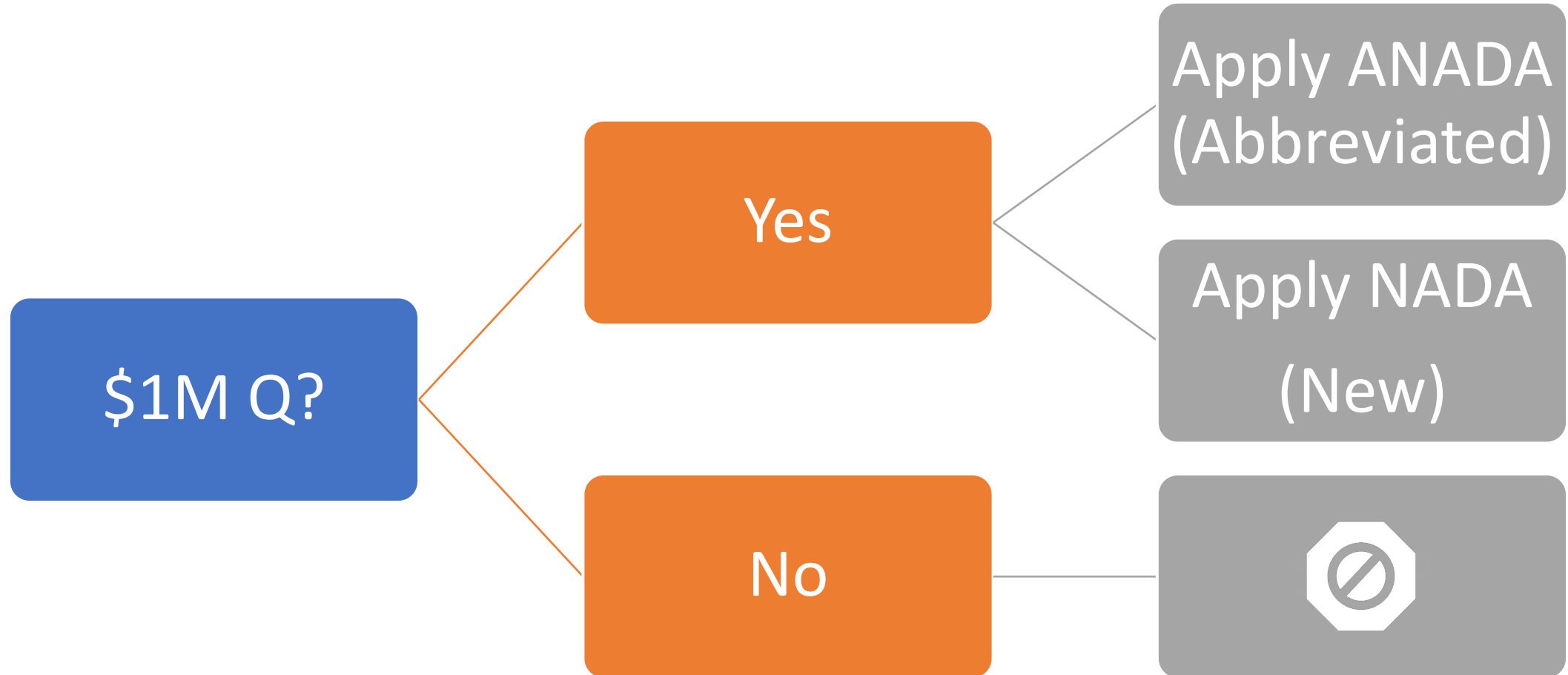
- The labeling for the generic copy must match the labeling for the approved brand name animal drug.
- The Animal Generic Drug User Fee Act authorized CVM to collect fees from drug sponsors to support the center's review of generic animal drugs.

Step 5

- Calculate the Net Present Value (NPV)
- Document Assumptions



Decision Tree



Team's Verdict and Rationale

Group 1	Go or No Go
Group 2	Go or No Go
Group 3	Go or No Go
Group 4	Go or No Go
Group 5	Go or No Go



Alternatives

Would it be safer to use other pain-relief products approved for human use to companion animals?

NO.

These pain-relief products are not good alternative to the approved veterinary products. In fact, besides not being approved for use in companion animals, they can pose even more adverse reaction risks for dogs. The use of an approved product is always preferable because its safety and effectiveness have been reviewed. While it is true that approved products can have adverse events associated with them and reported to FDA, it is true that FDA works with the sponsor to address these events and improve the ability of the product to be more safely used. There is no reporting requirement for unapproved products.