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iJobs Workshop: Business Development Case Study

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Co-Founder and CEO of JABED Tech Solution



- Professional with over 15 years of experience in the life science regulated companies.
- Degrees: BS@NJIT, MS@NJIT (with Grad Cert in PM), EMBA@Rutgers
- Professional Certifications: CLSSBB, ASQ CQA, CMQ /OE*
- Founder and CEO of a Tech Start-up Company

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



Vision

STAGES



Strategy & Execution



Commercialization







Balance Sheet

Income Statement

Cash Flow Statement

Accounting and Finance Overview

Asset	Liabilities	Owner's Equity
Current Assets	Current Liabilities	Paid in Capital
Fixed Assets	Non-current Liabilities	Retained Earnings
Intangible Assets		

Balance Sheet

Assets = Liabilities + Equity

Income Statement

Also, known as "Profit or Loss"

Revenue

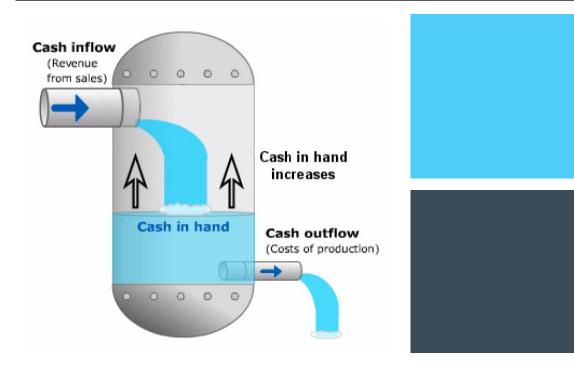
- Variable Costs

Gross Profit

- Fixed Costs

Net Profit (Loss)

Cash Flow Statement



- Operating Activities
- Financing Activities
- Investment Activities

Analysis Tools

Horizontal (Trend) Analysis

• Evaluates a series of financial statement data over a time period.

Vertical Analysis

• Expresses each item in a financial statement as a percent of a base amount.

Ratio Analysis

• Expresses the relationship among selected items of financial statement data.

Ratio Analysis



1) Liquidity Ratio

Current Ratio

Current Asset

• Current Liabilities

Quick Ratio

• (Current Assets – Inventory)

• Current Liabilities

Inventory Turnover Ratio

Raw Material

• (Average inventory / Material usages) x 365 days

Work In Progress

• (Average inventory / Production cost) x 365 days

Finished Goods

• (Average Inventory / Cost of Goods Sold) x 365 days

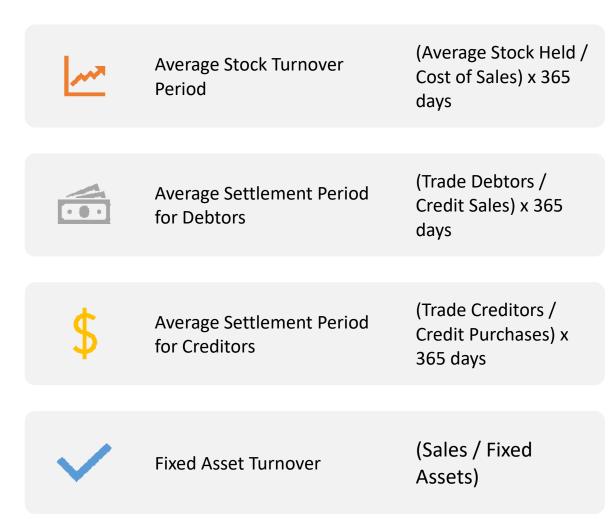
2) Working Capital Ratio

3) Asset Turnover Ratio

- Depending on the different concepts of assets employed, there are many variants of this ratio. These ratios measure the efficiency of a firm in managing and utilizing its assets.
 - Total Asset Turnover Ratio
 - (Sales / Cost of Goods Sold) / Average Total Assets
 - Fixed Asset Turnover Ratio
 - (Sales / Cost of Goods Sold) / Average Fixed Assets
- Higher ratios are indicative of efficient management and utilization of resources while low ratios are indicative of under-utilization of resources and presence of idle capacity.



4) Efficiency Ratio



NP	Net Profit of Sales Ratio = Net Income / Net Sales
GP	Gross Profit Margin = Gross Profit / Net Sales
ROA	Return on Assets = (Net Income + Interest Expense) / Average Assets
ROE	Return on Equity = (Net Income + Preferred Dividends) / Average Common Equity

5) Profitability Ratio

Advantages of Ratio Analysis

- Allows for comparison of companies to be made despite size of the companies.
- Ratios provide information that raw data cannot.
- Large companies can be compared reliably to smaller companies.
- Companies can be evaluated across industries.
- Trends of growth, increased performance, and deterioration within the firm can be evaluated against itself, as well as across the industry.

Limitations of Ratio Analysis

- All formulas are only as good at the input data.
- The ratios are calculated based on accounting data provided by the company.
- Accounting procedures may differ, or data may not be as reliable as another firm's data.
- When comparing past rates, for example, inflation may skew interpretations

Net Present Value



- If the NPV is a **positive** number, **accept** it.
- If the NPV is **negative** number, **reject** it.
- If all NPV numbers for the project are **positive**, **rank** it in descending order.



SCENARIO



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



What should you do?

What are your "Creative Solutions"?





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

Source: Grand View Research, Inc.

POTENTIAL MARKET



\$1M QUESTION

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

Groupings

(3 - 4 Members / Group)

Group 1 – Bethamethasone Valerate

Group 2 – Clindamycin Hydrochloride

Group 3 – Doxycycline Hyclate

Group 4 – Fluocinolone Acetonide

Group 5 – Gentamicin Sulfate

Group 6 – Nystatin

Group 7 – Triamcinolone Acetonide



PROPOSED ACTIONS:

- 1. Assess existing inventory / pipeline
- 2. FDA Green Book (e.g., drug information, exclusivity, competitors, labeling, etc.)
- Conduct Competition Analysis (e.g., Market Share Analysis)
- 4. Perform Financial Analysis (e.g., NPV)

Prepare a list of active, approved NDA/ANDA

Prepare a list of expiring pharmaceutical finished goods

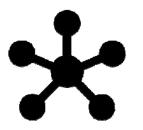


Compare the list of active, approved ANDA /NDA against the list of FDA's Approved Animal Drug Products (Green Book)



Identify API in the Green Book that your firm have ANDA.

Step 3



Identify market share, competitors, and their ANADA (include API that matches your firm's API)

Step 4

Understand Regulatory requirements

Requirements to Proceed Marketing Product

The information in the ANADA must show that the generic copy has the same quality, performance, and intended uses 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 regimen, including route of administration.



The labeling for the generic copy must match the labeling for the approved brand name animal drug.



The Animal Generic Drug User Fee Act (AGDUFA) authorizes CVM to collect fees from drug sponsors to support the center's review of generic animal drugs.

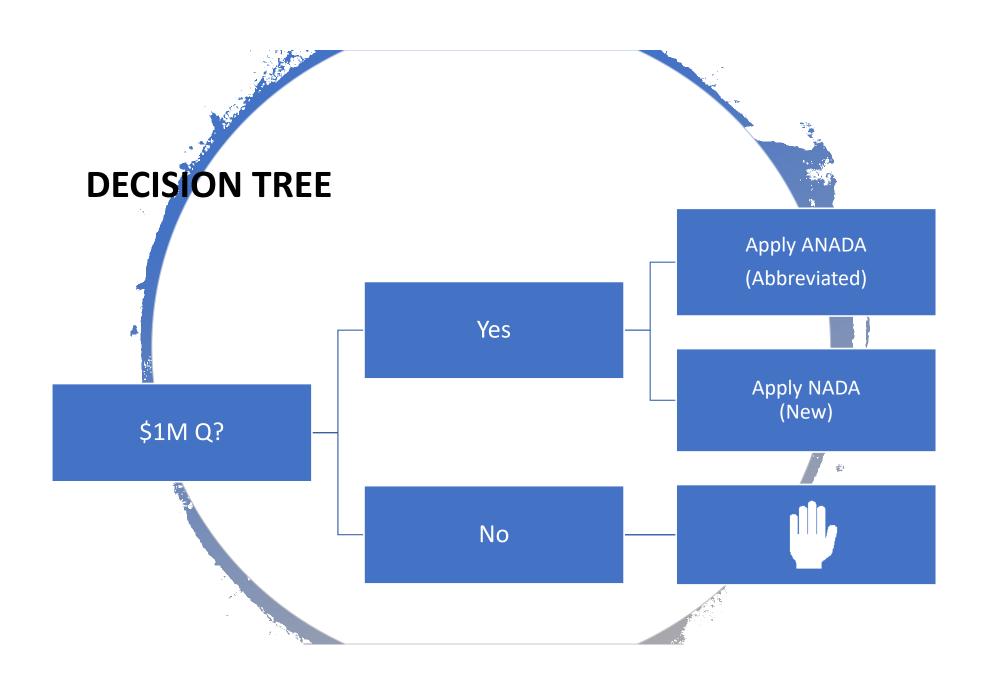
Requirements to Proceed Marketing Product

Step 5

Calculate the Net Present Value (NPV)

• Document assumptions





Group 1 –
Group 2 –
Group 3 –
Group 4 –
Group 5 –
Group 6 –
Group 7 –

NPV

Team
Decision

Group 1 –

Group 2 –

Group 3 –

Group 4 –

Group 5 –

Group 6 –

Group 7 –

Would it be safer to use other pain-relief products approved for use in humans?

- No
 - These pain-relief products are not good alternatives 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 also 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.

QUESTIONS?

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