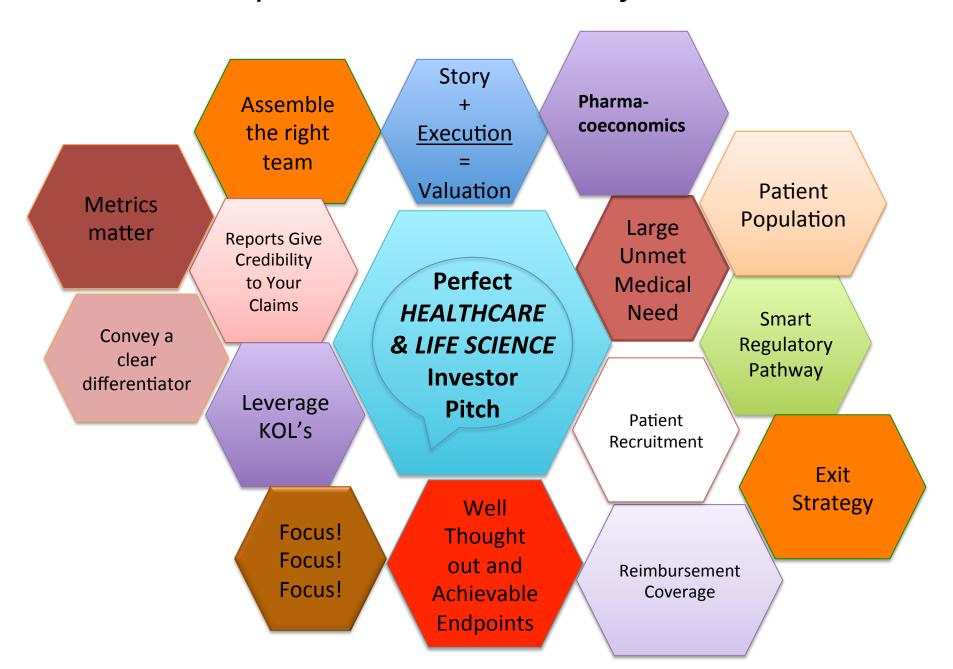
How to test your biotech entrepreneurial business plan

March 21, 2017

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Kaminski Partners – Healthcare Investment Banking

What Entrepreneurs **Must** Convey to Investors



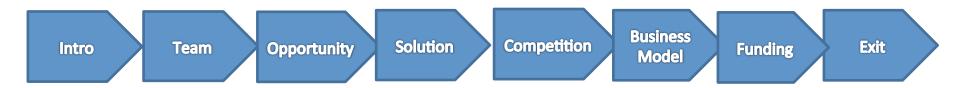
The Spheres of Success



"If you can't explain it to a six year old, you don't understand it yourself."

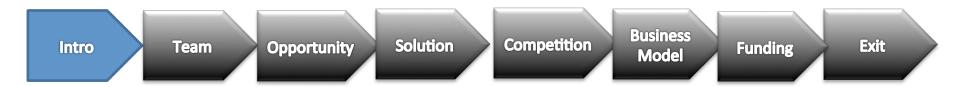
— Albert Einstein

The Life Science Investor Presentation Template



- Intro: Define the company, business, service or product in a single sentence.
- > **Team**: Identify the core group of talent that can execute on the next set of milestones.
- > **Opportunity**: Establish the need for your company's solution and the size of the market.
- > **Solution**: Demonstrate how you will solve the problem and validate your differentiation.
- > **Competition**: Identify your competitors, validate your differentiator.
- > **Business Model**: Explain how you will generate revenue, show us what you've accomplished to date, and make future forecasts.
- Funding Required & Use of Funds
- Exit: Outline recent exit activity in your therapeutic area(s)

Introduction



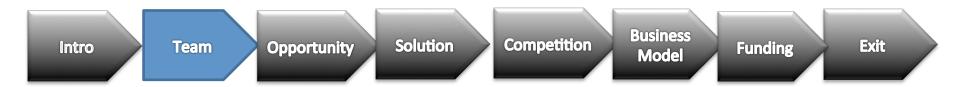
Tell Investors:

- Give a brief history of the company, when it was started, how it's been funded.
- Define the company, business or product in a single sentence.
- Concisely state your core value proposition, including the target patient market.
- What unique benefit will you provide to what patients to address what medical need?

Goal:

Investors should know the basic idea and value proposition of the company.

Team



Tell Investors:

- Management crisp & relevant experience on key players
- Prior companies/startups
- Educational backgrounds
- Prior exits & IPOs
- Board of Directors
- Board of Advisors (if applicable)
- Key future hires

Goal

Give investors confidence that there is a core group that believes in the company and *can execute the next set of milestones*.

Opportunity



Tell Investors:

- > State the medical need
- Describe the pain
- Why does the medical need persist?.
- Define recent trends that make your so .
- How is it currently addressed? .
- Why are we at an inflection point now?
- Identify the patient market size.
- How does this patient population change and grow over time?

Goal:

Establish the need for your company's solution and convince investors that solving the medical need is worth the effort.

(Clear) Medical Need+(Large) Patient Population= (Great) Opportunity

Opportunity

I. What are the recognized and unrecognized medical needs?

II. How can we best address the unmet need?

 Just because there is a need does not mean there is a viable opportunity. It is critical for companies to clearly define where and how they want to play.

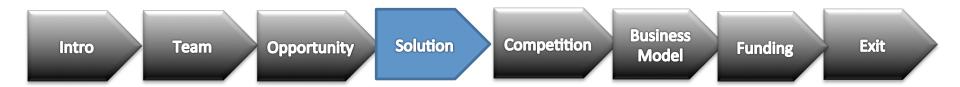
III. Is the science to address the unmet needs differentiated in a clinically relevant way?

- Does the company's science support an improved efficacy, safety or dosing and is it truly differentiated?
- Companies need to carefully assess how their science stacks up in the marketplace versus existing and emerging competition.

IV. Who is the target patient population?

- Who are they? How many are there? How many will there be in the future?
- A company needs to understand the real sub-population for a given indication and the need. It is critical to accurately define the commercial opportunity.

Solution



Tell Investors:

- Demonstrate your solution.
- Validate your differentiation.
- Explain your technology / IP.
- > How is the new solution better?
- Help us understand how you will solve the problem.
- Clearly quantify three or four key benefits you provide, and who specifically
- realizes these benefits. (Pharmacoeconomics)
- Patent approval status or status of key regulatory approvals

Goal:

Help us understand how you will solve the problem.

The Market

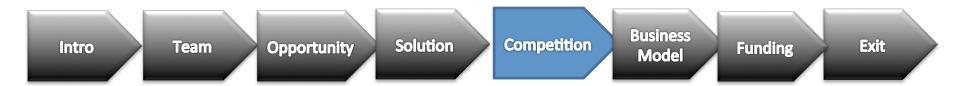
After defining the market, a company needs to ask itself;

- ◆ Whether it is going to play in that market, or EXIT and the end of Phase n
- ◆ How can it (or the acquirer) win
- ◆ Who is it (or the acquirer) going to have to fight with to get its fair share of the market.
- I. Who are the prescribers and what do they think?
 - Engage KOLs
 - > They help shape and design evolving treatment guidelines
 - A company must be able to obtain those professional medical practitioner insights that underlie the successful development and ultimate adoption of a given product.
 - Drive qualitative discussions and quantitative surveys with these stakeholders
- II. How intense is the competitive landscape?
 - Identification of those emerging market entrants
 - makes an impact analysis necessary for defining the evolving opportunity and assessing how the commercial opportunity could possibly be reduced.
 - The product landscape of the future needs to be defined in terms of both direct and indirect competition

The Market

- II. How intense is the competitive landscape? (cont.)
- Competitive Pipelines
 - Important to quantify the potential impact of
 - Important to quantify the order into the market of
 - Just as important to value the impact of indirect competition, particularly in the treatment algorithm.
 - A guideline for therapy linked to information on a number of parameters and a decision tree..(See next slide)
 - The continuing emergence of bio-markers and companion diagnostics will also revolutionize the use and the application of assets in development

Competition



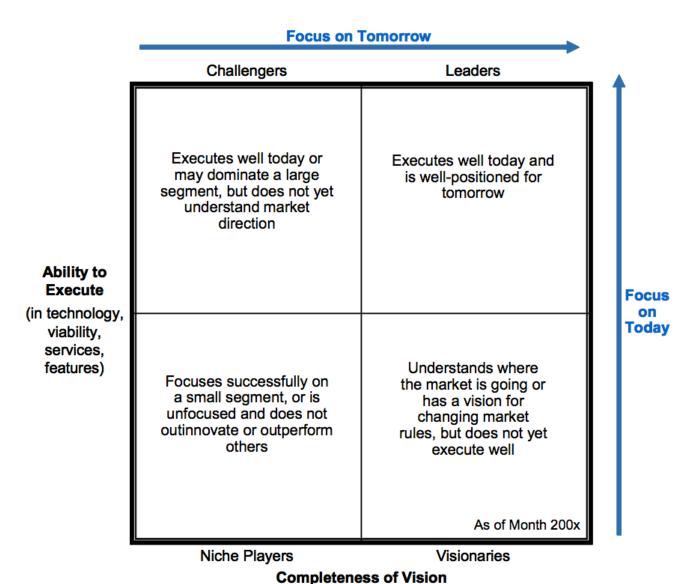
Tell Investors:

- Competitive matrix with: Strengths & weaknesses . Metrics . Investors of competitors
- Where do you play in the environment outlined above? » How does this market change over time?

Goal:

Help us understand who you compete with, why you have a better product or solution and how you can win.

Competition Example 2 (MQ)



(in technology, viability, services, features)

Competition Example 1 (Matrix)

	feature A	feature B	feature C
your company	yes	yes	yes
competitor 1	no	NO	yes
competitor 2	110	yes	yes
competitor 3	yes	*10	NO

Business Model



Tell Investors:

- Revenue model & metrics
- Pricing, average account size, lifetime value, churn, views, uniques, registered users, sub base, etc.
- Sales & distribution model, customer pipeline, wins and metrics What milestones are you going to realistically hit with the new capital?

Goal:

Tell investors how you will generate revenue; show what you will accomplish in a given period of time.

Business Model

Two Essential Questions on Investors' Minds

- What are the revenues and
- How do you mitigate risk and preserve and realize the maximum value?
- I. What are the potential revenues associated with this opportunity?
- This information can be broken up into four key buckets:
 - Target Patients (Epidemiology, Diagnosed, Treated, Access)
 - Volume (Persistence, Compliance, Dosing)
 - > Share (Analogs, Attributes, Adoption, Penetration, Cannibalization)
 - ➤ Game Changers/Event Impact Analysis, e.g. generic entry, new launches

Financials

I. Background

it is critical to develop a rNPV to ensure that the true value is thoroughly understood inside the organization. Clinical development and operating costs are built in, cash flow streams through the life cycle of the compound are generated utilizing the revenue forecast and cost assumptions and then these streams are risk adjusted for the probabilities of success or failure. These resulting risk adjusted cash flows are finally discounted for the opportunity cost of capital, either company or project specific.

II. It's all About the Assumptions

In an opportunity assessment and a product development process that can easily involve a decade, decisions are made and values accepted on the basis of assumptions and not on the numbers themselves.

USE "PAINTING WITH NUMBERS" by Randall Bolten Painting-with-Numbers.com

Funding



Tell Investors:

- > Financials, including prior backers, date(s) and amount of investments
- Valuation expectations
- Amount you are looking to raise
- Milestones you will hit with the new capital
- > Your burn rate
- How much runway will the new money buy (pro forma burn)
- Post-money of the last round

Goal:

Outline what you need from investors to make your business a success and what you are looking for in an investor

Use of Funds

Risk Mitigation

How can risk be managed, value preserved and resources allocated in an optimal way?

I. Use of Funds

II. Risk mitigation

- identifying possible partnerships, options assessments, follow-on products and portfolio synergies – all of which need to be assessed together to preserve individual project and total value for the corporation.
- A key element in this analysis is laying out the clinical development uncertainty measured through asset specific probabilities of technical and regulatory success (PTRS).
- A useful approach to making these kinds of decisions is developing a trade-off analysis among assets to identify portfolio scenarios. This approach is different from stand-alone valuations that are rolled up into a single portfolio of a given value. Instead, the true value of the company's portfolio is optimized by providing an understanding of the effect of asset interdependencies on the total value of the portfolio. It is also necessary to recognize that these values are ever-changing and dynamic as events happen; thus, portfolio values require consistent monitoring

Exit



Tell Investors:

- You know the marketplace
- You have a clear vision for exit

Goal:

Outline how compelling your business thesis is (the therapeutic area has big, early exits)

Appendix A

Resource Materials by Topic

The "Pharmaco's"

- <u>Pharmacodynamics</u> is the study of the biochemical and physiological effects of drugs on the body or on microorganisms or parasites within or on the body and the mechanisms of drug action and the relationship between drug concentration and effect. One dominant example is drug-receptor interactions
- <u>Pharmacovigilance</u> (abbreviated PV or PhV) is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects particularly long term and short term side effects of medicines.
- <u>Pharmacokinetics</u>, sometimes abbreviated as **PK**, is a branch of pharmacology dedicated to the determination of the fate of substances administered externally to a living organism.
- <u>Pharmacokinetics</u> may be simply defined as what the body does to the drug, as opposed to pharmacodynamics which may be defined as what the drug does to the body

Pharmacokinetics

Pharmacokinetics is divided into several areas including the extent and rate of absorption, distribution, metabolism and excretion. This is commonly referred to as the ADME scheme:

Absorption - the process of a substance entering the blood circulation.

<u>D</u>istribution - the dispersion or dissemination of substances throughout the fluids and tissues of the body.

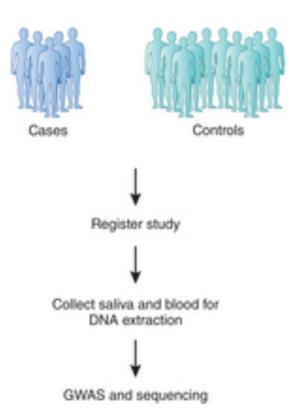
<u>M</u>etabolism (or Biotransformation) - the irreversible transformation of parent compounds into daughter metabolites.

Excretion - the removal of the substances from the body. In rare cases, some drugs irreversibly accumulate in body tissue.

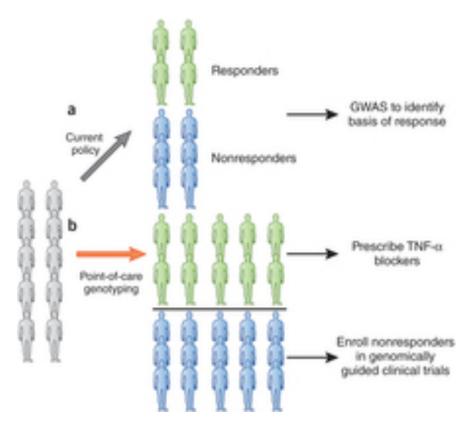
Pharmacoeconomics

What & Why

- I. Genome-wide association studies (GWAS) of responses to drugs
- Leads to the identification of specific patient subgroups that benefit from therapy.







Current & Future Strategies

Appendix B

What Happens Next?

Typically a 2-6 week process

- > First meeting introductory meeting
- > 2nd meeting deep dive + due diligence
- Investors conduct their own assessment of the marketplace, the effectiveness of the solution and the merits of the team
- ➤ Diligence references (personal and customer)
- > Partnership presentation
- > Term sheet negotiation

Appendix C

Entrepreneur Resources

Best General Blogs

http://www.launchfn.com/id172.html

http://www.sramanamitra.com/

http://www.bothsidesofthetable.com/

http://steveblank.com/

http://www.feld.com/

http://www.angeltoolkit.com/

http://markpeterdavis.com/

Best Life Science Blogs

http://lifescivc.com/

Best Life Science Websites

http://www.nature.com/bioent/index.html

http://www.elsevierbi.com/

http://www.ri-val.com/index.html (Valuations)

http://www.ache.org/HEOnline/heonline_index.cfm

Best eHealth & Healthcare IT Websites

http://www.nationalehealth.org/

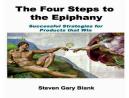
http://www.kaiserhealthnews.org/

http://www.fiercehealthit.com/

http://www.ihealthbeat.org/

Books

The Four Steps to the Epiphany



Business Model Generation by Alexander Osterwalder

Term Sheets & Valuations by Alex Wilmerding

Raising Venture Capital for the Serious Entrepreneur by Dermont Berkery

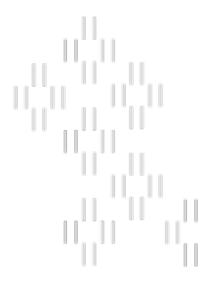
Using Financial Tools

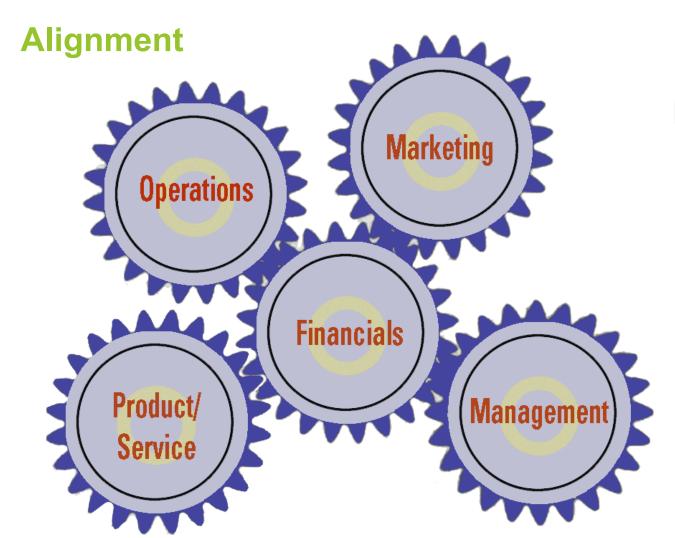




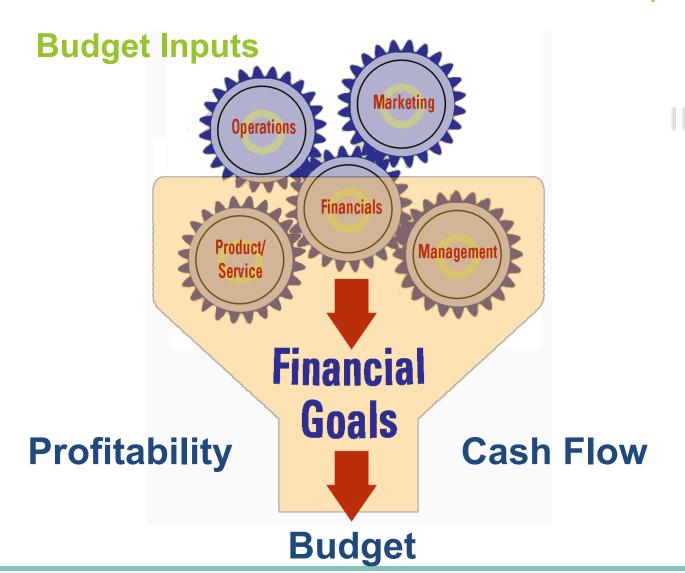
FastTrac® GrowthVenture™ Modules











FastTrac® GrowthVenture™ | Taking Action | Using Financial Tools



Company Info Worksheet

Existing Company Set-Up Worksheet

Sales Worksheet

Inventory Worksheet

Operating Expenses Worksheet

Capital Budget Worksheet

Equity & Debt Worksheet

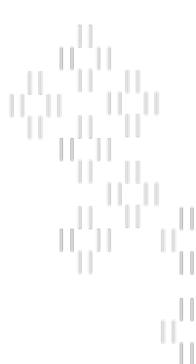
Amortization Schedule for Debt





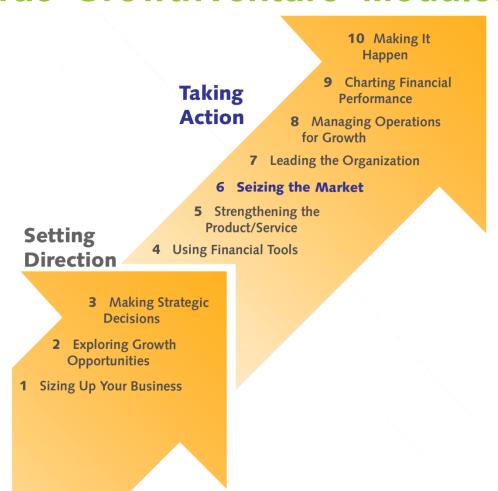


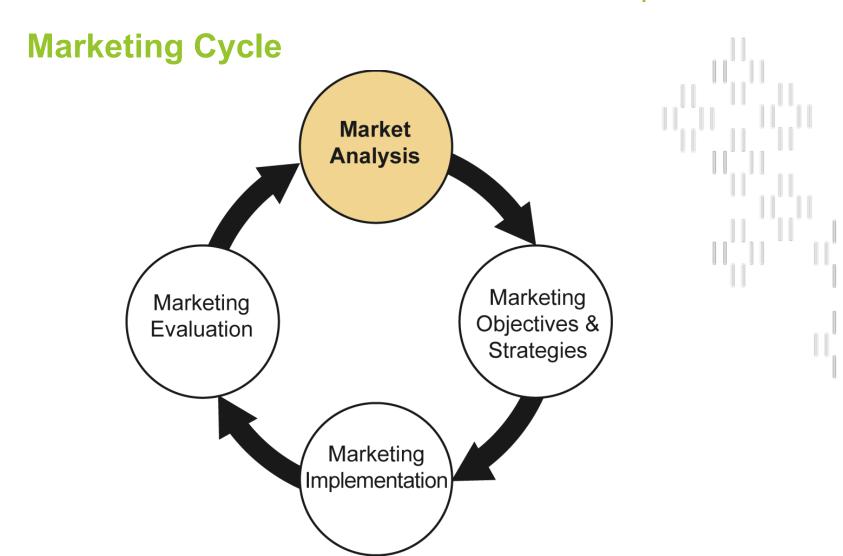
Seizing the Market





FastTrac[®] GrowthVenture™ Modules

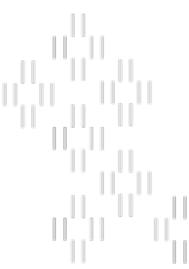




Market Analysis

- Industry Profile
- Competitive Analysis
- Target Market Analysis





Industry Profile

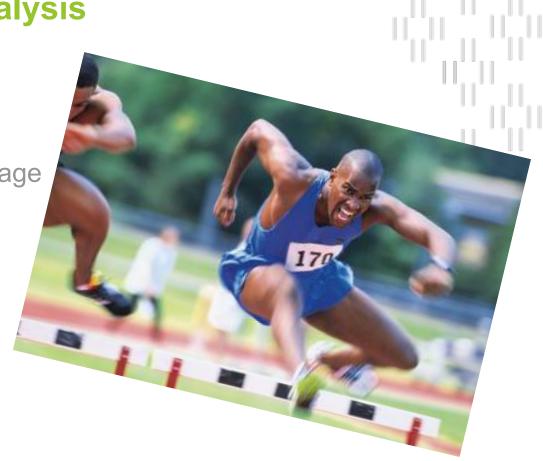


- Size
- Growth Potential
- Trends
- Other Characteristics
- Distribution Channels

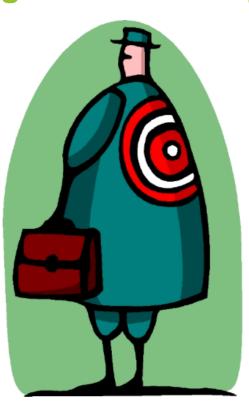


Competitive Analysis

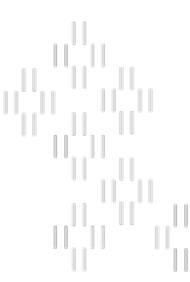
- Direct competition
- Indirect competition
- Future competition
- Competitive advantage

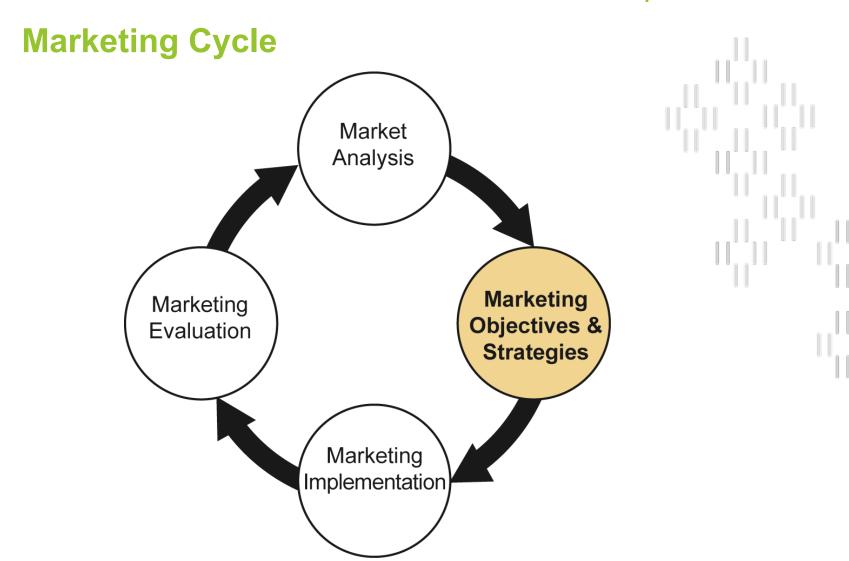


Target Market Analysis



- Target Market Profile
- Customer Profile
- Future Markets

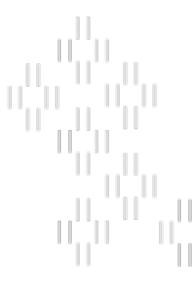




Marketing Objectives



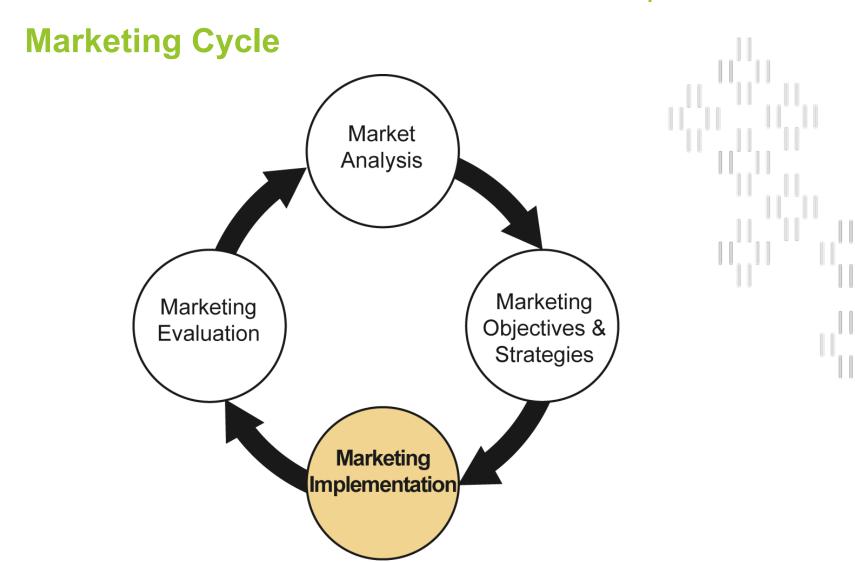
- Target market
- Distribution
- Market penetration
- Sales revenues & transactions
- Pricing



Types of Marketing Strategies

- Branding
- Visibility
- Sales and distribution
- Exceptional customer experiences

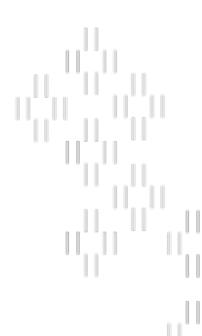




Marketing Implementation

Effective Marketing Activities

- Reach the target market.
- Provide a variety of ways to promote the business including advertising, publicity, and promotion.
- Fit within the resources—time, money, and people.
- Align with marketing strategies and objectives.



Marketing Implementation

Marketing Activities Schedule

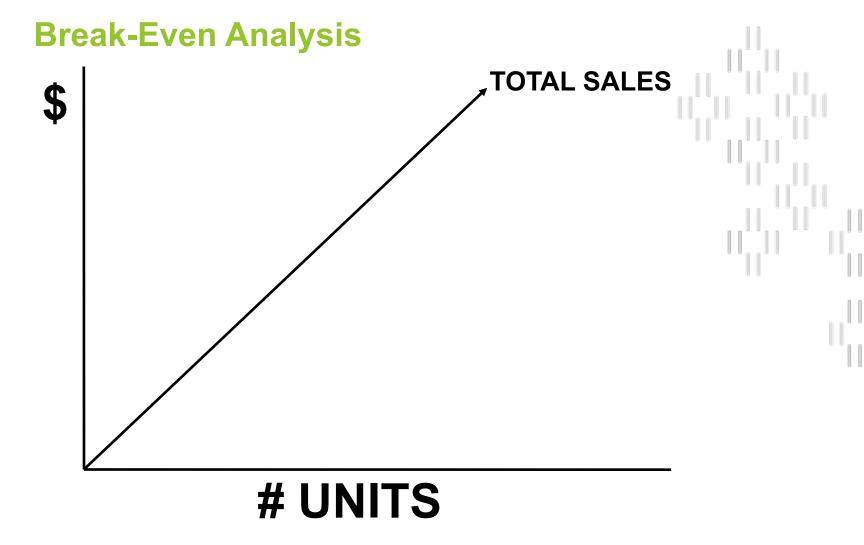
- Identifies which activities will be implemented for the time period.
- Provides focus for marketing initiatives.
- Forecasts and allocates marketing resources.
- Can be implemented in-house or outsourced.

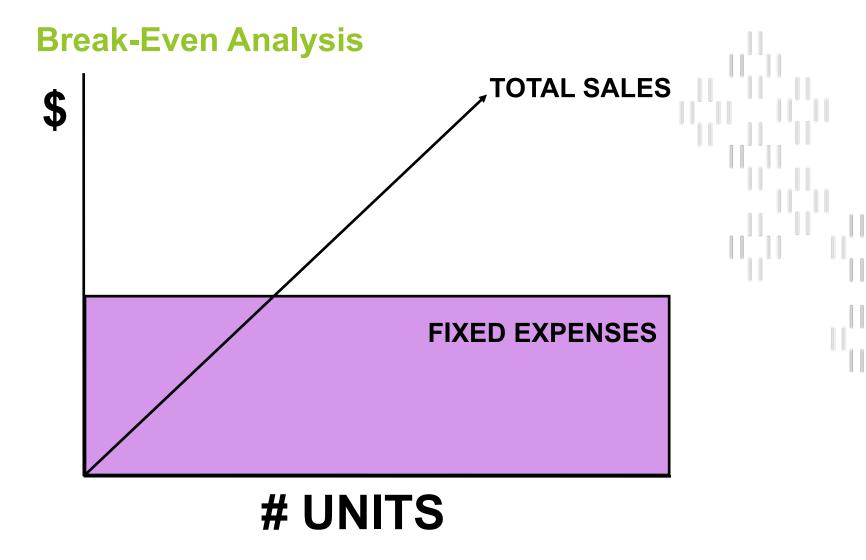


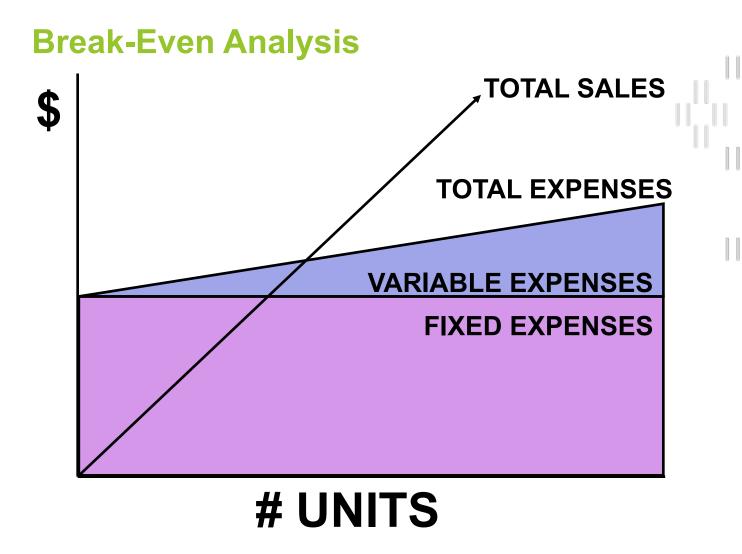


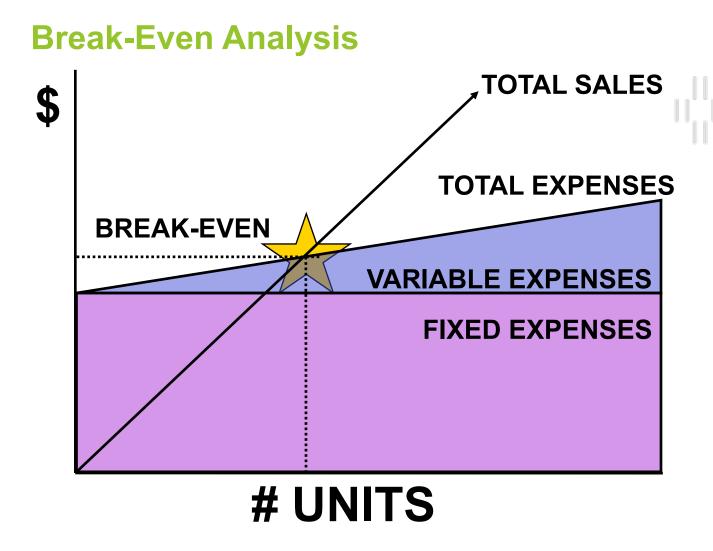
Break-Even Analysis







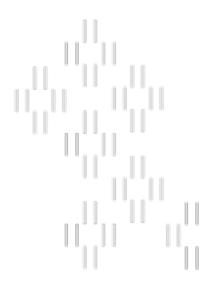






Midwest Lab Services

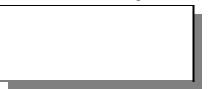
Income Statement	Total	Per Unit
Units		1
Sales		
Cost of Sales (Variable)		
Gross Margin		
Operating Costs (Fixed)		
Net Profit		

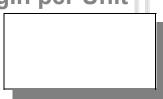




Midwest Lab Services







Break-Even Total Sales = Fixed Costs / Gross Margin %







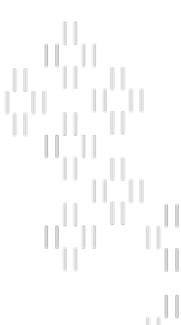
Leading Change



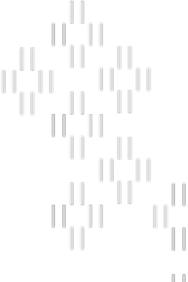


Leading Change

- Opportunities and growth result in the need to make changes within the business.
- Effective planning and implementation can mitigate the risks and obstacles associated with change.
- Leadership plays a vital role in the success of change initiatives.



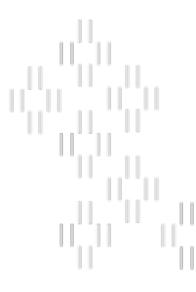
Networking Meeting and Greeting





Networking:

To engage in informal communications for the purpose of building relationships that provide mutual assistance and support.



Selecting an Organization

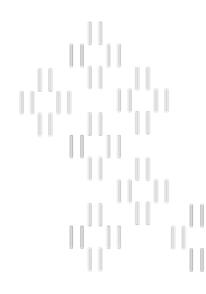
- Are the organization's goals consistent with yours?
- Is the organization a vehicle for individuals to exchange information, ideas, support, and contacts?
- Is the organization's leadership competent and members welcoming?



Greeting

- Identify networking goal.
- Identify ahead of time who you would like to meet.
- Identify in advance what you have to offer.
- Prepare your unique selling proposition.









Answer Key - Break-Even Analysis Activity

What is break-even? Break-even is the point at which net profit is <u>zero</u>.

In order to establish a break-even point, you must distinguish between fixed and variable expenses.

What are fixed expenses? Fixed expenses remain <u>fixed</u> over a period of time, and the level of sales does not influence them.

Examples: Management salaries, utilities, rent. Fixed costs are critical to manage because they exist despite the amount of revenue that is made. Some people call this overhead—the costs that are fixed and do not vary.

What are variable expenses? Variable expenses tend to <u>vary</u> over a period of time, and they are correlated with sales.

Examples: Cost of goods, sales commissions, production labor. Variable costs change based on the level of revenue coming in. These costs are directly related to the sales function.

What are semi-variable expenses? Semi-variable expenses have a <u>fixed</u> portion and a <u>variable</u> portion to them. Examples: Utilities, telephone. Telephone costs may have a base fee, but as sales in other states increase, so do long-distance charges. To calculate the break-even point, an estimate must be made to allocate these semi-variable costs between fixed and variable.





Answer Key – Calculate Break-Even – Scenario: Midwest Lab Services

Directions

Step 1 Read the Scenario: Midwest Lab Services below and fill in the information you know in the Income Statement that follows it.

Midwest Lab Services does comprehensive laboratory testing. They provide 24-hour courier service as well as on-site testing and collection. MLS has developed a personal, multiple-use cholesterol testing kit that could revolutionize the industry by its ease of use and potentially low cost. Based on bids from one manufacturer, it will cost \$30,000 per year for the annual manufacturing contract. In addition, it will cost \$5 to produce each testing kit. MLS believes it can sell 20,000 units the first year at \$7 each to distributors.

Step 2 Calculate missing values.

Income Statement	Total	Per Unit
Units	20,000	1
Sales	\$140,000	\$7
Cost of Sales (Variable Costs)	\$100,000	\$5
Gross Margin	\$ 40,000	\$2
Operating Costs (Fixed Costs)	\$ 30,000	\$1.50
Net Profit	\$ 10,000	\$0.50



of break-even analysis to evaluate pricing strategy at www.fasttrac. org/toolkits.

Step 3 Calculate break-even using formulas. How many units does Midwest Lab Services need to sell to break even?

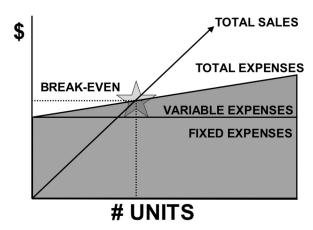
Break-Even per Unit = Fixed Costs / Gross Margin per Unit

Break-Even Total Sales = Fixed Costs / Gross Margin %

Step 4 Illustrate your findings by placing your calculations on the graph below.

Break-Even Graph

This step is to help entrepreneurs visualize break-even on a graph, as presented in Overhead OEA4, not a test in plotting a graph. Although each entrepreneur's graph will be different, completed graphs should resemble the graph on the right.



Name:	

Action Step 1.1 Conduct a SWOT Analysis

Create an overview of your business's strategic situation.

A. Complete the chart below. Include the strengths and weaknesses you identified in your internal assessment and the opportunities and threats from your environmental scan.

Strengths	Opportunities
Weaknesses	Threats

B. Identify the 3 or 4 most important items to work on first. Add a star next to the most important items in each of the four categories above.

want to research? Make a list of things you want to research as a resultysis.					
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Name:

Action Step 2.1 Assess Industry Potential

Research information to determine industry potential. Conduct preliminary industry research which will be completed when preparing a marketing plan.

Directions

In this action step you will conduct market research to fill your information gaps and evaluate your industry for growth and profit potential. Read the topics and suggested questions in the first column. Then, in the second column, list the information you want to find. In the third column, identify sources for this information. Refer to the sources on Industry Research, at the end of this handout, to get started.

In conducting your research, do not merely collect information about your industry. Draw conclusions about what the information means to you and your business. Look for patterns, see how it fits together, and integrate this information into your existing knowledge about your business.

Questions	Information	Source(s) of information
Current Size What is the current size of your industry for this product/service? What is the size at the national, regional, state, and local levels? How many dollars are spent annually and/or how many units are consumed annually?		
Growth Potential Is the industry growing and, if so, by how much? Is it stabilizing or declining?		
Profitability Characteristics What are typical gross margins within the industry?		
Industry Trends What are the trends in the industry? What effect does technology have on the business?		

Based on your research		nity for you to re	each the

Industry Research

You will want to start your industry research by identifying your industry's North American Industry Classification System (NAICS) or Standard Industrial Classification (SIC) code. To find a NAICS or SIC code, go to the U.S. Census NAICS Web site at www.census.gov/naics. Enter a key word into the search box on the left-hand side of the page that describes your industry or browse codes by clicking the NAICS to SIC / SIC to NAICS button.

Once you've located the relevant industry code(s), use the U.S. Economic Census and related reports as a resource to assist you in gathering industry statistics. You can also use these codes to access other industry information, some of which is grouped by industry type:

Manufacturing — *Manufacturing* & *Distribution USA* provides statistical information and leading companies in all manufacturing and wholesale industries. The Annual Survey of Manufacturers, available online at www.census.gov/mcd/asm-as1.html, gives more detailed statistics.

Restaurants – The National Restaurant Association publishes a number of resources that provide relevant industry data, including a *Restaurant Industry Forecast* and *Quickservice Restaurant Trends*. Get started online at www.restaurant.org.

Service businesses – The Census produces the Service Annual Survey, online at www.census.gov/econ/www/servmenu.html. Many trade magazines cover specific service industry sectors, such as ABA Banking Journal, Best's Review of Life & Health (Insurance), and Spa Management.

Retail – Many trade magazines focus on retail, including *Chain Store Age* and *Stores*. Additionally, the National Retail Federation provides some timely information online at www.nrf.com.

Technology businesses – Use information services such as the *American Bulletin of International Technology, Selected Business Ventures* (published by General Electric Co.), *Technology Mart, Patent Licensing Gazette*, and *The National Technical Information Service*.

Gale Business & Company Resource Center – This online database includes data from publications such as *Market Share Reporter*, *Encyclopedia of American Industries*, *Encyclopedia of Global Industries*, and other industry publications and company directories. Search for specific company information or find market share, industry overviews, company rankings, and articles on just about every industry.

Franchises – You can find lists of franchises for sale, franchising tips, and more at the *Start-Up Journal* from the *Wall Street Journal*. Another useful resource is Franchise Opportunities, an online resource for franchise business opportunities and information, at www.franchiseopportunities.com.

Licensing resources – One resource is the International Licensing Industry Merchandisers' Association (LIMA), which sponsors an annual show in New York City; see their Web site at www.licensing.org. The Licensing Resource Directory, published annually by Expocon Management Associates, lists alphabetically more than 3,000 owners and categories of products and services as well as tips, support organizations, consultants, designers, and other professionals specializing in licensing. Other resources include The Licensing Letter and The Licensing Letter Resource Sourcebook from EPM Communications, which lists the top 4,000 executives involved in the licensing industry. Two other publications relating to the industry are The Licensing Report, a weekly newsletter, and The Licensing Book, a monthly magazine, from Adventure Publishing.

Additional Governmental Resources

Department of Commerce – Locate information about industry products and services, www.commerce.gov.

Patent and invention resources – Find patent information online through the U.S. Patent & Trademark Office, www.uspto.gov.

Libraries

Industry growth and trends – An easy way to find out industry growth trends is through newspaper and trade journal articles.

Dun & Bradstreet and Standard & Poor's Company Profiles – These resources report financial information and statements from existing businesses. Dun & Bradstreet provides a number of databases, such as the Dun & Bradstreet Million Dollar Database, which lists public and private companies and their annual sales, and Dun & Bradstreet Business Information Reports, which provides information on over 11 million businesses in the United States regarding operations, profitability, and stability. Standard & Poor's Company Profiles also has a number of resources, such as NetAdvantage, which has more in-depth financial information on larger public companies.

The Statistical Abstract of the United States - This resource provides basic information such as income

levels, employment figures, industry outputs, and useful market information, and is available online at www.census.gov/statab/www. Many of the charts are summaries of more detailed data; check the source listed for more information.

Encyclopedia of Associations – Trade associations often collect valuable statistics and provide networking information on the industries they represent. Use this encyclopedia to find information on more than 25,000 United States trade associations, including lists of publications available and association contact information including Web sites.

Encyclopedia of Business Information Sources – This encyclopedia lists resources such as trade magazines, databases, handbooks, trade associations, statistics and more for over 1100 business and financial topics. Use this guide to get started finding relevant sources for your industry and market research.

Standard & Poor's Industry Surveys – S & P provides in-depth surveys on over fifty major industries such as apparel & footwear, biotechnology, healthcare, and retailing. The industry surveys are updated four times per year and include information on industry trends, consumers, market share, leading companies, and leading company financials.

Trade and Professional Organizations

Encyclopedia of Associations – See reference above.

American Society of Associations – Get started by searching the American Society of Association Executives Gateway to Associations – online at www.asaenet.org/cda/asae/associations_search – for more than 6,000 local and national association Web sites.

Trade publications provide timely information about activities in your industry and are a great way to recognize and capitalize on emerging trends.

HillSearch Members

In HillSearch, simply click on "Research an Industry," then "Search industry trade journals" to search in EBSCO or ABI/Inform, databases with access to thousands of key industry journals. In those databases, simply enter in key terms for your industry and "growth" or "trends" to find topical information.

Name:	

NewVenture Action Step 2.1 Conduct Market Research

Identify resources for questions that I need to answer through market research.

Directions

This worksheet lists all the categories in which you may collect information for your market research. You may also want to review Reality Checks in this module to decide if there is additional information you want to know.

Category – Information Needed	Possible Sources	Comments
INDUSTRY/OPPORTUNITY	<i>(</i>	
What is the history of this industry?		
What is the current state of the industry?		
What are the trends?		
What are the long-term prospects?		
Do seasonal factors exist?		
What are the existing distribution networks?		

How does the industry treat new enterprises or the introduction of new products?	
What are the industry's pricing policies?	

Category – Information Needed	Possible Sources	Comments
MARKET		
What are the customer- perceived benefits of what you are selling?		
How do your products/ services differ from competitive products/services?		
If your product/service were not special, why would people buy from you?		
What is the present size and growth potential of the market as a whole?		
What percent of the market will you have now and in the future?		
What is the present size and growth potential of your target market?		

What are the characteristics of your target customers? (Use demographic and psychographic variables.)	
What are customer reactions to your product/service?	

Category – Information Needed	Possible Sources	Comments		
COMPETITION				
Who are your direct and indirect competitors?				
Are competitors' sales steady? Decreasing? Increasing?				
How are competitors' operations similar and dissimilar to yours?				
What products do competitors offer? What price? How do they promote?				
What is your competitive advantage?				

Category – Information Needed	Possible Sources	Comments		
ADDITIONAL INFORMATION TO COLLECT				