

June 4-5, 2023

#BIO2023 #StandUpForScience

Biotechnology Entrepreneurship Boot Camp

Presented by:

James Jordan, MBA, CHT

President & CEO, StraTactic Inc

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Intellectual Property Law



Positioning Life Science Companies For Accurate Valuation & Strong Exit

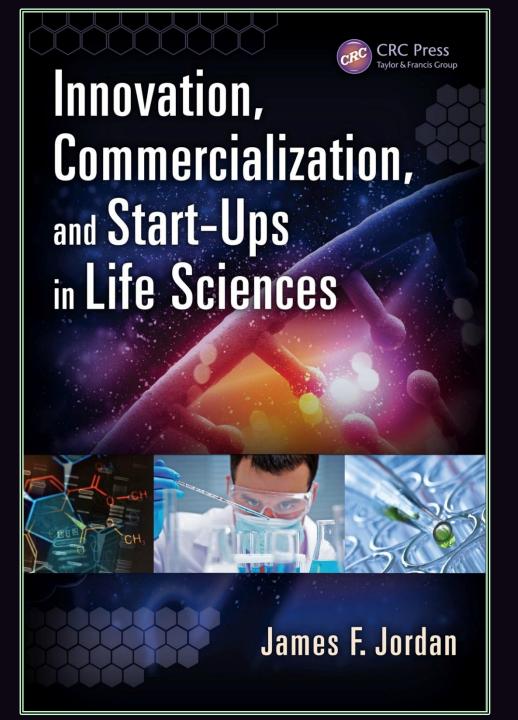


Table of Contents

Part 1 – Innovation is a Process of Connected Steps

Chapter 1: Investment Uses a Translation Process to Deliver Innovation

Chapter 2: Investment is Critical to a Nation's Prosperity

Chapter 3: The Journey of Innovation Begins With Investment

Chapter 4: The U.S. Helps Small Companies Develop Technology

Chapter 5: Commercialization is Primarily Executed Through Two Organizational Types

Part 2 – Investment Must Be Connected to Exit

Chapter 6: Angels and Venture Capitalists Invest in Commercialization

Chapter 7: Create Liquidity For Your Investors

Chapter 8: A Liquidity Event is Not Consummated Without Due Diligence

Chapter 9: Due Diligence Reputation is a Critical Business Process

Part 3 – Align With the Industry Norms

Chapter 10: Find the Industry Norms

Chapter 11: Solve an Important Customer Problem

Chapter 12: Demonstrate the Ability to Access the Sales Channel

Chapter 13: Gather Domain-Experienced Personnel to Reduce Risk

Chapter 14: Determine Acquirers' Strategic Future and Purchase Triggers

Chapter 15: Align Investor's Fundable Milestones and Acquirer's Exit Points

Chapter 16: Create an IP Pyramid for Impervious Positioning

Part 4 – A Startup Must Tell a Compelling Story

Chapter 17: Address Your Story to the Needs of All Constituencies

Chapter 18: Deliver to Your Plan

Chapter 19: Tell a Compelling Story With the Investor Pitch

Chapter 20: Continuously Improve Your Message With the Plan-Do-Check-Act Cycle

Uncovering your Exit Triggers

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Aligning Objectives & Concerns Customer = Investor = Acquirer

A poorly planned and ill-provisioned journey for probability of failure

Navigational instruments ascertain position & direction to a destination

Waypoints are planned milestones to re-provision (\$) & capture value

Planning & provisioning are aided through the use of tools

1

Find **BENCHMARK**

- Evaluate by comparison

2

To uncover the **STANDARD**

- A measure, norm or model in comparative evaluation

3

Through use of **TOOLS**

- An implement to carry out a particular function

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To obtain **KNOWLEDGE**

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To obtain **KNOWLEDGE**

	Customer	Investor	Acquirer
Objectives	□ Outcomes = ↑Access + ↑Quality + ↓Cost	IRR, ROI, MultiplesPlacement amount	Price/Earning RatioRevenue/margin accretionMarket share
Concerns	 Produce multi-year, accretive revenue stream Clinical trial participation New procedures (aka robotics) Attain top-tier operating margins Multi-year agreements (formulary) Reimbursement category PPV Predictable horizontal/longitudinal costs Sustainability of NewCo Capture regional market-share Technology guarantee Clinical trial access 	 Portfolio balance & timing Validation of business model Validation of product category Venture capital requirements Inability to participate in later rounds Implications of public financing 	 □ Aligned business models □ Defend/expand existing categories □ Enter new categories/markets □ Formulary competitiveness □ Maintain/improve financial ratios □ Salesforce leverage



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	- Technology guarantee- Clinical trial access		



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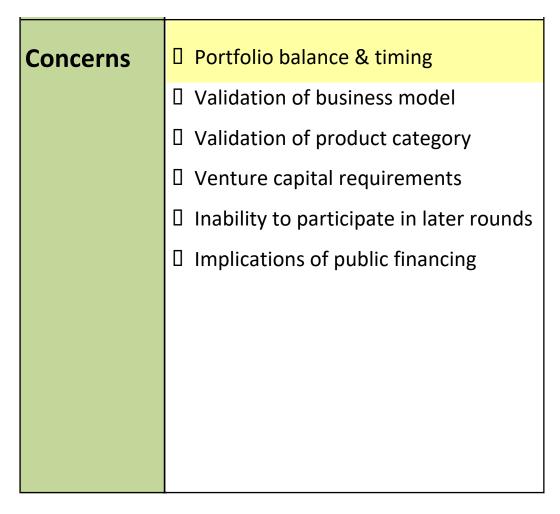
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The Investor

Objectives

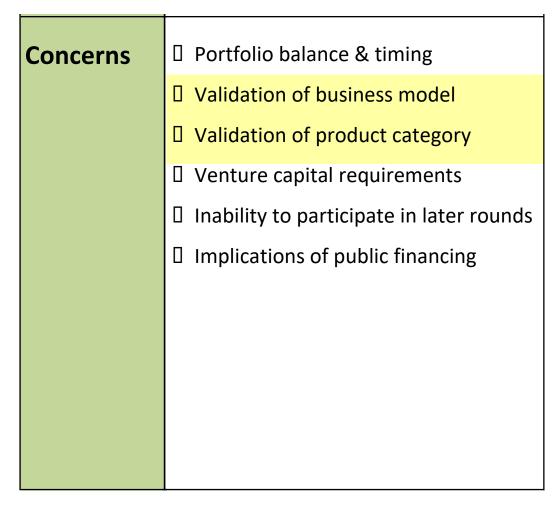
IRR, ROI, Multiples
Placement amount



The Investor

Objectives IRR, ROI, Multiples

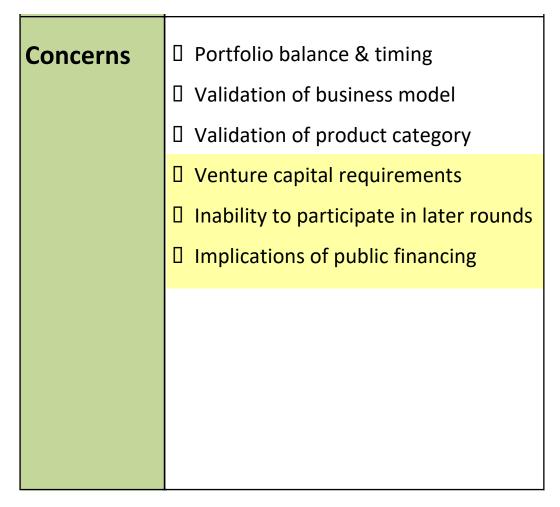
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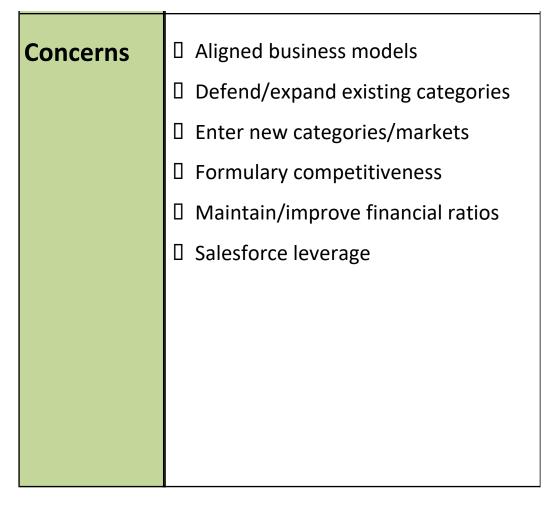


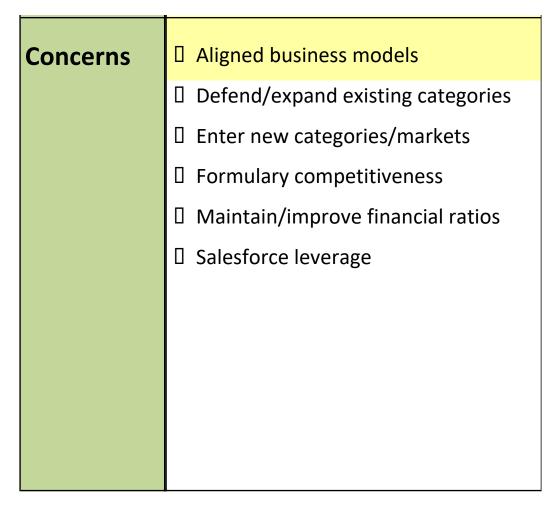
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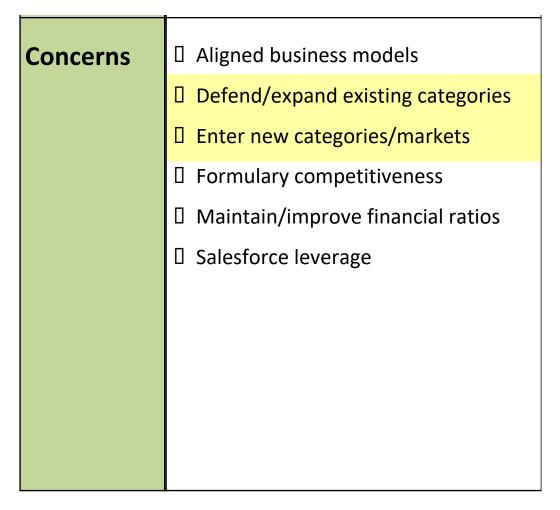
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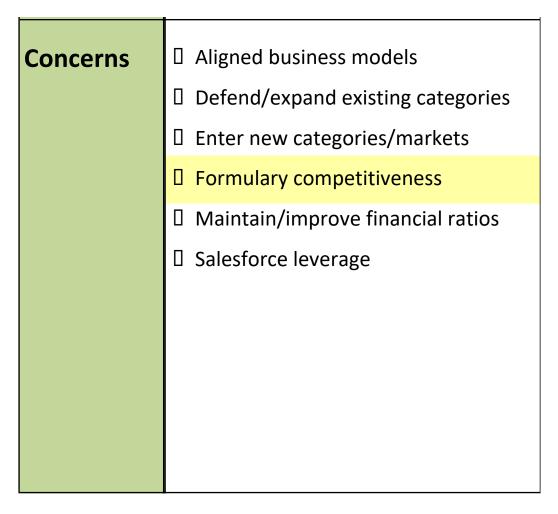
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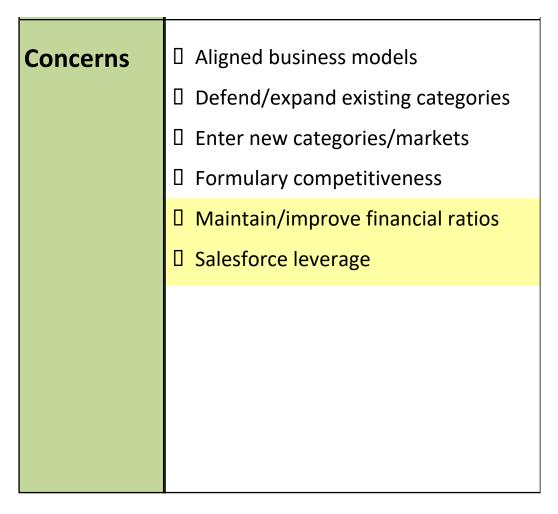












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Tools reveal standards so you can plot a winning strategy

- Valuation Milestones: A review of standard, not comparatives, avails and aligns valuation and fundable milestones with those of investors and acquirers
- Disease State Fact Book: Distinguish the difference between an incremental market improvement and a monumental innovation
- Industry Life Cycle: Incumbent's resist acquiring until their existing investment is threatened or expiring
- Purchase Trigger Database: Reliance on an early exit is misplaced if uninformed, know your acquirer's habits



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Let's look at an example

- Each life sciences vertical differs
 - Pharmaceutical Diagnostics
 - Medical Devices
- Healthcare IT
- Each product category may differ
 - Cardiovascular - Cancer
- Each regulatory category may differ
 - 510k

- PMA



Data points from Venture Source & Pitchbook

- 2011 Venture Data Set for regional companies
- F = Fundable milestone move to next class
- V = Value milestone company value increases















Series A - in millions				
Pre-Money		Capital Raise Post-Mon		
	2.7	1.3 +/- 1	4 +/-2	
	11 months +/ 2 /			

Series B - in millions			
Pre-Money Capital Raise Post-Money			
8.0	4 +/- 1.9	12 +/- 4.3	

Series C - in millions			
Pre-Money	Capital Raise	Post-Money	
15.9	8.9 +/- 3.5	24.8 +/- 7.6	

Note:

2011 Venture Data Set for regional companies
F = Fundable milestone – move to next class

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|----- 15 months +/- 3.4 -----

☐ Creat proof of concept (F/V)

☐ Commercialization plan vaibility (F/V)

☐ Buildout technical team (V)

☐ Attain regulatory pathway (V)

☐ 1st in-human data/ start clinical trial (F/V)

☐ Design System Audit (V)

☐ Commercial approval - OUS (V)

☐ Regulatory trial approval - US (F/V)

Launch US trial (V)

☐ Hire sales & marketing team (V)

Series D - in millions			
Pre-Money	Capital Raise	Post-Money	
32.1	11.6+/- 5.9	43.7 +/- 15	

	2	20 months +/- 8.7	,

Series E - in millions			
Pre-Money Capital Raise Post-Money			
62.0	16. +/- 5.9	78.3 +/- 24	

Exit Details			
Capital Raise	Exit Value	Months	
54 +/- 15	107 +/- 43	72 +/-21.6	
Multiples	CAGR %		
2.2 +/- 0.7	14.8 +/- 7.6		

☐ Regulatory approval - US (F/V)

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☐ US Revenue in excess of \$xxM run-rate (F/V)

☐ Demonstrate viability of 2nd product (V)

☐ Demonstrate hockey-stick revenue growth (F/V)

☐ Pass cash-flow BE Point (F/V)



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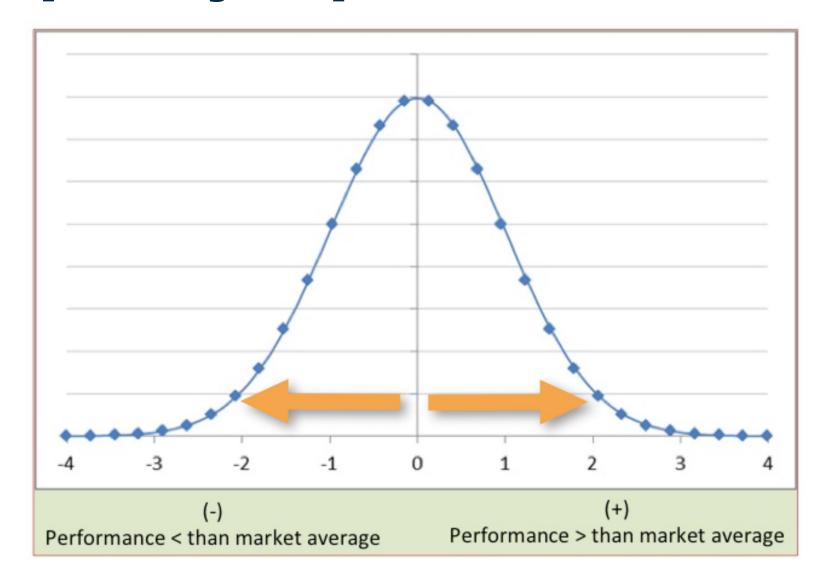
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Standard deviation is a measure used to quantify dispersion



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A value milestone increases company value

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A fundable milestone allows movement to next investor class

|-----|

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Valuation standards define your waypoints (Medical Device)

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Early exits are not always practical

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- ☐ Demonstrate hockey-stick revenue growth (F/V)
- ☐ Pass cash-flow BE Point (F/V)
- ☐ Regulatory trial path 2nd product US (V)



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Valuation standards for a Therapeutic

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Seed Round - in millions					
Pre-Money	Post-Money				
6.5 +/- 2.3	0.9 +/- 0.8	7.4 +/- 3.1			

1st Round - in millions						
Capital Raise	Post-Money					
6.9 +/- 7.7	16.5 +/- 14.7					
	Capital Raise					

2nd Round - in millions					
Pre-Money	Capital Raise	Post-Money			
35.7	13.2 +/- 13.9	48.9 +/- 13.9			

|------ ~15 months ------

|----- ~19 months -----

|------ ~17 months -----

- Proof of concept with IND candidates
- Selection of clinically relevant animal model(s)
- Rodent and non-rodent tox da
- Selection of IND enabling compound

• Human safety (Phase I)

3rd Round - in millions						
Pre-Money	Capital Raise	Post-Money				
50.0	17.3 +/- 17	67.3 +/- 17				

4th Round - in millions						
Pre-Money Capital Raise Post-M						
148.3	29.8	178.1				

Exit Details						
Capital Raise	Months					
~70	~226.7	~60 - 84 months				

- Efficacy studies in patients
- Patient dose range studies (Phase IIb)

Phase III



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Determine if a technology is an innovation or a modification

Row #	: -		Base Year	_	Year 2	
1	Disease Prevalence	Portion of the population found to have the condition (1 in 1000)	24,652,555		25,268,869	
2	Incidence % Percentage of new cases (generally a year)				20%	
3	Incidence Occurrence of new cases since last time periodlater year or in a period of time (generally a year)				5,053,774	
4	Percentage Recurring	Percentage of population with a reoccurring event in a given year			20%	
5	Prevelance Population [Disease prevalence less incidence] x percentage recurring				4,043,019	
6	Number Diagnosed Number diagnosed patients (the act of identifying trateable disease)				9,096,793	
7	Diagnosis Rate %	Number diagnosed/disease prevalence (this included incident patients)			36.0%	
8	Procedural Approaches	Diagnostic, Medical Devices, Pharmaceutical, Long-term Care, Rehabilitation, etc.		Medical Therapy	CABG	Inteventional Procedure
9	Procedure/Service Approach %	The percent of diagnosed cases that would use this product/service		84.5%	3.5%	12.3%
10	Number of Procedures/Services	Number of diagnosed x procedure/service approach %		7,687,700	318,388	1,119,815

11	Type of Products/Sub-services	List the individual products or services performed
12	Units per Procedure/Service	Example: 2 Stents per Procedure, 30 pills per cycle, 30 days in long-term care
13	Market Units/Services	Number of Procedures x Units per Procedure/Service
14	Average Revenue per Event	Revenue value per event or service - note revenue by manufacturer would be different than at the hospital level
15	Market Dollars or Cost	Maket Units x Average Price

Stent			uide Catheter	Guide Wire		
	2.2		1.75		1.1	
	2,463,593		1,959,677		1,231,797	
\$	550.00	\$	9.87	\$	6.93	
\$1,	354,976,390	\$	19,342,008	\$	8,536,351	

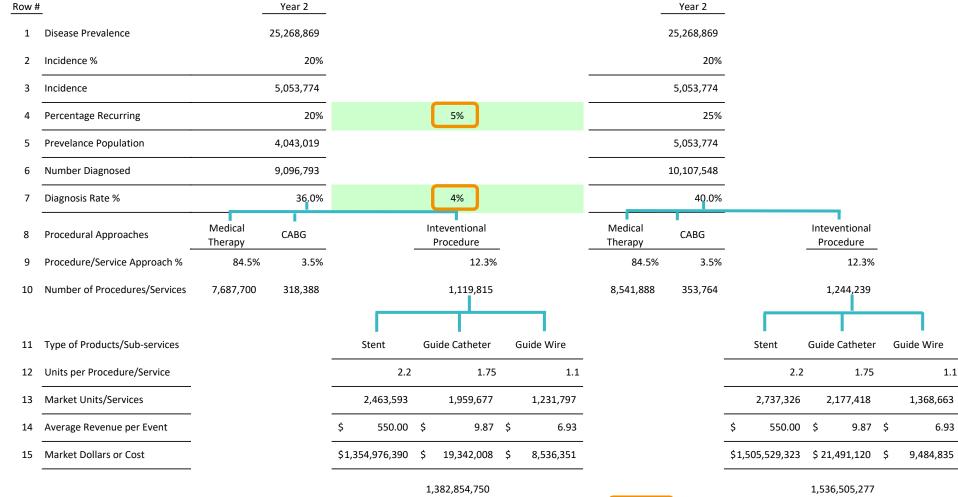
Factors that increase market value

1.	Disease Prevalence	Portion of the population found to have the condition (1 in 1000)
2.	Incidence %	Percentage of new cases (generally a year)
3.	Incidence	Occurrence of new cases since last time period — later year or in a period of time (generally a year)
4.	Percentage Recurring	Percentage of population with a recurring event in a given year.
5.	Prevalence Population	[Disease prevalence less incidence] x percentage recurring
6.	Number Diagnosed	Number diagnosed patients (the act of identifying treatable disease)
7.	Diagnosis Rate %	Number diagnosed/disease prevalence (includes incident patients)
8.	Procedural Approaches	Diagnostic, Medical Devices, Pharmaceutical, Long-Term Care, Rehabilitation, etc.
9.	Procedure/Service Approach %	The percentage of diagnosed cases that would use this product/service
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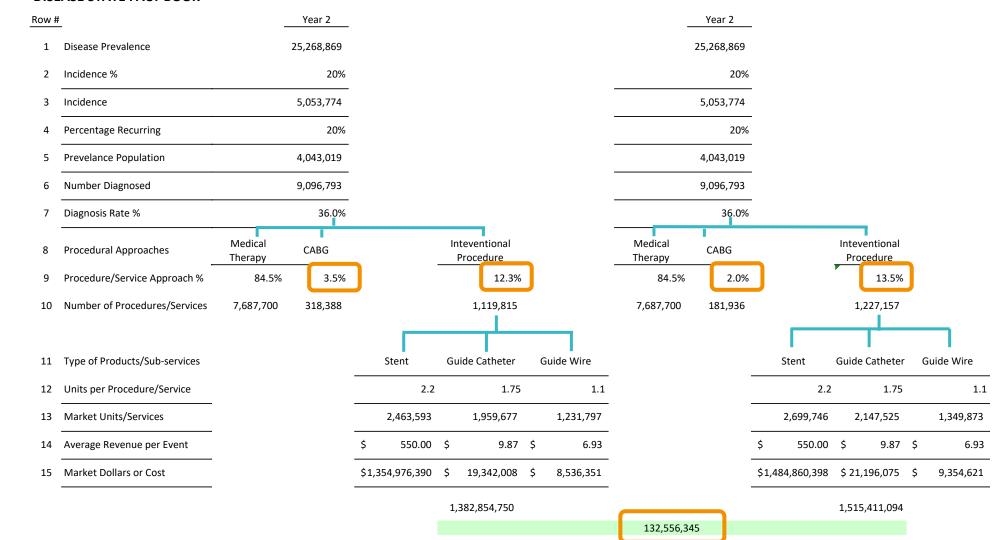
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13	Market Units/Services	Number of Procedures x Units per Procedure/Service				2,463	,593	1,959,677	1,231,797
14	Average Revenue per Event	Revenue value per event or service - note revenue by manufacturer would be different than at the hospital level	_			\$ 55	0.00	\$ 9.87	\$ 6.93
15	Market Dollars or Cost	Maket Units x Average Price	_			\$1,354,976	,390	\$ 19,342,008	\$ 8,536,351

A 4% change in diagnosis rate can increase the market by 11%



A 1.2% procedural shift can change the market dollars by 10%



Market factors that attract acquirers

Factors that increase market value: (all tides rise boats)

- Diagnosis rate
- Procedure rate
- Units p/procedure

Factors that require taking share: (fighting incumbents)

- Type of products
 - —Category transitions
- Market units
- Average selling price
- Market dollars

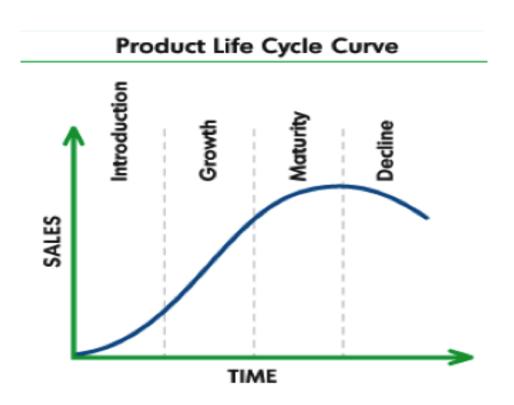


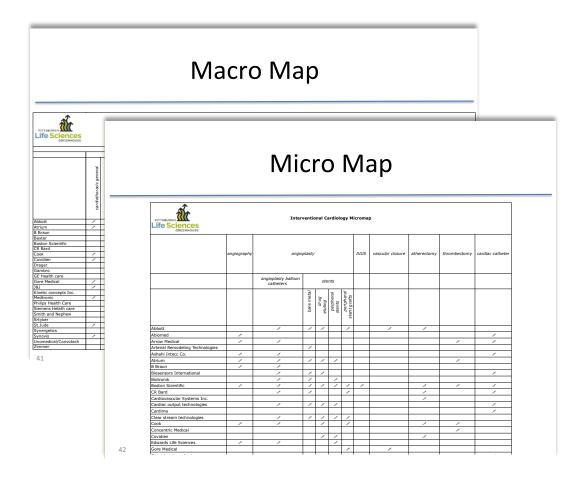
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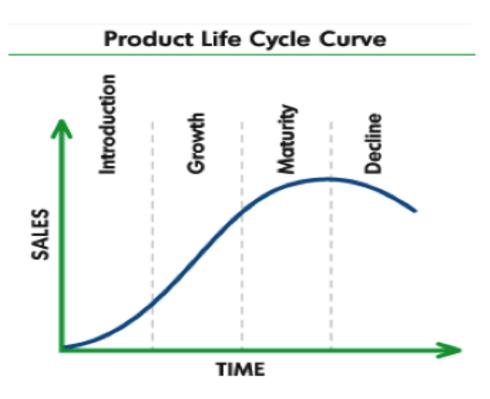
Determine an industry's readiness







Determine an industry's readiness

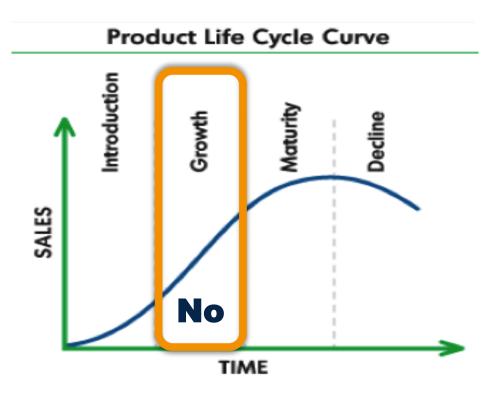


Wang developed the CRT Word Processor 61% CAGR between 1979-1984





Industry & companies in a growth phase will fight a category shift

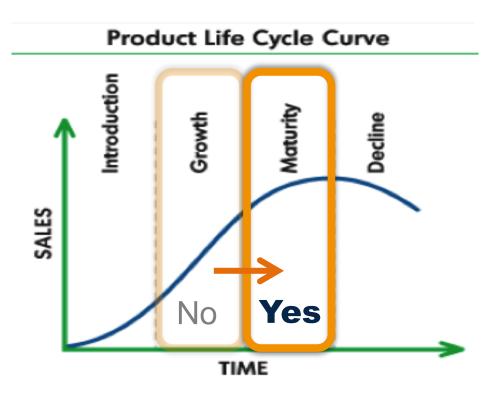


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Industry & companies in a growth phase will fight a category shift



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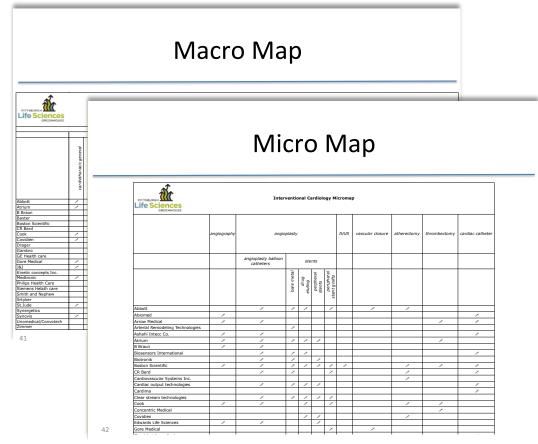
Macro/Micro maps help uncover industry readiness

Thermo Fischer Acquirers PPD for \$17.4 billion

Baxter Acquirers Hillrom for \$10.5 billion

Steris and Cantel Medical stock deal for \$4.6 billion

Boston Scientific aquires Baylis Medical for \$1.75 billion





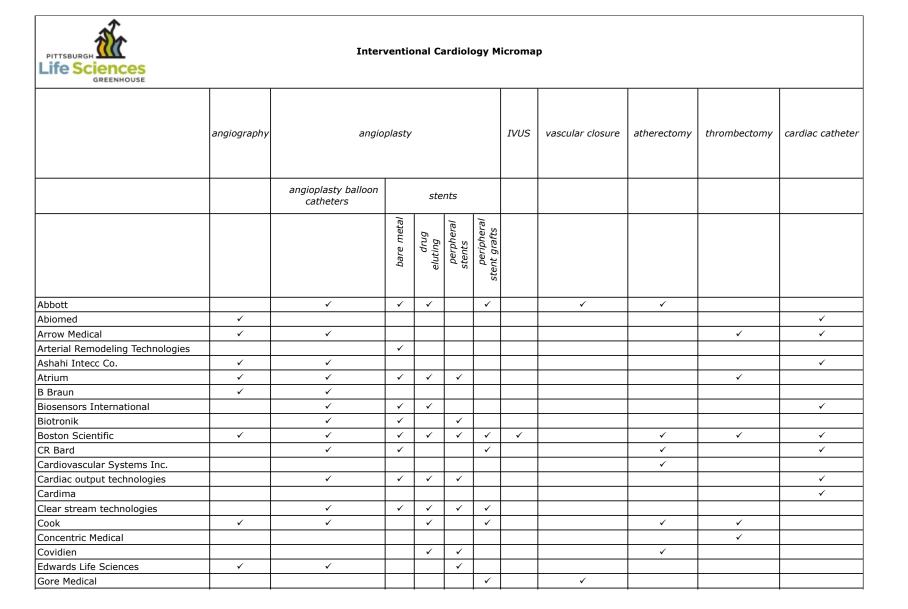
Macro Map



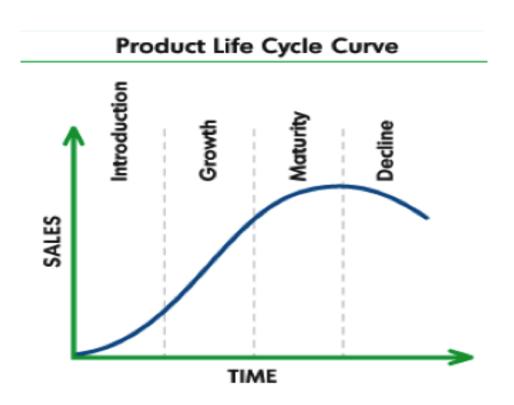
MEDICAL DEVICE INDUSTRY MACRO MAP

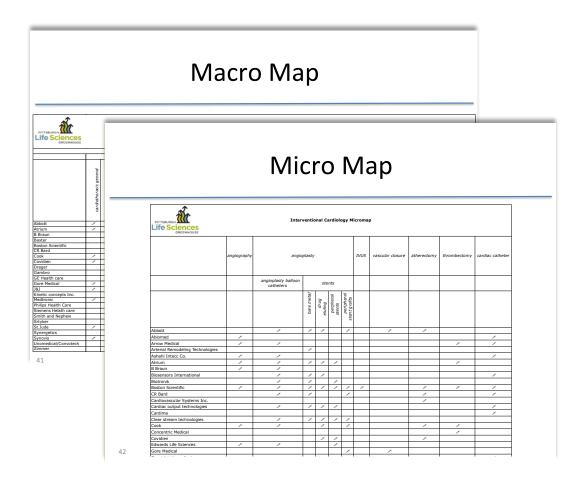
													HOSP	PITAL	S																
	Operating Room					Multi speciality					ICU/CCU Laboratory based			sed	Specialty																
	cardiothoracic general	colon rectal	otolaryngiology	orthopedic	plastic surgery	ophthalmology	nye-qo	general laproscopy	general-other	Vascular	urology	endoscopy	neurology	Robot assisted/image guided	anasthetics	respiratory devices	hemostats	tissue sealants	adhesion prevention	monitoring systems		Interventional cardiology	Interventional radiology	Electrophysiology	Interventional neurology	CRM	Radiology(imaging)	Renal	Neurology	Infusion systems	wound care and management
Abbott	✓					✓				✓							✓					✓	✓								✓
Atrium	✓								✓	✓												✓									
B Braun										✓					√							✓	✓					✓	✓	✓	✓
Baxter															✓		✓	✓	✓									√		✓	✓
Boston Scientific		√					✓		✓		✓	✓	✓									✓	✓		✓	✓					
CR Bard			✓	✓					✓	✓	✓	✓					✓					✓	✓	✓		✓		✓			✓
Cook	✓	✓					✓		✓	✓	✓	✓										✓	✓							✓	
Covidien	✓	✓	✓				✓	✓	✓	✓	✓	✓	✓			✓		✓	✓		✓	✓	✓		✓	✓	✓	✓		✓	✓
Drager	Ī														√	✓				✓											
Gambro																												√			
GE Health care			✓				✓		✓		✓			✓	✓	✓				✓	✓		✓	✓		✓	✓				
Gore Medical	✓	✓		✓					✓	✓			✓									✓	✓								✓
]&J	✓			✓	✓	✓	✓	✓	✓		✓		✓									✓	✓		✓	✓			✓	✓	✓
Kinetic concepts Inc.							✓				✓																				✓
Medtronic	✓		✓	✓							✓										✓	✓				✓			✓	✓	
Philips Health Care	Ī														√					✓							✓				
Siemens Helath care															√	✓				✓		✓		✓			✓				
Smith and Nephew				✓								✓																			✓
Srtyker				✓								✓	✓	✓						✓	✓						✓			✓	
St.Jude	✓	√												✓								✓		✓		✓			✓		
Synergetics													✓																		
Synovis	✓				✓		✓	✓	✓	✓	✓		✓																		
Unomedical/Convotech																✓					✓		✓							✓	✓
Zimmer	Ì			✓																							✓				

Micro Map



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62% of PMAs are acquired after FDA approval

Note:

- 2011 Venture Data Set
- Sample size = 18
- Most likely less today before PMA

Series A - in millions					
Pre-Money	Capital Raise	Post-Money			
2.7	1.3 +/- 1	4 +/-2			

Series B - in millions						
Pre-Money	Capital Raise	Post-Money				
8.0	4 +/- 1.9	12 +/- 4.3				

Series C - in millions						
Pre-Money	Capital Raise	Post-Money				
15.9	8.9 +/- 3.5	24.8 +/- 7.6				

|----- 11 months +/- 2.4 -----|

|----- 14 months +/- 2.5 -----

|----- 15 months +/- 3.4 -----

7 (38%) acquired before regulatory approval

Series D - in millions					
Pre-Money	Capital Raise	Post-Money			
32.1	11.6+/- 5.9	43.7 +/- 15			

------ 20 months +/- 8.7 -------

Series E - in millions					
Pre-Money	Capital Raise	Post-Money			
62.0	16. +/- 5.9	78.3 +/- 24			

Exit Details						
Capital Raise	Exit Value	Months				
54 +/- 15	107 +/- 43	72 +/-21.6				
Multiples	CAGR %					
2.2 +/- 0.7	14.8 +/- 7.6					

☐ Regulatory approval - US (F/V)

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A value proposition must address constituency objectives & concerns

- Identify constituency measures of success
- Valuation standards define your waypoints
- Distinguish innovation from improvement
- Determine an industry's readiness to change
- M&A history defines triggers (timing)





Questions?

