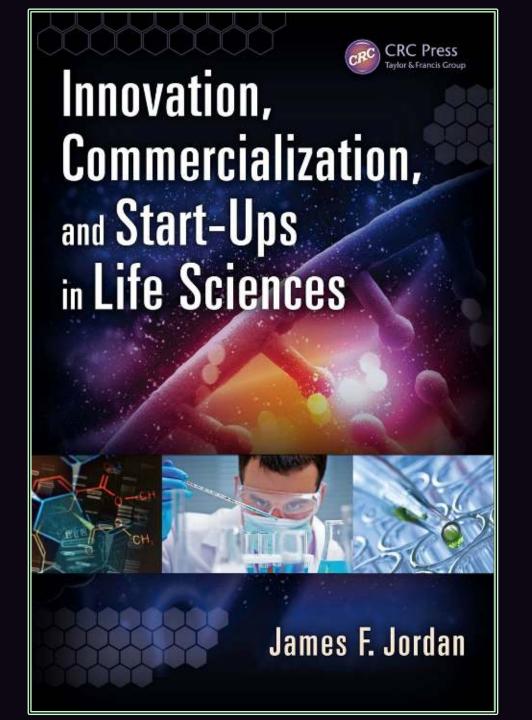


# Positioning Life Science Companies for Accurate Valuation & Strong Exit



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Chapter 1: Investment Uses a Translation Process to Deliver Innovation	Chapter 10: Find the Industry Norms	

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

Chapter 5: Commercialization is Primarily Executed Through Two Organizational Types

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Chapter 18: Deliver to Your Plan

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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 🎓 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

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  - Evaluate by comparison

- 2 To uncover the **STANDARD** 
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Objectives	□ Outcomes = ↑Access + ↑Quality + ↓Cost	☐ IRR, ROI, Multiples ☐ Placement amount	<ul><li>Price/Earning Ratio</li><li>Revenue/margin accretion</li><li>Market share</li></ul>
Concerns	<ul> <li>Produce multi-year, accretive revenue stream         <ul> <li>Clinical trial participation</li> <li>New procedures (aka robotics)</li> </ul> </li> <li>Attain top-tier operating margins         <ul> <li>Multi-year agreements (formulary)</li> <li>Reimbursement category PPV</li> <li>Predictable horizontal/longitudinal costs</li> <li>Sustainability of NewCo</li> </ul> </li> <li>Capture regional market-share         <ul> <li>Technology guarantee</li> <li>Clinical trial access</li> </ul> </li> </ul>	<ul> <li>I Portfolio balance &amp; timing</li> <li>I Validation of business model</li> <li>I Validation of product category</li> <li>I Venture capital requirements</li> <li>I Inability to participate in later rounds</li> <li>I Implications of public financing</li> </ul>	<ul> <li>I Aligned business models</li> <li>Defend/expand existing categories</li> <li>Enter new categories/markets</li> <li>Formulary competitiveness</li> <li>Maintain/improve financial ratios</li> <li>Salesforce leverage</li> </ul>

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## Tools reveal standards so you can plot a winning strategy

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

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#### Let's look at an example

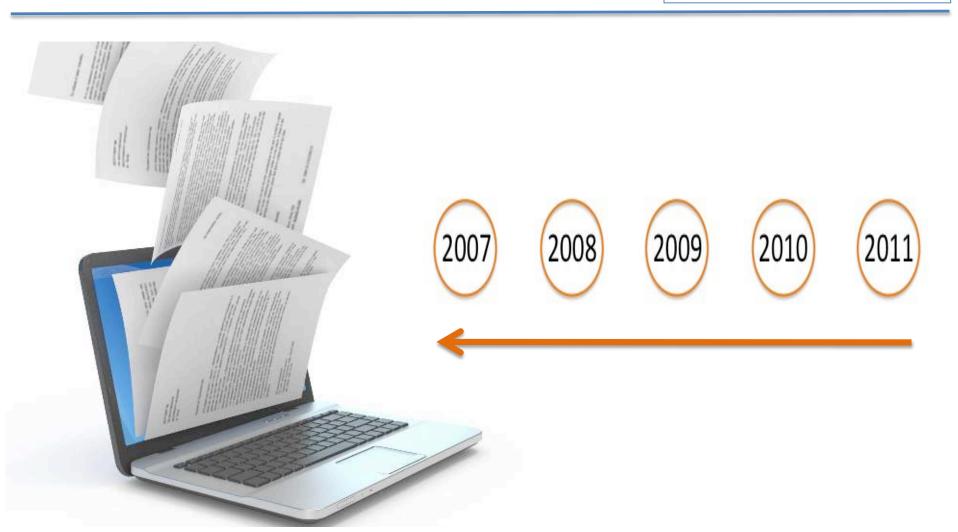
- Each life sciences vertical differs
  - Pharmaceutical
- Diagnostics
- Medical Devices Healthcare IT
- Each product category may differ
  - Cardiovascular

- 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



#### Note:

- 2011 Venture Data Set for regional companies
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Series A - in millions			
Pre-N	loney	Capital Raise	Post-Money
	2.7	1.3 +/- 1	4 +/-2
11 months +/- 2.4			

Series B - in millions			
Pre-Money	Capital Raise	Post-Money	
8.0	4 +/- 1.9	12 +/- 4.3	
14 months +/- 2.5			

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

15 months +/- 3.4 -

- [] Creat proof of concept (F/V)
- D Commercialization plan vaibility (F/V)
- [] Buildout technical team (V)

- [] Attain regulatory pathway (V)
- [] 1st in-human data/ start clinical trial (F/V)
- Il Design System Audit (V)

[] Commercial approval - OUS (V)

B Regulatory trial approval - US (F/V)

Il Launch US trial (V)

I Hire sales & marketing team (V)

Series D - in millions		
Pre-Money	Capital Raise	Post-Money
32.1	<b>11</b> .6+/- 5.9	43.7 +/- <b>1</b> 5

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 +/- <b>1</b> 5	107 +/- 43	72 +/-21.6
Multiples	CAGR %	
2.2 +/- 0.7	14.8 +/- 7.6	

- Regulatory approval US (F/V)
- [] Launch US product (V)
- [] US Revenue in excess of \$xxM run-rate (F/V)
- [] Demonstrate viability of 2nd product (V)
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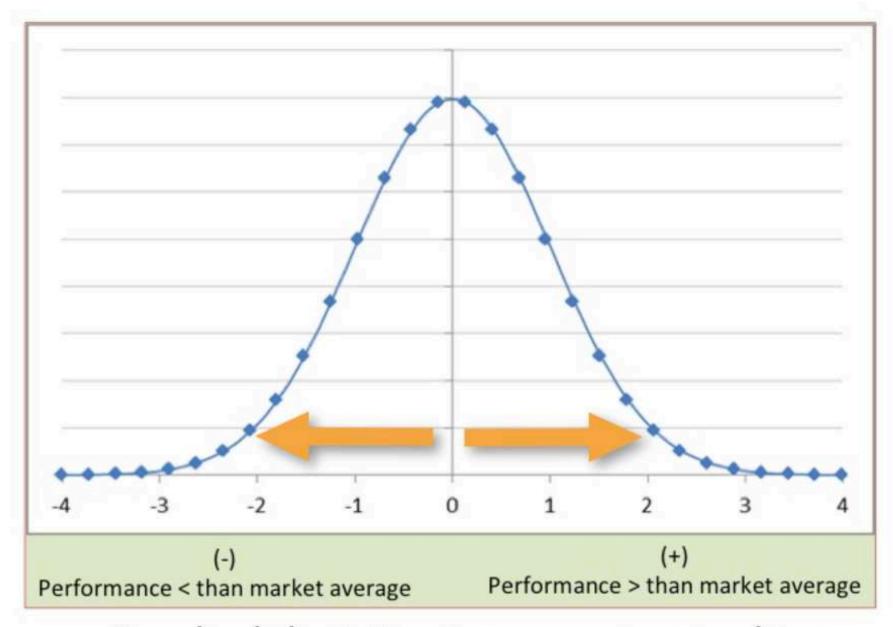
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Standard deviation is a measure used to quantify dispersion

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### A value milestone increases company value

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

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# A fundable milestone allows movement to next investor class

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

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## Valuation standards define your waypoints (Medical Device)

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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	

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

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

Series E - in millions		
Pre-Money	Capital Raise	Post-Money
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Multiples	CAGR %	
2.2 +/- 0.7	14.8 +/- 7.6	



## Valuation standards for a Therapeutic

#### Note:

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

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

1st Round - in millions		
Pre-Money	Capital Raise	Post-Money
9.6 +/- 7	6.9 +/- 7.7	16.5 +/- 14.7

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

- · Proof of concept with IND candidates
- Selection of clinically relevant animal model(s)

~15 months

- · Rodent and non-rodent tox da
- · Selection of IND enabling compound

<ul> <li>Human safety</li> </ul>	(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-Money									
148.3	29.8	178.1									

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

|------ ~13 months ----

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

# Tools reveal industry 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
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- <u>Purchase Trigger Database</u>: Reliance on an early exit is misplaced if uninformed, know your acquirer's habits

## Determine if a technology is an innovation or a modification

	DISE	EASE STATE FACT BOOK							
ŀ	twof	<u>-</u>		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				Stent	Guide Catheter	Guide Wire
	12	Units per Procedure/Service	Example: 2 Stents per Procedure, 30 pills per cycle, 30 days in long-term care				2.2	1.75	1.1
	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				\$ 550.00	\$ 9.87	\$ 6.93
	15	Market Dollars or Cost	Maket Units x Average Price				\$1,354,976,390	\$ 19,342,008	\$ 8,536,351

#### Factors that increase market value

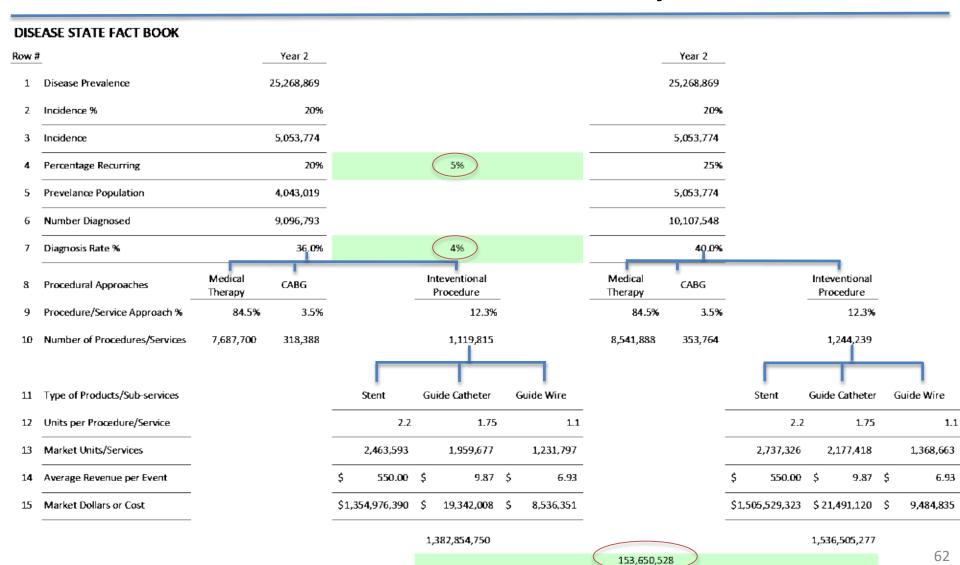
1.	Disease Prevalence	Portion of the population found to have the condition (1 in 1000)
2.	Incidence %	Percentage of new cases (generally a year)
3.	Incidence	Occurrence of new cases since last time period — later year or in a period of time (generally a year)
4.	Percentage Recurring	Percentage of population 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.
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#### The factors that increase market value

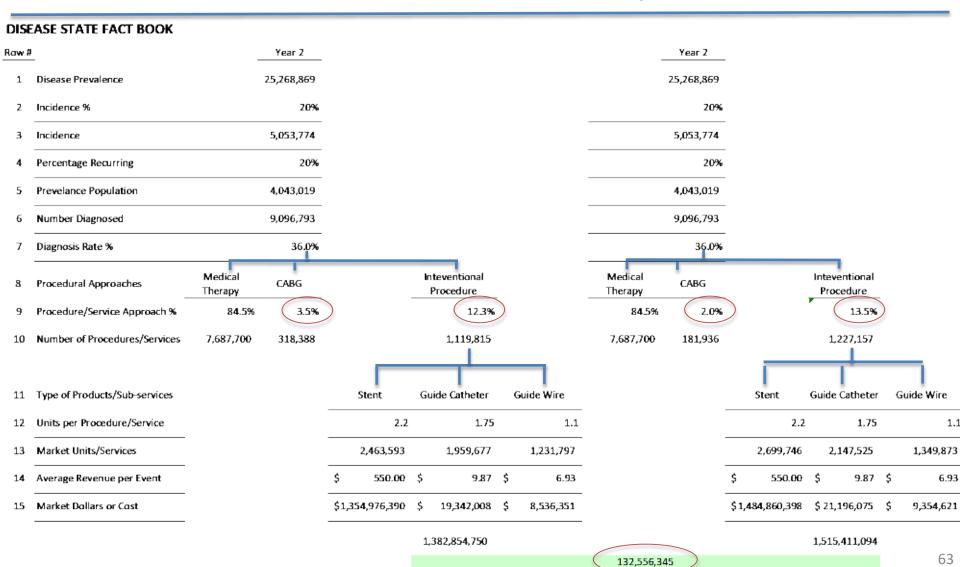
#### DISEASE STATE FACT BOOK

Row A	<u> </u>		Base Year	_	Year 2						
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								_	+		_
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13	Market Units/Services	Number of Procedures x Units per Procedure/Service				2,463	3,593		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	50.00	\$	9.87	\$	6.93
15	Market Dollars or Cost	Maket Units x Average Price	_			\$1,354,97	6,390	\$	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

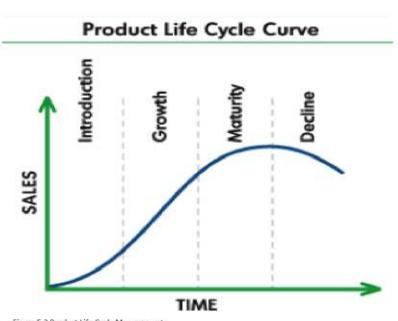
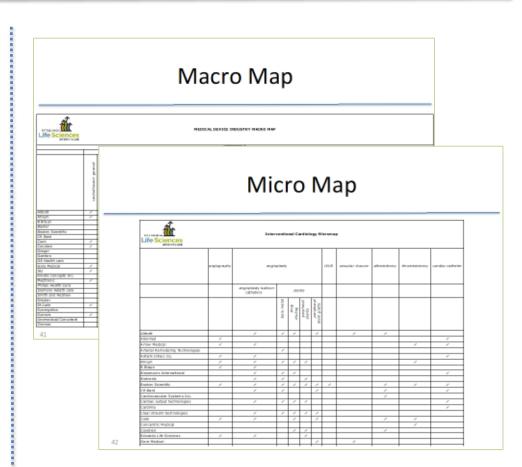
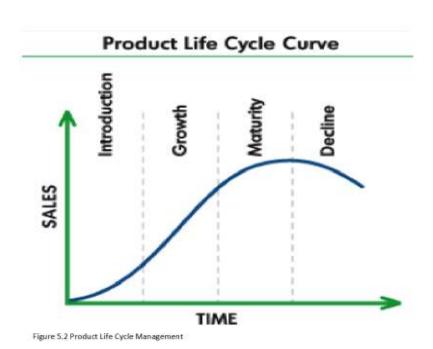


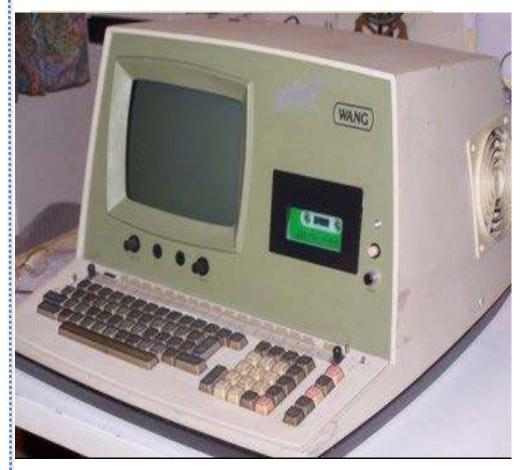
Figure 5.2 Product Life Cycle Management



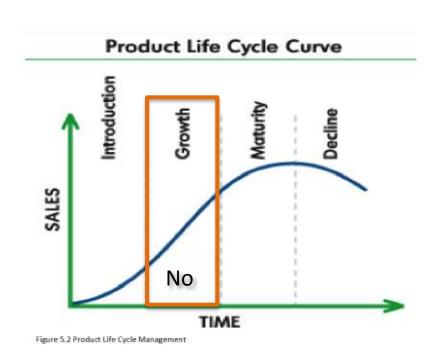
#### Determine an industry's readiness



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



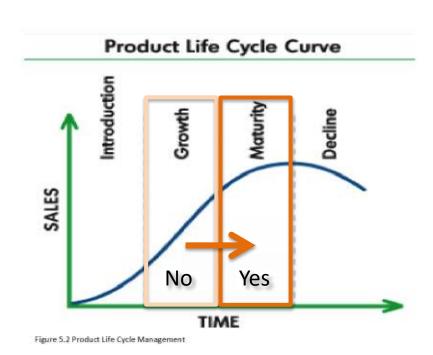
## Industry & companies in a growth phase will fight a category shift



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



- Wang developed the CRT Word Processor
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# Macro/Micro maps help uncover industry readiness

#### Zimmer-Biomet: The Deal That Shook Warsaw, Ind.

Merger, Valued at \$13.35 Billion, Combines Two Medical-Device Makers

#### Abbott Labs to Buy Private Medical Device Company Topera

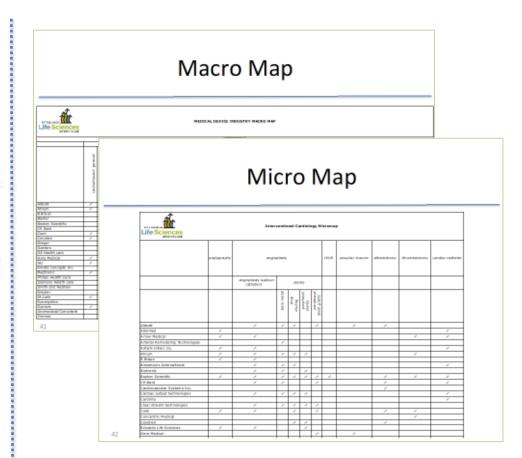
Health-Care Company Also Secures Right to Acquire Advanced Cardiac Therapeutics

#### Johnson & Johnson to Seek Buyer for Cordis Medical-Device Unit

Division Could Fetch as Much as \$2 Billion in a Sale.

#### Medtronic, Covidien Shareholders Approve Deal

Deal Is On Track To Close By The End Of January Or Early February



### Macro Map



#### MEDICAL DEVICE INDUSTRY MACRO MAP



1	HOSPITALS																														
/						Opera	ating R	200m	)							м	ulti sı	peciali	ty		ICU/CCU	Lab	orati	ory ba	sed			Spec	cialty	/	
	cardlothoracic general	colon rectal	otolarynglology	orthopedic	plastic surgery	ophthalmology	nyg-do	general laproscopy	gener	Vascular	Valoru	endoscopy	neurology	Robot assisted/Image guided	ลกสรชาชธ	respiratory devices	hemostats	geste seatents	adhesion prevention	monitoring systems		Interventional cardiology	Interventional radiology	Electrophysiology	Interventional neurology	CRM	Radiology(Imaging)	Renal	Neurology	Infusion systems	wound care and management
Abbott	·					1				✓							✓					1	1								1
Atrium	·		'		'			است	<b>✓</b>	1												✓							لت	للت	
B Braun			'	1				$\Box$		1					<b>*</b>							<b>✓</b>	1					1	1	1	1
Baxter															4		4	4	1									1		1	1
Boston Scientific		1					1		1		1	1	1									4	1		1	1					
CR Bard			1	1				1 - 1	✓	1	1	✓					4					✓	1	4		1		1			1
Cook	1	1					<b>V</b>	$\Box$	1	1	<b>✓</b>	<b>✓</b>										✓	1						$\Box$	1	
Covidien	1	<b>V</b>	1				V	1	<b>V</b>	1	1	·	<b>✓</b>			✓		·	✓		·	1	<b>V</b>		·	<b>V</b>	<b>√</b>	✓	$\Box$	1	1
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Gambro								$\Box$																				1	$\overline{}$	$\overline{}$	
GE Health care			1				1		1		1			1	4	1				-/	1		1	1		1	1		$\Box$		
Gore Medical	1	1		1					1	1			1									1	1						$\Box$		1
18.1	1			1	V	· /	1	1	1		1		1									1	1		1	1			1	·	1
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Medtronic	1		1	1				$\Box$			1										✓	✓			1	1			1	~	
Philips Health Care								$\Box$							1					1							1		$\overline{}$	$\overline{}$	
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Smith and Nephew				1			$\Box$	$\Box$				1																	$\overline{}$	$\overline{}$	1
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St. Jude	1	1					$\overline{}$	$\overline{}$						1								1		1		1			1	$\overline{}$	
Synergetics							$\Box$	$\overline{}$					V																$\overline{}$	$\overline{}$	_
Synovis	1	$\overline{}$			1		1	1	1	1	1		1																-	$\overline{}$	
Unomedical/Convotech							$\Box$	$\Box$								1					1		1						$\overline{}$	1	1
Zimmer				1																							4				

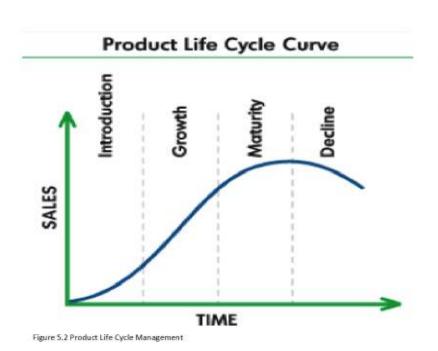
### Micro Map



#### Interventional Cardiology Micromap

- The same of the											
	angiography	an gio	plasty				īvus	vascular closure	atherectomy	thrombectomy	cardiac catheter
		angioplasty balloon cathelers		ste	nts						
			bare metal	drug eluting	perpheral stents	peripheral stent grafts					
Abbott		✓	1	<b>✓</b>		1		✓	/		
Abiomed	· /										·
Arrow Medical	· ·	✓								<b>✓</b>	·
Arterial Remodeling Technologies			1								
Ashahi Intecc Co.	· /	✓									1
Atrium	· ·	✓	1	✓	✓					<b>✓</b>	
B Braun	· /	✓									
Biosensors International		✓	1	✓							1
Biotronik		✓	1		1						
Boston Scientific	·	✓	1	1	1	1	1		<b>V</b>	✓	4
CR Bard		✓	1			1			·		1
Cardiovascular Systems Inc.									·		
Cardiac output technologies		✓	1	1	✓						1
Cardima											1
Clear stream technologies		✓	1	✓	✓	✓					
Cook	· /	✓		✓		✓			✓	✓	
Concentric Medical										✓	
Covidien				✓	✓				✓		
Edwards Life Sciences	·	✓			✓						
Gore Medical						✓		✓			

#### Determine an industry's readiness



Macro Map MEDICAL DEVICE INDUSTRY MACKS HAS Micro Map

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## 62% of PMA's 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									
11 months +/- 2.4 ———————————————————————————————————											

Series B - in millions											
Pre-Money	Pre-Money Capital Raise Post-Mon										
8.0	4 +/- 1.9	12 +/- 4.3									
14 months +/- 2.5											

Series C - in millions		
Pre-Money	Capital Raise	Post-Money
15.9	8.9 +/- 3.5	24.8 +/- 7.6
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
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□ Regulatory approval - US (F/V)

11 (62%) acquired after regulatory approval

## 62% of PMA's are acquired after FDA approval

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□ Regulatory approval - US (F/V)

## 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)