Bio

Biotechnology Innovation Organization

June 4–5, 2023

#BIO2023 #StandUpForScience



http://bit.ly/BIOBUSMODELTALK2023

Biotechnology Entrepreneurship Boot Camp

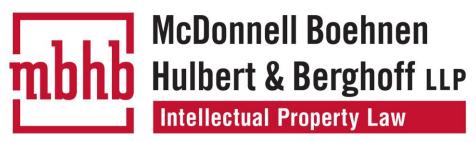
Presented by:

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Principal & CEO, Akita Biomedical

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BIO Recognizes Course Sponsor:



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OVERARCHING QUESTIONS

How can biopharmas quickly assess biomedical startups of different maturity (development & commercial) levels?

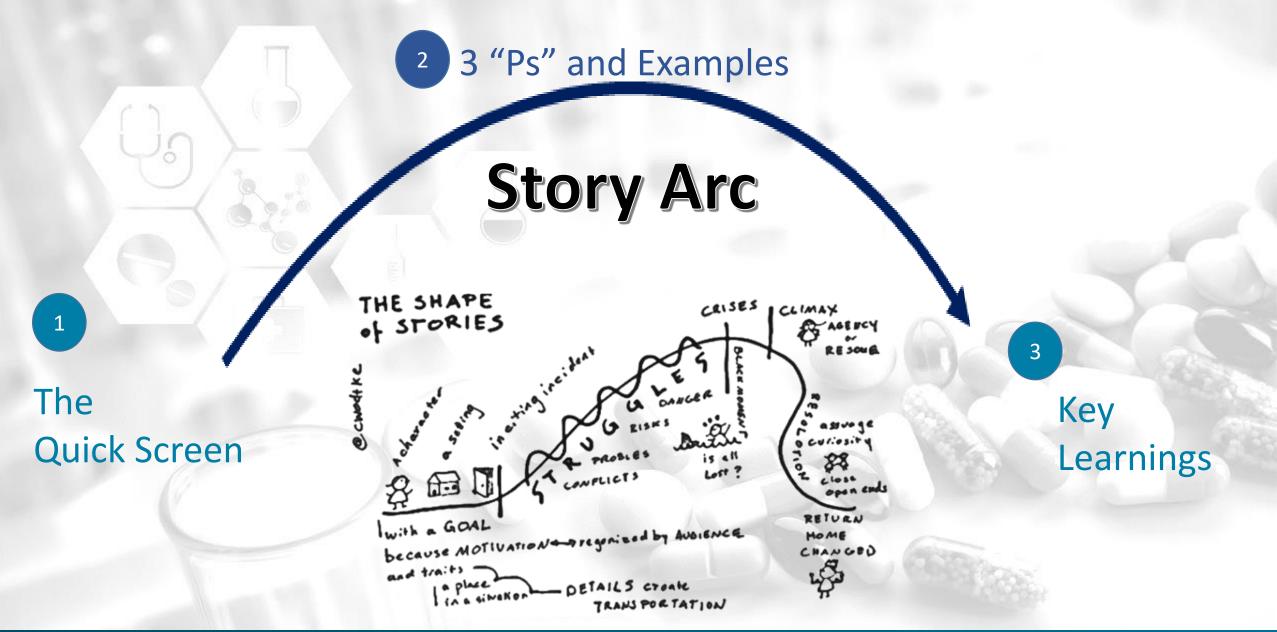
How can startups and biopharmas engage at different maturity levels?



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JACOBS SCHOOL OF ENGINEERING RADY SCHOOL OF MANAGEMENT

In the Beginning

Setting the Basis for the Quick Screen



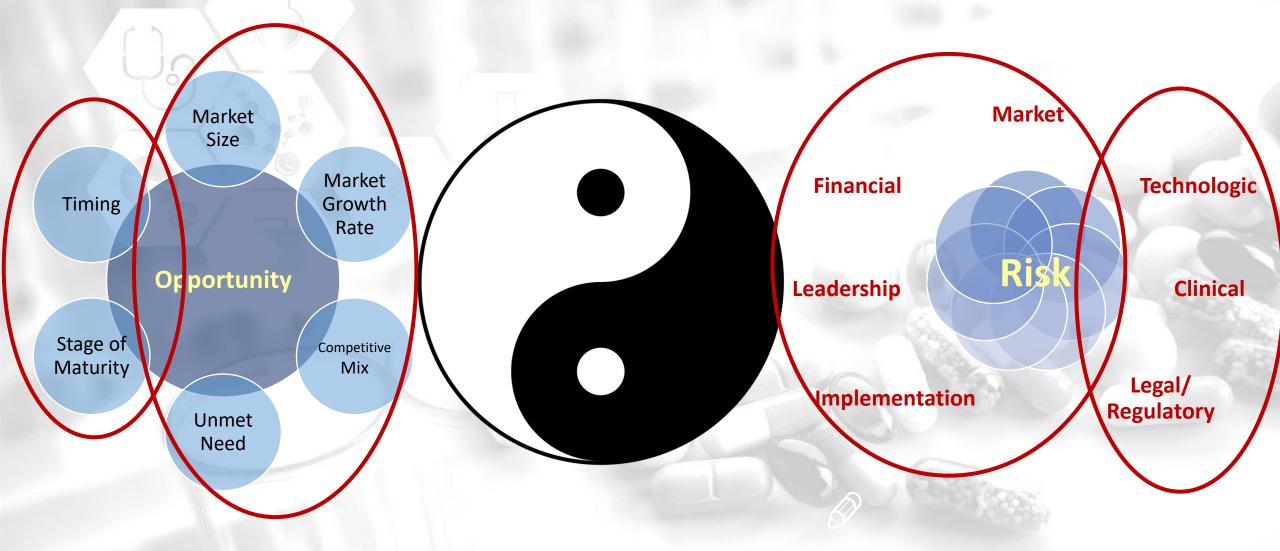
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First, There Is Opportunity and Risk (Yin and Yang!)



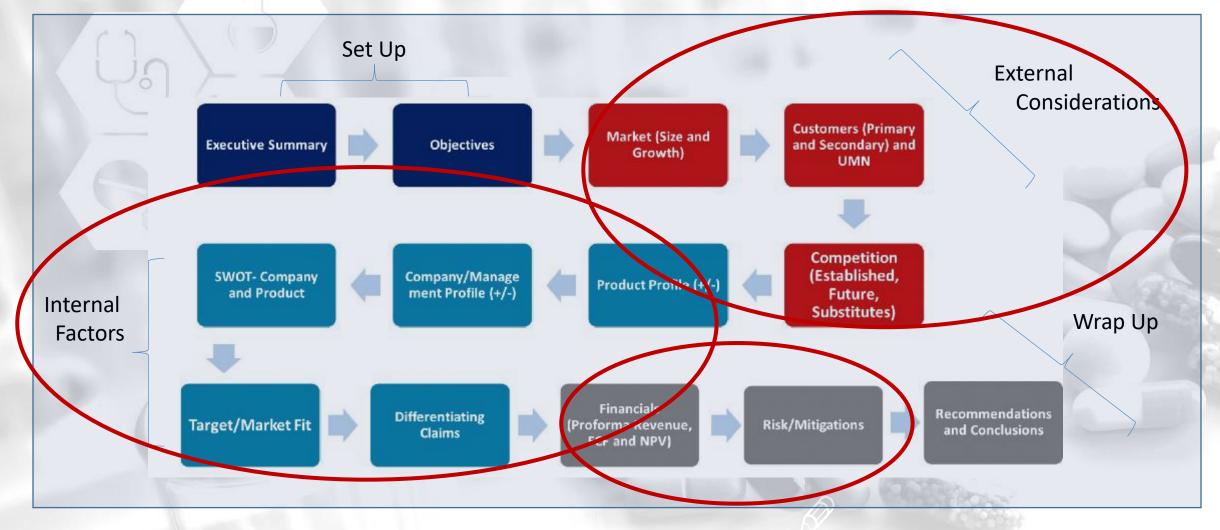


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BD Case Assessments Consider Such Factors



Erbes A BD Class Berkeley, 2014 Sheen and Gallo HBR Guide to Building Your Business Case HBR , 2015



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Don Sull, PhD MIT



Kathleen M Eisenhardt, PhD Stanford

There's a Need for Some Simplicity

Copyrighted Materi

"Whether you run an organization or are simply trying to survive modern life, this book is gold." – CHRIS ANDERSON, curator of TED Talks



SIMPLE RULES

HOW TO THRIVE

DONALD SULL | KATHLEEN M. EISENHARDT

<u>Guidelines</u> (3-5 points) tailored to the user and the task, balancing guidance with the freedom to exercise judgment.

<u>Purpose</u>: Help individuals thrive in complex situations.

Application- business to sports to personal life.

Types: How to, Boundary, Priority, Timing, and Exit.

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Boni Introduced the Quick Screen as a Useful Set of Rules



Art Boni, PhD Professor Emeritus, CMU Editor Emeritus, JCB

Article

Evolution of the Screening Metaphor: Project, Product, or Platform?

Arthur A. Boni

John R. Thorne Distinguished Career Professor of Entrepreneurship, Emeritus, Tepper School of Business at Carnegie Mellon, Editorin-Chief, Journal of Commercial Biotechnology

ABSTRACT

There are multiple options or paths to the market to be considered when developing the commercialization strategy for translating a technology or invention into an innovation. We present a very simple screening methodology that may be applied to facilitate a quick, but structured approach for the entrepreneur to identify which option or options may be most viable to create, deliver and capture value in potential markets. We construct the metaphors "project, product, or platform" to categorize three potential commercialization pathways to reach the market Projects are best pursued with commercial partners via licensing arrangements. Products may be pursued using a research and development company business model. Platform is intended to signify creation and growth of a lasting, scalable organization intended to develop and bring multiple disruptive or transformative innovations to market. Which path to the marketplace is appropriate, or even possible will depend on a number of factors. These include: the magnitude of value being created for the market; the competitive set; and, the uniqueness of the solution and its sustainable, competitive advantage that can be created. It is also necessary to determine whether the value captured by the business model that may be constructed could generate sufficient profitability to balance the commercialization risks, while meeting the goals and objectives of the founders, investors and partners over an appropriate time line.

Journal of Commercial Biotechnology (2019) 24(4), 7-13. doi: 10.5912/jcb909

INTRODUCTION

This article focuses on articulating a simple, structured screening methodology for identifying and evaluating original article is now being updated herein, and includes ideas as potential opportunities for commercialization. The methodology is structured around 5 pillars that are

needed to build and grow profitable, sustainable businesses. A key component of the methodology is to identify appropriate business models that create, deliver, and capture value consistent with the strength and viability With emphasis on simplicity, we took a metaphorical of the opportunity being pursued and the risks associated with commercialization.

session of the annual Biotechnology Entrepreneurship ization challenges, and identify an "appropriate" path to Bootcamp held at the international BIO convention the market consistent with the risks, rewards, investment each year. An article was then published as part of our first special edition in J. Commercial Biotechnology, c. landscape. f. Boni (2012)¹. Since that time, we have also published a much more comprehensive, and in-depth overview of odology that may be applied to facilitate a quick, but the entire commercialization and innovation methodol-structured approach for the entrepreneur to understand ogy that deals with the development and implementa- which options may be most viable and lowest risk to tion of commercialization and innovation strategies, create, deliver and capture value through the business

Commercialization and Innovation, Boni et al (2018)2. This more recent, cross-industry perspective also includes case studies pertinent to biopharma, MedTech and Digital Medicine. Given this more recent work, our some new perspectives.

The original article was titled, "Project, Product, or Company" since we focused on a development of categories of business model variations for potential opportunities in the broad biopharma and MedTech industries approach and suggested a framework that describes three potential pathways "from the laboratory to the market". This methodology was developed to kick off the first All of these characterize and highlight the commercial required, and with the extant or expected competitive

We first presented a very simple screening methc. f. Special Edition of JCB, titled "The Business of model that is to be created and validated.

JUNE 2019 I VOLUME 24 I NUMBER 4 7

Boni, JCB 2019



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Boni Introduced the Quick Screen as a Useful Set of Rules

The Quick Screen Addresses Three Questions and Considers the Five Anchors of a Good Opportunity



Boni, JCB 2019



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Pressing on to the 3 "Ps"

What Are They?



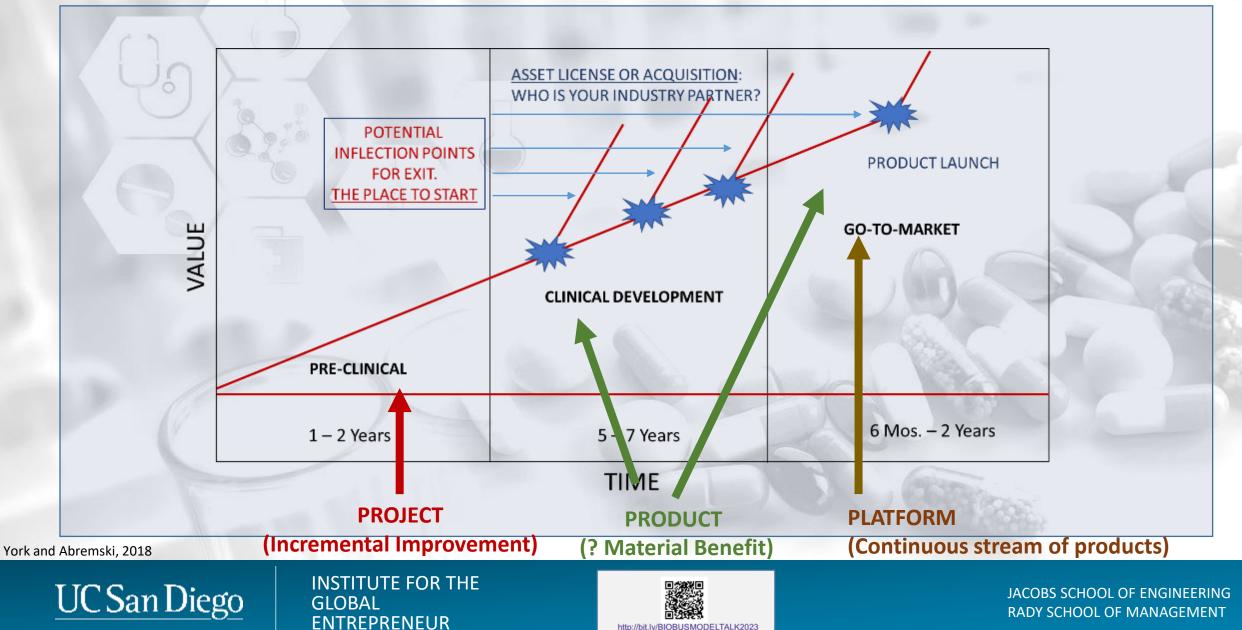
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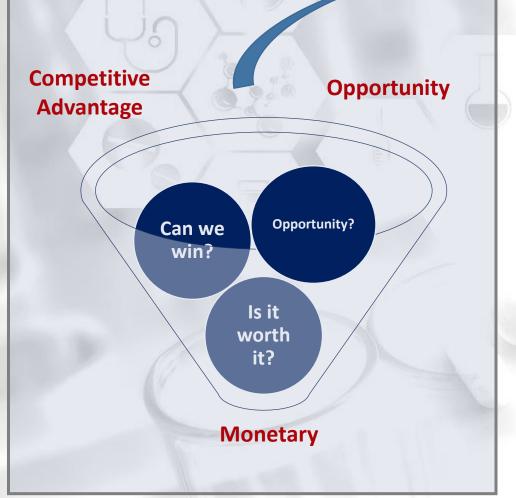
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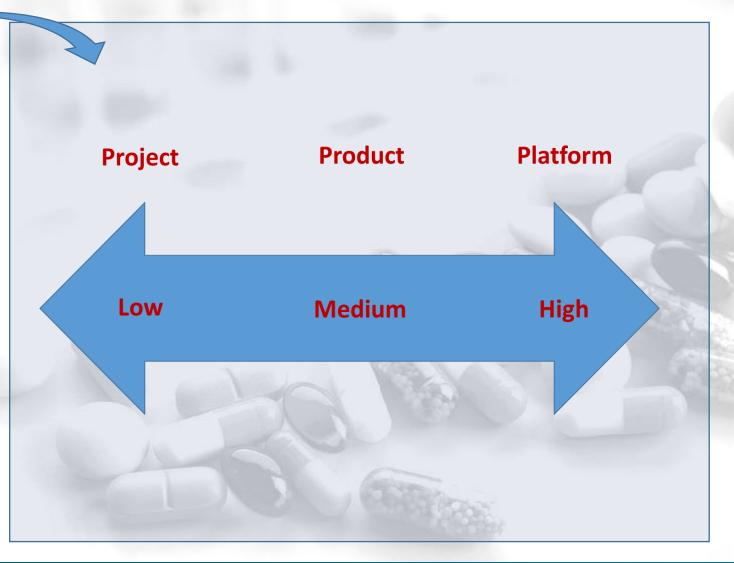
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The Three "Ps" Reflect Maturity Levels and Value Inflection Points



And the Quick Screen Can Sort Out How the 3 "Ps" Fit





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WHAT ABOUT PROJECT?

Defining Characteristics

Examples

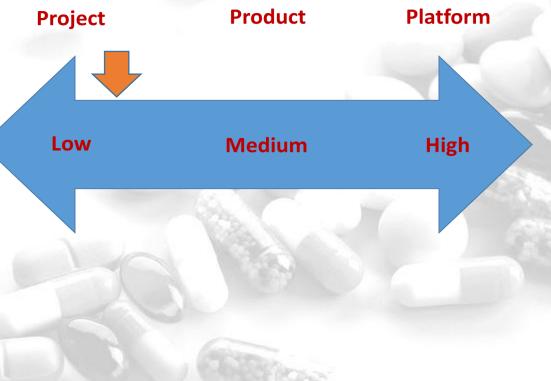


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Project- A Good Licensing, Grant, or Collaboration Option





Boni, JCB 2019 POD= Point of differentiation; FTO= Freedom to Operate; IP= Intellectual Property

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Veneno Technologies: Three-year-old, Japanese Startup

Technology: Disulfide-Rich Peptide (DRP) Discovery Suite

• Accelerate DRP drug discovery $\rightarrow \uparrow$ library screening \downarrow timing

Management: Strong Science, Seasoned

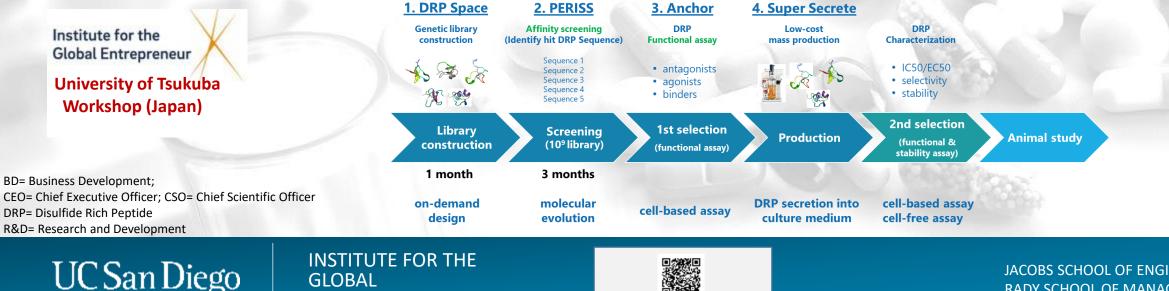
• K Yoshinkawa (CEO), T Kimura, PhD (CSO), Y Matsukawa, PhD, MBA (BD), H Taira, PhD (BD) (>10 years biopharma R&D)

Stage: Early (pre, pre-clinical)

Interactions: Building collaborative biopharma relationships

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Assessment: While Early, Can Benefit from R&D Collaborations

MAPPING KEY CONSIDERATIONS USING THE "QUICK SCREEN"→ ALL LOW

	Positives	Negatives
Opportunity	 <u>Markets</u>: Peptide→\$28.5B (2020, Global), 9.66% CAGR¹ Drug discovery→ \$58.3B (2021, Global), 8.21% CAGR² <u>UMNs</u>→ Rapid, productive screening, faster developed, expanded library, and ↑stable, novel targets 	 ↑ competition, especially in the drug discovery service space <u>Suite</u>→ early → service vs. product→ lower value (incomplete)
Monetary	• Raised \$2M seed (2021)	 Significant capital to mature to a product and a significant inflection
Competitive Advantage	 Throughput, productivity, and efficiency Multiple patents (Japan, US) Scientific expertise Projects, alliances, and licensing of technology or outputs will enhance 	 Tool/service business may be questionable for a durable POD

KEY POINTS FROM THE MAP

- 1. Attractive markets
- UMNs for screening/library production and sustainable oral peptides
- 3. Suite \rightarrow Advantages, but early
- 4. \$ raised \rightarrow Need more
- 5. Recent Astellas Pharma collaboration.
- Drug discovery competitive → ? the tool/service business durability
- 7. Projects or alliances $\$ \rightarrow$ lead peptide
 - \rightarrow Animal POC \rightarrow Clinical testing

CAGR= Compounded Annual Growth Rate; POD= Point of Differentiation; ?=Questionable



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<u>AgPlus</u>: A UK Point-of-Care Diagnostic Venture to Deliver Personalized Healthcare Using Individual Biomarker Profiles

<u>Technology</u>: Novel electrochemistry + metallic nanoparticles → signaling with diagnostic immunoassays

<u>Management</u>: Experience >100 years (R&D, project, Manufacturing)

<u>Stage</u>: Preclinical

Interactions: Contract Work (Primary) and Own Assays

- <u>Contract</u> →New diagnostics products and develop new assays
- <u>Additional</u> → Own assays for licensing and integration into partners' products





Innovate UK EDGE

Assay development and manufacturing services provider – moving into point of care diagnostics (PoC) platform provision.



R&D= Research and Development; PoC= Point of Care

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Assessment: Build Out Collaborative Alliances and Contract Development Projects

MAPPING KEY CONSIDERATIONS USING THE "QUICK SCREEN"→ ALL LOW

	Positives	Negatives	Uncertain	KEY POINTS FR
Opportunity	 PoC dx: \$32.9→\$73.3 B (2020-20), CAGR 8.3% 	 Early stages of implementing multiple assays 	 Offering assay development and manufacturing 	 PoC diagnostics at Faster regulatory r
Monetary	 Service revenue offsets Grants and angel investments → BP 1.5M Planning to raise GBP 5M for customer validation 	 Still have significant investment for development 		 3. Early → Needs pred 4. Technology is not 5. IP is trade secret
Competitive Advantage	 Ability to create a range of assays in a consistent cartridge form factor for use in their readers Service revenue from partners 	 IP → Patents (UK, EU), knowhow and trade secrets 	 Technology not the industry standard Early stage 	6. Service \$s from pa more for a regulat
				A CONTRACTOR

ROM THE MAP

- ttractive
- route
- eclinical validation
- the industry standard
- $artners \rightarrow Need$

tory-approved product

BP= British Pounds; CAGR= Compounded Annual Growth Rate; EU= European Union; GBP= Great Britain Pounds; IP= Intellectual Property; UK= United Kingdom



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WHAT ABOUT PRODUCT?

Defining Characteristics

Examples

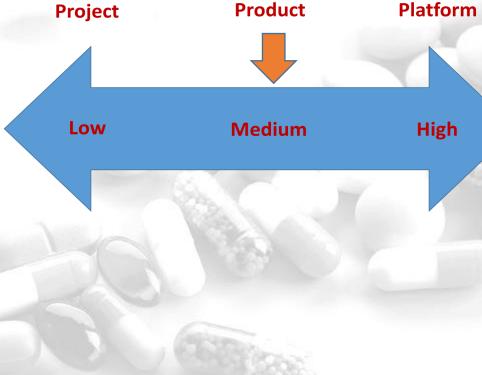


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Product- A Development Stage Set to Commercialize





IGTM= Go to Market; P= Intellectual Property; POC= Proof of Concept

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JD Bioscience: An Emerging 6-year-Old, Clinical-Stage Firm from Korea

Institute for the Global Entrepreneur

Global Entrepreneurship Accelerator (Korea)

Technology: GM-60106 (a peripheral 5HT2A inhibitor) is 1st in class

Management: Science-Oriented, with a Track Record and Expertise

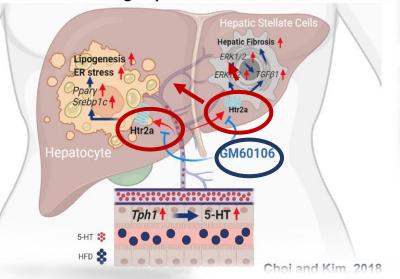
- J. Ahn, Ph.D. (CEO) \rightarrow Med Chem Prof, > 5 L/O to pharma
- D. Kim, Ph.D. (Director) → Merck (20 years, Januvia[®]), Kainos (9 years, CTO)
- R. Loomba, MD (SAB) → Professor & Director, NAFLD Center, UCSD

Stage: Completing FIH Phase 1 2023 in Australia for SAD and MAD

Interactions: Engaging industry partners for alliance opportunities

MOA of GM-60106 during hepatic steatosis and liver fibrosis

JD BIOSCIENCE



CEO= Chief Executive Officer; CTO= Chief Technology Officer; MOA= Mechanism of Action; NAFLD= Non-alcoholic Fatty Liver Disease; SAB= Scientific Advisory Board; SAD= Single Ascending Dose; MAD= Multiple Ascending Dose; 5HT= Serotonin

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Assessment: Early-Stage Clinical Can Benefit from Alliances

MAPPING KEY CONSIDERATIONS USING THE "QUICK SCREEN" → ALL MID

	Positives	Negatives
Opportunity	 Moving into Ph 1 a/b <u>Market</u>: \$144.4M→\$27.2B (2019-29), 68.8% CAGR (Global)¹ <u>UMN</u>→ lipid, inflammation, and fibrosis management^{2,3} <u>Trend</u>→ Movement to combo therapy² (Pfizer fast track) 	 Uncomfortable investors/BD regarding NASH
Monetary	 Series A and B Funding (~\$20M, Lead, Mirae Asset Capital) 	• Funding needed for Ph 2 and 3
Competitive Advantage	 1st-in-class peripheral 5HT2A antagonist Defined IP (Korea, US) ↓ fibrosis, inflammation, and lipids (4 animal models) No BBB crossing Alliance/licensing → enhance development position 	 No real H/H with other assets through development

KEY POINTS FROM THE MAP

- 1. Large market \rightarrow No approved treatments.
- 2. Madrigal Pharmaceuticals, Inc.
 - \rightarrow breakthrough designation and Phase 3.
- 3. Combo therapy (Gilead/Novo Nordisk)
- 4.Unique MOA (fibrosis, inflammation, and lipid reduction) with POC (4 animals).
- 5. JDB Completes FIH with no safety issues.
- 6. Complicated disease. Issues with clinical studies and approvals (Intercept).
- 7. Has funding; Needs more for Ph 2 and $3 \rightarrow$

Alliance/licensing \rightarrow Move asset along.

BBB= Blood Brain Barrier; BD= Business Development; CAGR= Compounded Annual Growth Rate; FIH= First in Human; H/H= Head to Head; NASH=Non-Alcoholic SteatoHepatitis; Ph= Phase; UMN= Unmet Need

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Reviva Pharma: Late-stage Drug Development That's Gone Public

<u>Technology</u>: Chemical Genomics-driven and Proprietary Chemistry Approach

- Brilaroxazine \rightarrow Multimodal D/5HT ag/antag (central & peripheral)
- POC- Animal- PAH, IPF, Schizophrenia Human- Schizophrenia

Management: Seasoned Industry Scientists

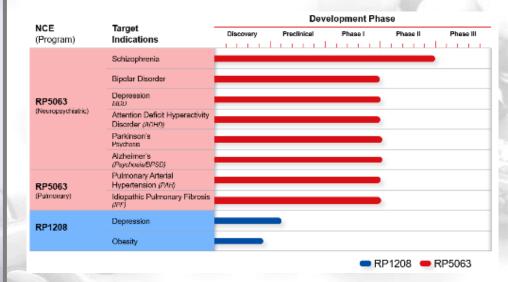
• L. Bhat, PhD- CEO, M. Cantillon, MD (CMO) (>16 yrs with co., > 20 yrs industry)

Stage: Phase 3 Schizophrenia, Phase 2 PAH, IPF (ODD)

Interactions: SPAC (Tenzing) 2020 (Public)

•Exploring industry options for development and commercialization





TENZING ACQUISITION CORP. (TZACU)

CEO= Chief Executive Officer; CMO= Chief Medical Officer; D= Dopamine; IPF=Ideopathic Pulmonary Fibrosis; ODD= Orphan Drug Designation; PAH= Pulmonary Artery Hypertension; Ph= Phase; POC= Proof of Concept; SPAC= Special Purposes Acquisition Company; 5HT= Serotonin; Yrs.=Years

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Assessment: Strong, Late Stage with a Few Shots on Goal. Could Benefit from an Alliance

MAPPING KEY CONSIDERATIONS USING THE "QUICK SCREEN" -> ALL MID-LATE

	Positives	Negatives
Opportunity	 Schizophrenia → \$7.8B → \$9.3B, 3.68% CAGR, (2020-26).¹ <u>UMN</u>→ Broad efficacy, ↑ safety and clean PK (<u>B</u> → Ph 3) PAH→\$7B, 5.2% CAGR (2021)² IPF→ \$3.1B→\$6.16B, 7% CAGR (2020-30) <u>UMN</u>→ Dz modification → ↓ M&M (<u>B</u> → Ph 2) 	
Monetary	• Reverse merger (SPAC) 2020→ Tenzing (Public)	• Financing for Ph 3, but still needs for Ph 2s
Competitive Advantage	 Strong IP→ multiple layers (US, EU) Simple PK, attractive safety, and strong POC Later stage, Public company Lean management and business model Would benefit from an alliance 	 Still needs Ph 2 and Ph 3 data and commercialization plans
		RESOURCING

KEY POINTS FROM THE MAP

- 1. Interesting markets with UMNs.
- 2. Lead asset in Ph 3 and Ph 2 (ODD).
- 3. SPAC with Tenzing (public).
- 4. Multiple posters/papers in 2023.
- 5. New formulation with POC for

psoriasis.

6. Need \$ for Ph 2 ODDs & GTM for

schizophrenia.

7. Would benefit from alliance to

commercialize lead indication.

B= Brilaroxazine; B= Billion; CAGR= Compounded Annual Growth Rate; EU= European Union; GTM= Go to Market; IPF=Idiopathic Pulmonary Fibrosis; M&M= Morbidity & Mortality; ODD= Orphan Drug Designation; PAH= Pulmonary Artery Hypertension; Ph= Phase; PK= Pharmacokintics; POC= Proof of Concept; SPAC= Special Purposes Acquisition Company; US= United States



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WHAT ABOUT PLATFORM?

Defining Characteristics

Examples



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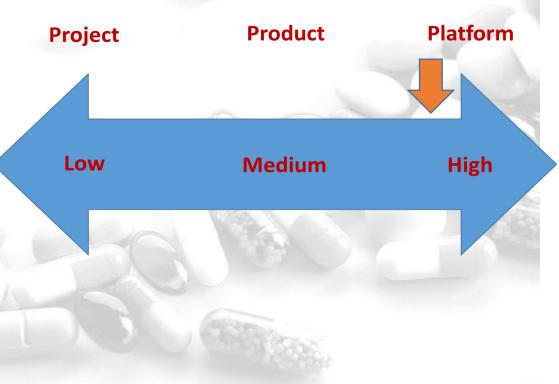


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<u>Platform</u>- Built to Last with Multiple Products and Management Team to Carry Products Further





Boni, JCB 2019 Clin: Clinical; IP= Intellectual Property; Reg= Regulatory; ROI= Return on Investment

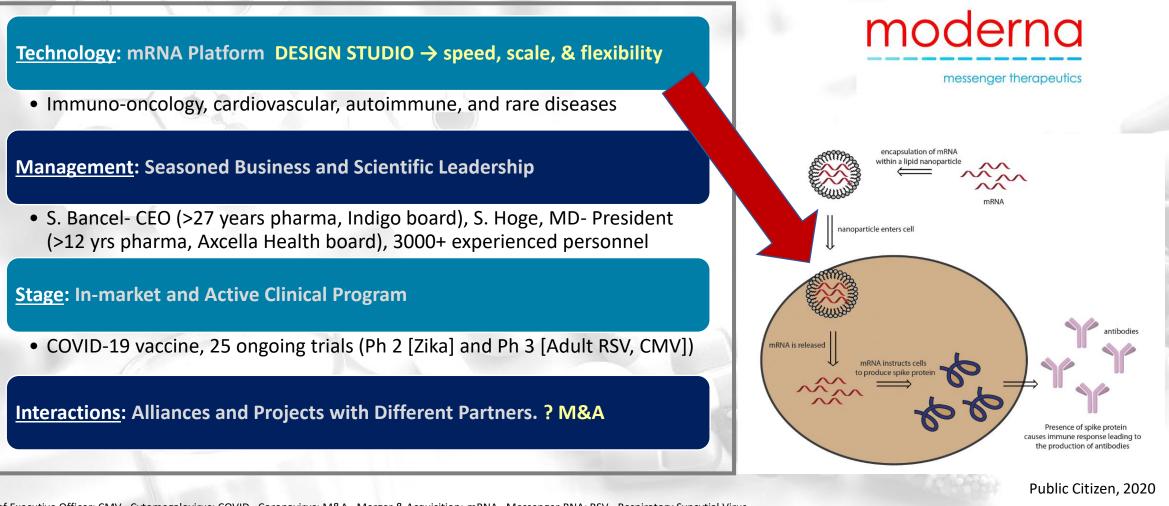
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Moderna: An In-market, mRNA Firm, with COVID-19 Success and a Diverse Pipeline



CEO= Chief Executive Officer; CMV= Cytomegalovirus; COVID= Coronavirus; M&A= Merger & Acquisition; mRNA= Messenger RNA; RSV= Respiratory Syncytial Virus.

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Assessment: Many Positives with Room for Growth in Alliances or May Engage in M&A

MAPPING KEY CONSIDERATIONS USING THE "QUICK SCREEN" → ALL HIGH

0/	Positives
Opportunity	 Market: Vaccines: \$67B→149B (2001-27), CAGR 10.2%¹ COVID-19: \$65B→\$157B (2020 -25) CAGR 19.29%² mRNA: \$47B → \$101B (2021-26)³ UMN→ HIV, RSV, CMV, Zika and cancer in the pipeline
Monetary	 <u>Revenue</u> → \$803.4M → \$18.5B (2020-21)⁴ <u>Market cap</u> → \$54.19 B (May 2022)⁵ Room for growth
Competitive Advantage	 Unique platform, strong COVID-19 experience, Strong IP Ph 1→ HIV vaccine (mRNA-1644 & mRNA-1574) and Immuno-oncology (IL-12, MEDI 1191) Seasoned mgmt.; large talented organization Multiple alliances (e.g., AZ, Merck, Vertex). Maybe M&A

KEY POINTS FROM THE MAP

1. Defined, effective platform with

commercial success

- 2. Pipeline ID and IO applications
- 3. Seasoned mgmt.; Talented organization
- 4. Attractive opportunities with UMNs
- 5. Strong revenue, but declining due to the
 - control of COVID.
- 6. \$ left on the table?
- 7. Benefit from alliance. Maybe M&A

(BioNTech-Pfizer \rightarrow \$37B

vs. Moderna \rightarrow \$18.5 B in 2021)



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AZ= AstraZeneca; B= Billion; CAGR= Compounded Annual Growth Rate; CMV= Cytomegalovirus; COVID= Coronavirus; HIV= Human Immunodeficiency Virus; IL= Interleukin; ID= Infectious Disease; IO= Immuno-Oncology' M&A= Mergers & Acquisitions; mRNA= Messenger RNA; RSV= Respiratory Syncytial Virus.

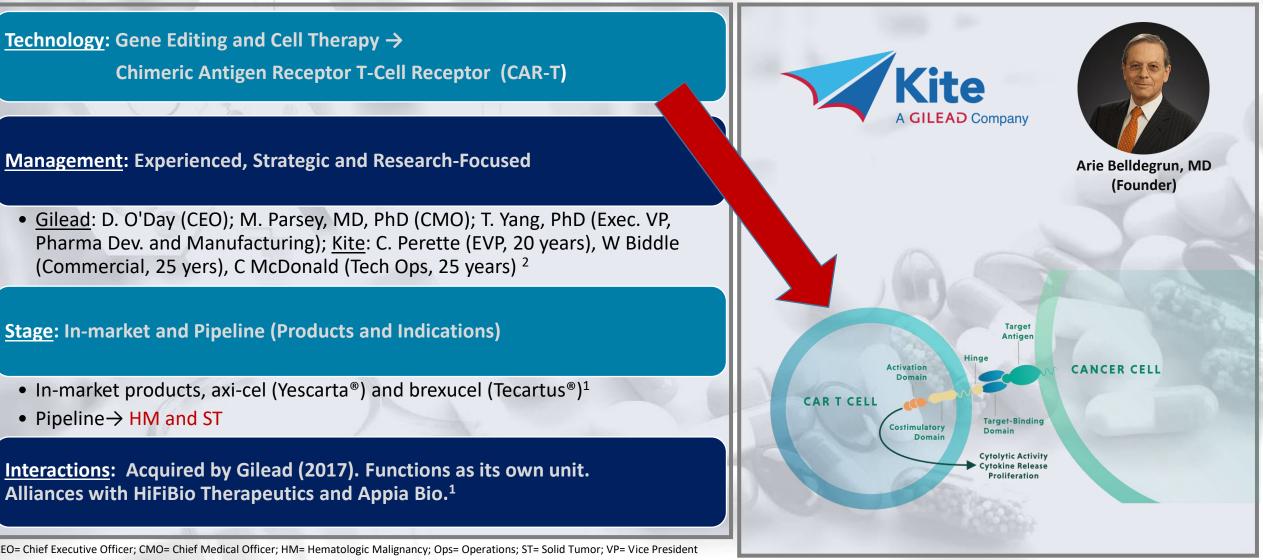


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Research and Markets 2022
 Williams S. The Motley Fool, 2021
 BCC Research, 2022
 Marketline 2022 5. Companies Market Cap

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Kite: Cell Therapy Pioneer within an Established Pharma



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CEO= Chief Executive Officer; CMO= Chief Medical Officer; HM= Hematologic Malignancy; Ops= Operations; ST= Solid Tumor; VP= Vice President

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Kite Pharma, 2022

GILEAD. 2021

Assessment: Healthy Platform Led to Gilead Acquisition, Robust Growth, and Potential for Acquiring Other Assets

MAPPING KEY CONSIDERATIONS USING THE "QUICK SCREEN" -> ALL HIGH

Positives	Negatives
 Market: CAR-T→1.96B→ \$20.56B(2021-29), 31.6% CAGR¹ UMN:↓ chemo and treatment time, needs in solid tumors, and ↑ survival and cures 	 <u>Competition</u>: G1 Tx, BioNTech, Amgen, Novartis, and Juno²
 Potential high revenue, profits, and margins <u>Revenues (Gilead total)</u>: \$27.3 B (2021)³ CAR-T: \$871M (up 43% due to Tecartus[®] launch)⁶ <u>Market Cap</u>: \$80B⁴ Room to grow 	
 Pioneer, with well-established IP In-market products → strong efficacy and safety Gilead. Experienced leadership. ↑ manufacturing capabilities Broad HM and ST pipeline; platform for continued innovation, especially allogenic for ST 	
	 Market: CAR-T→1.96B→ \$20.56B(2021-29), 31.6% CAGR¹ UMN:↓ chemo and treatment time, needs in solid tumors, and ↑ survival and cures Potential high revenue, profits, and margins Revenues (Gilead total): \$27.3 B (2021)³ CAR-T: \$871M (up 43% due to Tecartus[®] launch)⁶ Market Cap: \$80B⁴ Room to grow Pioneer, with well-established IP In-market products→ strong efficacy and safety Gilead. Experienced leadership. ↑ manufacturing capabilities Broad HM and ST pipeline; platform for

KEY POINTS FROM THE MAP

1. Defined, effective platform with
commercial success, revenue, and growth
2. Seasoned mgmt.; Talented organization
3. Attractive opportunities with UMNs
4. Multiple HM & ST pipeline programs-
Ph 3 (2), Ph 2 (4), and Ph 1 (2)
5. Evolving competitive space
6. Departure of C Shaw, the CEO in Q1 2023.
7. A great marriage. Could benefit
from alliance to fully tap pipeline.

B= Billions; CAGR= Compounded Annual Growth Rate' CAR-T=Chimeric Antigen Receptor T-Cell Receptor; HM= Hematologic Malignancy; IP= Intellectual Property; M= Million; Mkt= Market; Ph= Phase



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3 GII FAD, 2021 4.Yahoo Finance, 2022 5.Kite Pharma, 2022 6.Kite, 2021 10K

1.Polaris Market Research, 2022



TAKE HOME CONSIDERATIONS

3 Key Learnings And a Proposed Tool



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Key Learnings:

2

↓ Risk → ↑ Opportunity Development

3

Different Engagement Strategies Exist, which evolve from nascent to mature

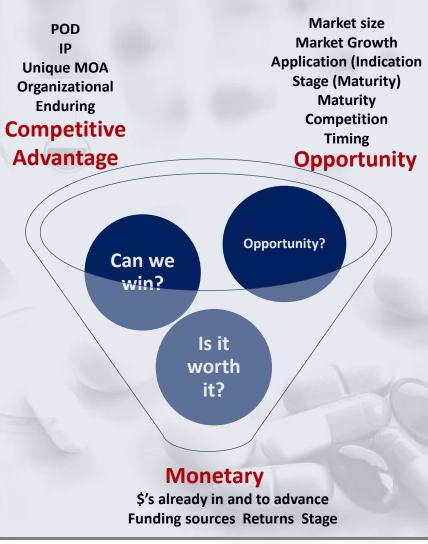
Quick Screen → Useful Lens for Sensemaking that Can Be Developed and Refined with Time and Experience



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And, There's More to the QS that Just Meets the Eye



Boni, JCB 2019 IP= Intellectual Property; MOA= Mechanism of Action; POD= Point of Differentiation

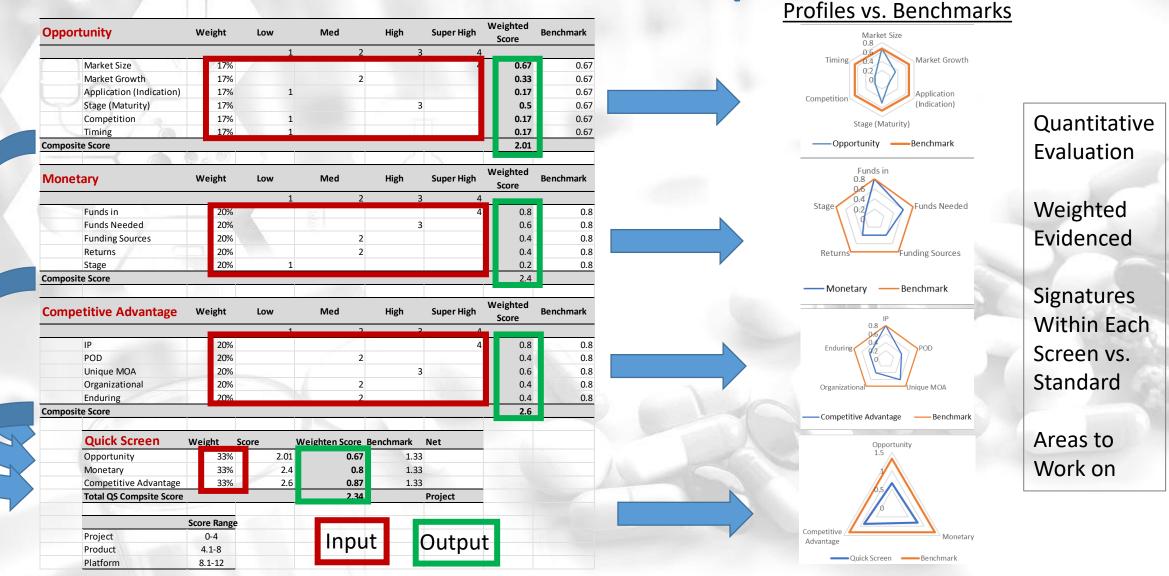


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A Score Card Tool to Explore



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CONCLUSION: BACK TO OUR OVERARCHING QUESTIONS

How can biopharmas quickly assess biomedical startups of different maturity (development & commercial) levels?

How can startups and biopharmas engage at different maturity levels?

Quick Screen → Useful Lens for Sensemaking Early in the Process and Complement More Detailed Due Diligence Later On

Among the 3 P Stages → Multiple, Unique Engagement Strategies Exist and Evolve with Maturity



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Closing Thought....

The beauty of simplicity is the complexity it attracts.

Tom Robbins



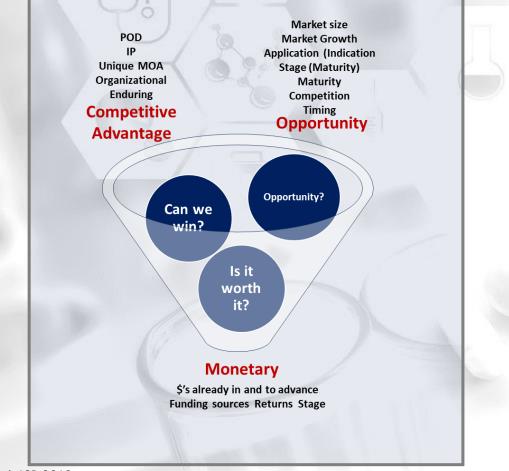
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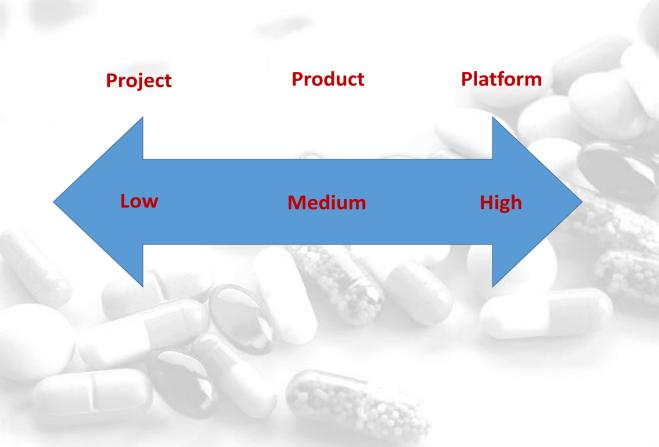


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Case Activity: Let's Take and Map Out a Company or Two From the Audience?





Boni, JCB 2019 IP= Intellectual Property; MOA= Mechanism of Action; POD= Point of Differentiation



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