Bio Events International Convention

Biotechnology Entrepreneurship Boot Camp
Workshop Session 2: Sunday, June 12, 2022 (10:15-11:15 AM)

The QUICK SCREEN in Action

Case Examples: Project, Product, or Platform?

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OVERARCHING QUESTIONS

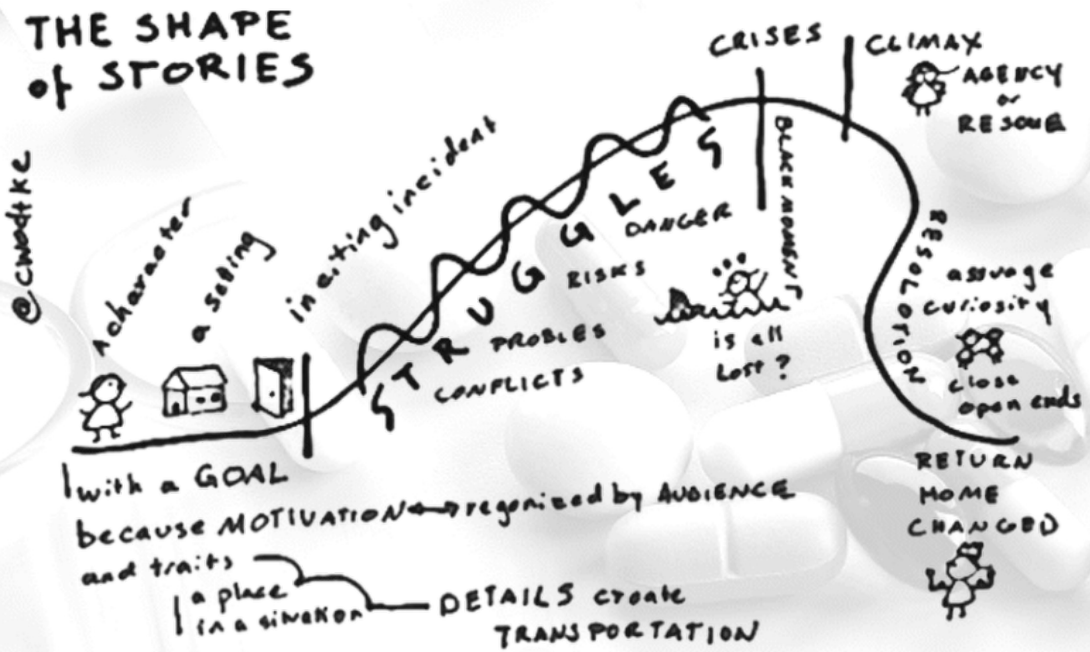
How can biopharmas quickly assess biomedical startups of different maturity (development & commercial) levels?

How can startups and biopharmas engage at different maturity levels?

2 3 “Ps” and Examples

Story Arc

1 The Quick Screen



3 3 Key Learnings

In the Beginning

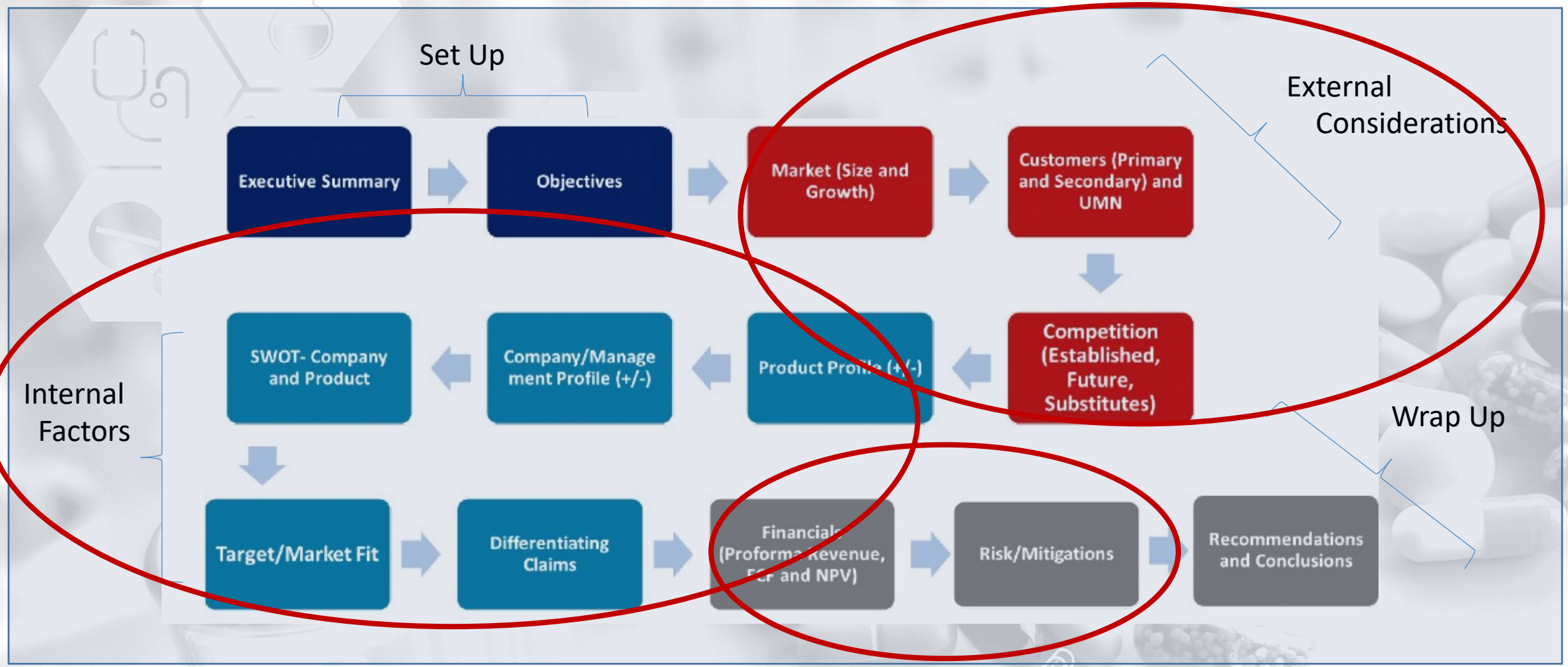
Setting the Basis for the Quick Screen

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

What are some elements of opportunity and risk that we need to consider with Life science startups?

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

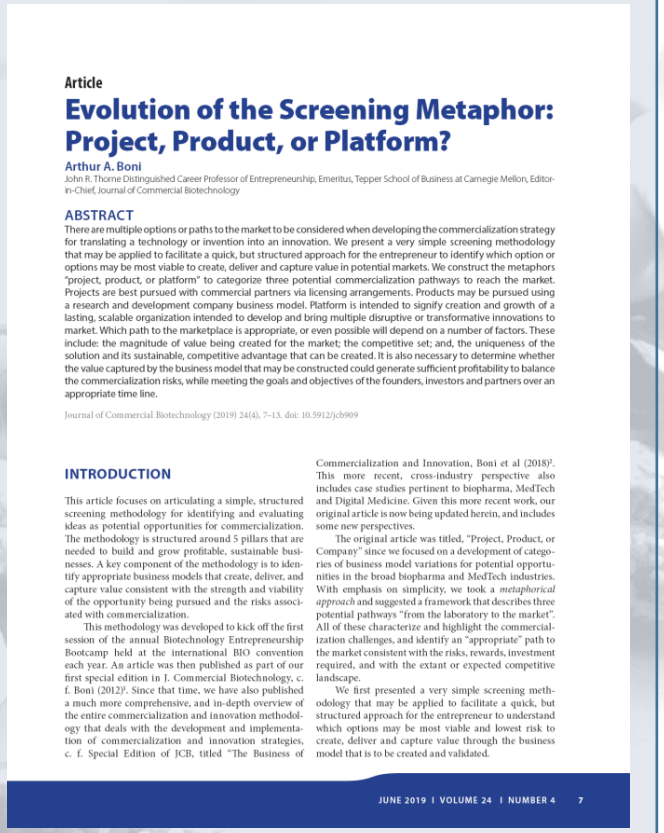
BD Case Assessments Consider Such Factors



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

That's What I Was Presenting at Pharma R&D This Year, But Art Boni, PhD Had Another Angle

Art Boni, PhD
Editor in Chief at
Journal of Commercial Biotechnology



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, Editor-in-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

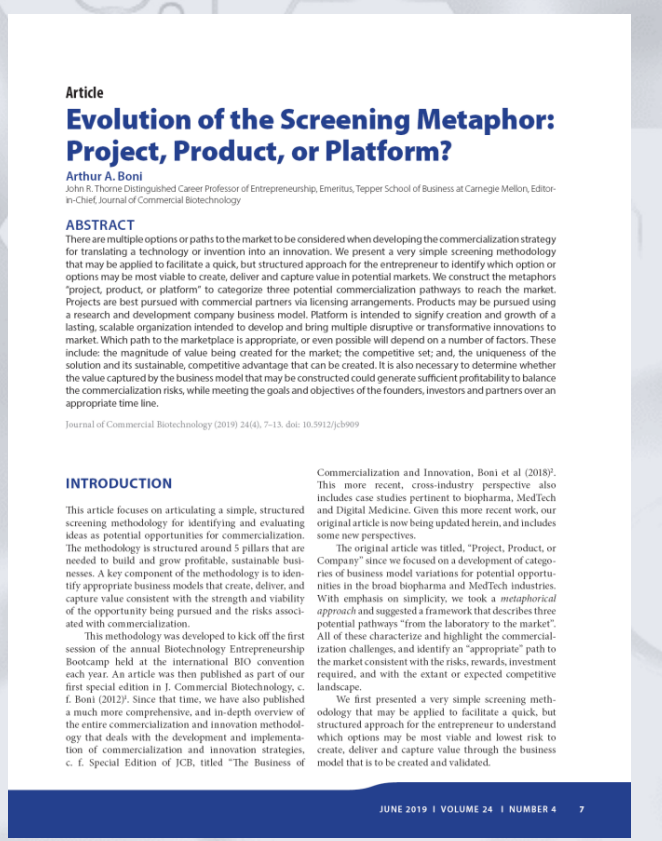
This article focuses on articulating a simple, structured screening methodology for identifying and evaluating ideas as potential opportunities for commercialization. The methodology is structured around 5 pillars that are needed to build and grow profitable, sustainable businesses. A key component of the methodology is to identify appropriate business models that create, deliver, and capture value consistent with the strength and viability of the opportunity being pursued and the risks associated with commercialization.

This methodology was developed to kick off the first session of the annual Biotechnology Entrepreneurship Bootcamp held at the international BIO convention each year. An article was then published as part of our first special edition in J. Commercial Biotechnology, c. f. Boni (2012)[2]. Since that time, we have also published a much more comprehensive, and in-depth overview of the entire commercialization and innovation methodology that deals with the development and implementation of commercialization and innovation strategies, c. f. Special Edition of JCB, titled "The Business of Commercialization and Innovation, Boni et al (2018)[3]. This more recent, cross-industry perspective also includes case studies pertinent to biopharma, MedTech and Digital Medicine. Given this more recent work, our original article is now being updated herein, and includes 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. With emphasis on simplicity, we took a *metaphorical approach* and suggested a framework that describes three potential pathways "from the laboratory to the market". All of these characterize and highlight the commercialization challenges, and identify an "appropriate" path to the market consistent with the risks, rewards, investment required, and with the extant or expected competitive landscape.

We first presented a very simple screening methodology that may be applied to facilitate a quick, but structured approach for the entrepreneur to understand which options may be most viable and lowest risk to create, deliver and capture value through the business model that is to be created and validated.

The Quick Screen?



Article

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What Is It?

What Are Some Key Questions and Criteria for Using It?

That Was the Quick Screen, a Useful Lens Before the Business Case

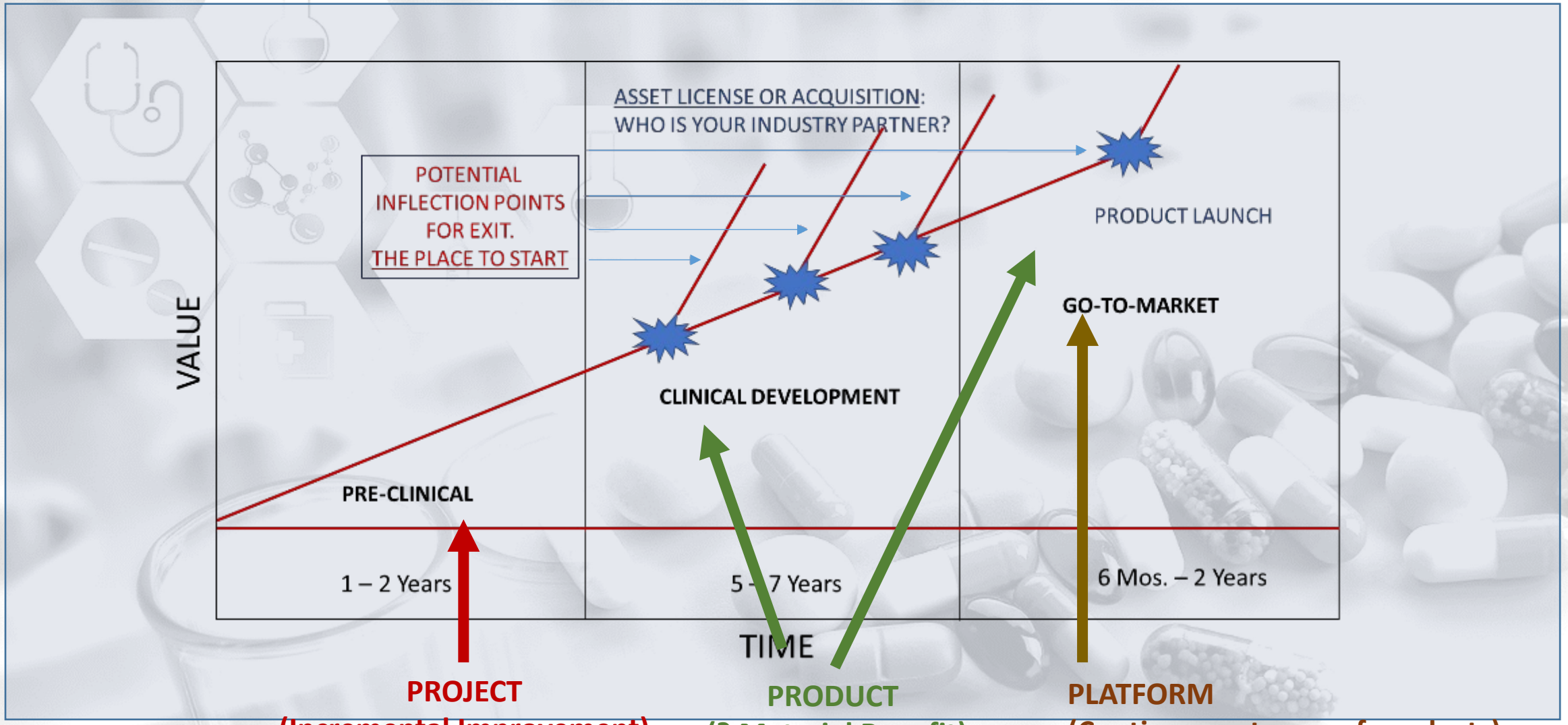
The Quick Screen Addresses Three Questions and Considers the Five Anchors of a Good Opportunity

Boni, JCB 2019

Pressing on to the 3 "Ps"

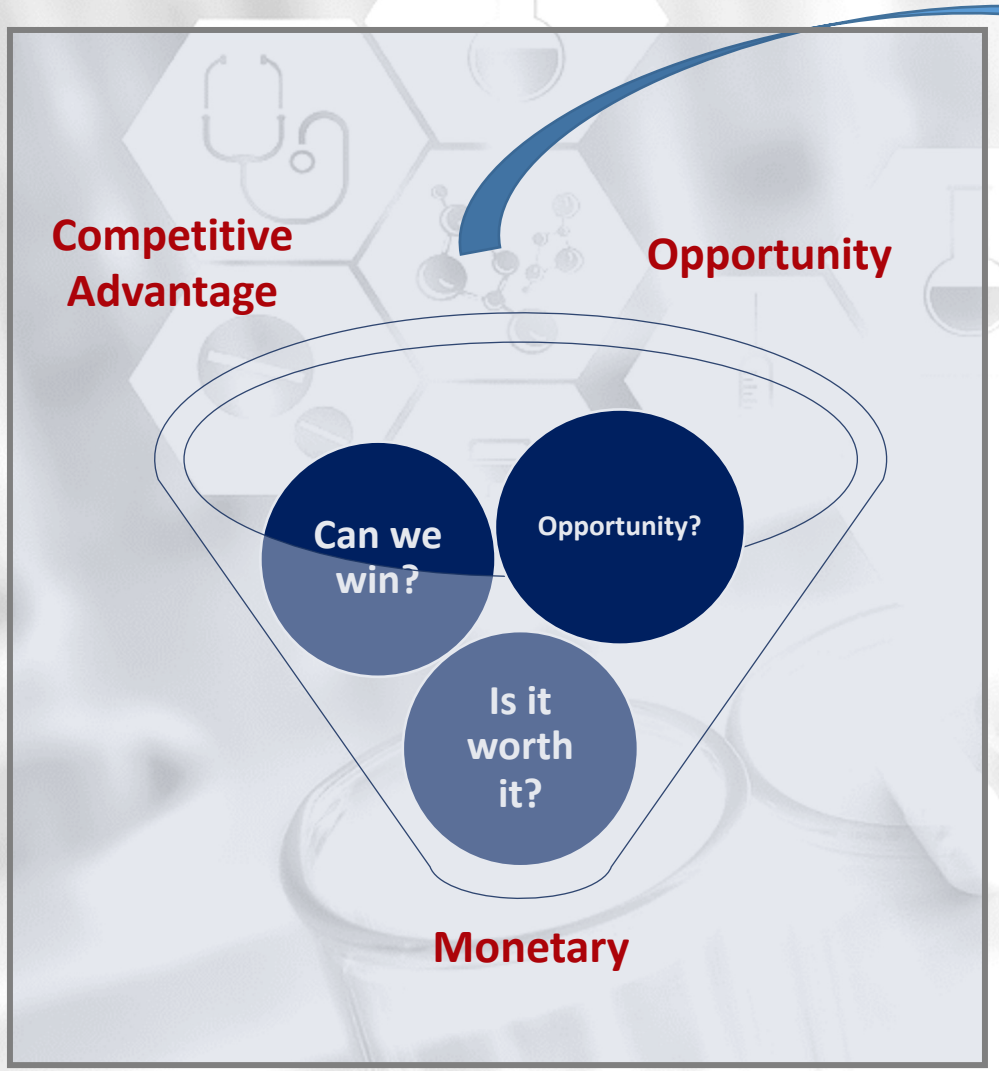
What Are They?

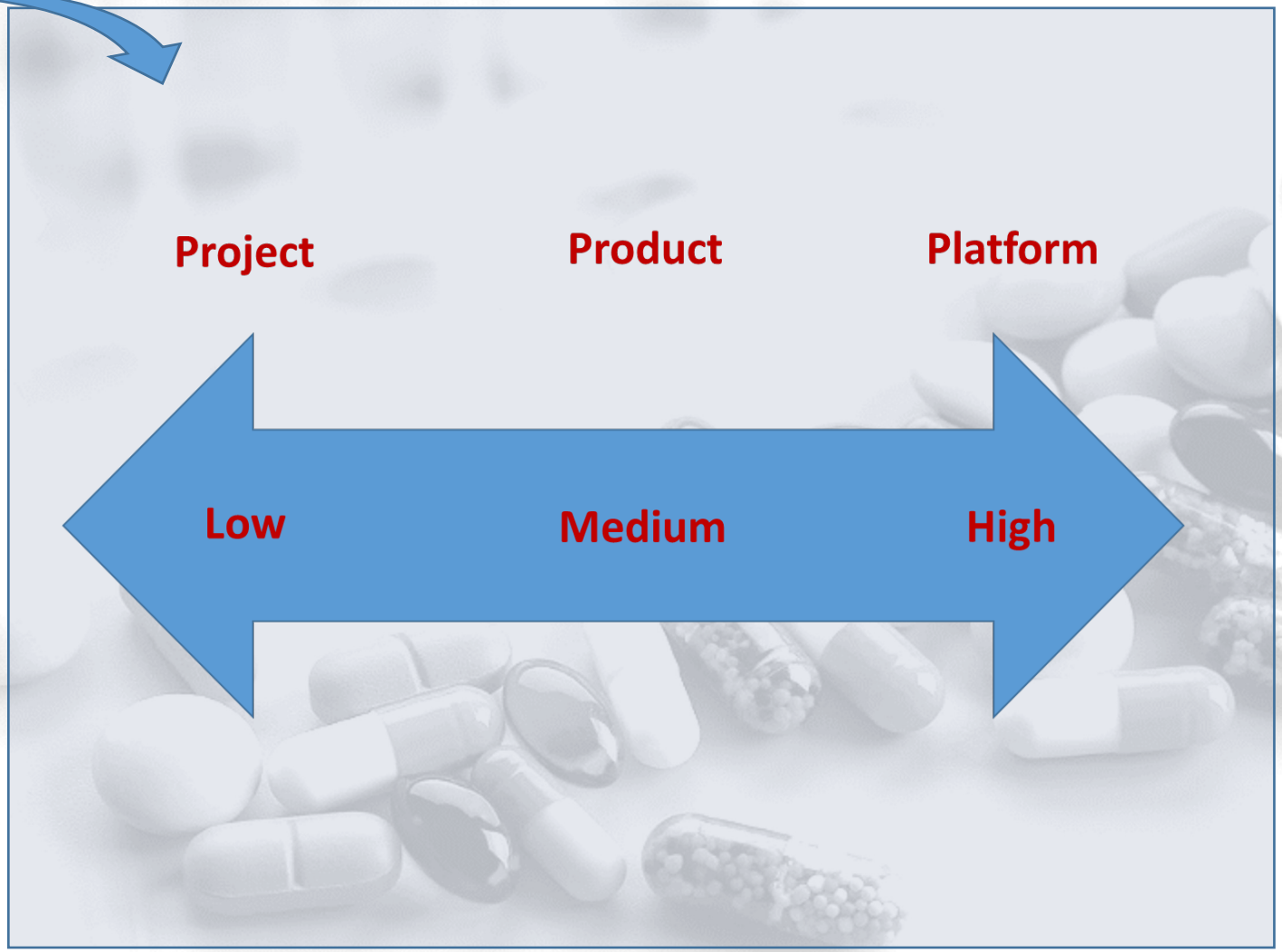
The Three "Ps" Reflect Maturity Levels and Value Inflection Points



York and Abremski, 2018

And the Quick Screen Can Sort Out How the 3 “Ps” Fit





Boni, JCB 2019

WHAT ABOUT PROJECT?

Defining Characteristics

Examples

Project- A Good Licensing, Grant, or Collaboration Option

Opportunity	• Early →
	  • Product not fully defined
	  • Value not yet compelling or significant

Monetary	• Low $ value in market (early stage) • Still, significant $s to ↓ tech/clinical risk
Competitive Advantage	• Other competitors • Limited IP and FTO • POD → not fully defined (early)

Boni, JCB 2019

POD= Point of differentiation; FTO= Freedom to Operate; IP= Intellectual Property

Veneno Technologies: Two-year-old, Japanese Startup

Technology: Disulfide-Rich Peptide (DRP) Discovery Suite

- Accelerate DRP drug discovery→↑ library screening ↓ timing

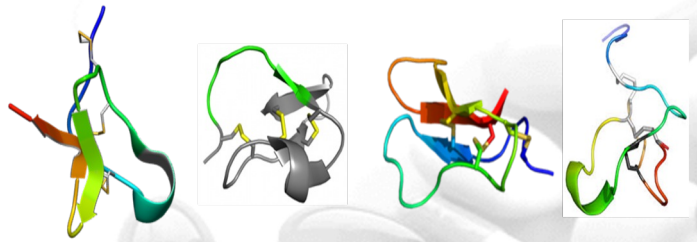
Management: Strong Science

- 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)

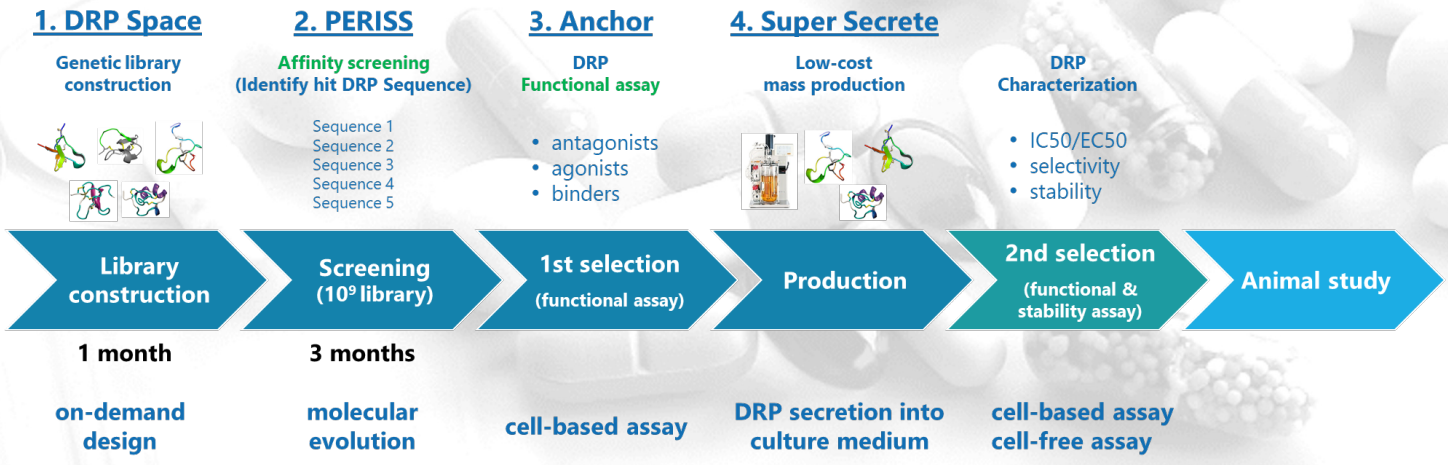
Interactions: Building collaborative biopharma relationships

VENENO TECHNOLOGIES



Institute for the Global Entrepreneur

University of Tsukuba Workshop (Japan)



BD= Business Development;
CEO= Chief Executive Officer; CSO= Chief Scientific Officer
DRP= Disulfide Rich Peptide
R&D= Research and Development

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

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

	Positives	Negatives
Opportunity	• Markets: Peptide→$28.5B (2020, Global), 9.66% CAGR[1] Drug discovery→ $58.3B (2021, Global), 8.21% CAGR[2] • UMNs→ Rapid, productive screening, faster developed, expanded library, and ↑stable, novel targets	• ↑ competition, especially in the drug discovery service space • Suite→ 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

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

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

KEY POINTS FROM THE MAP

POSITIVES→

1. Attractive markets
2. UMNs for screening/library production and sustainable oral peptides

RED FLAGS→

3. Suite → Advantages, but early
4. $ raised → Needs much more
5. Drug discovery competitive→ ? the tool/service business durability

RESOURCING & FINANCIAL→

6. Projects or alliances $s → lead peptide →Animal POC → Clinical testing

POC= Proof of Concept; UMN= Unmet Needs

MPRx, Inc.: A TSRL Accelerator Portfolio Company

Technology: Hydrogel Microarray Patch (MAP) Platform

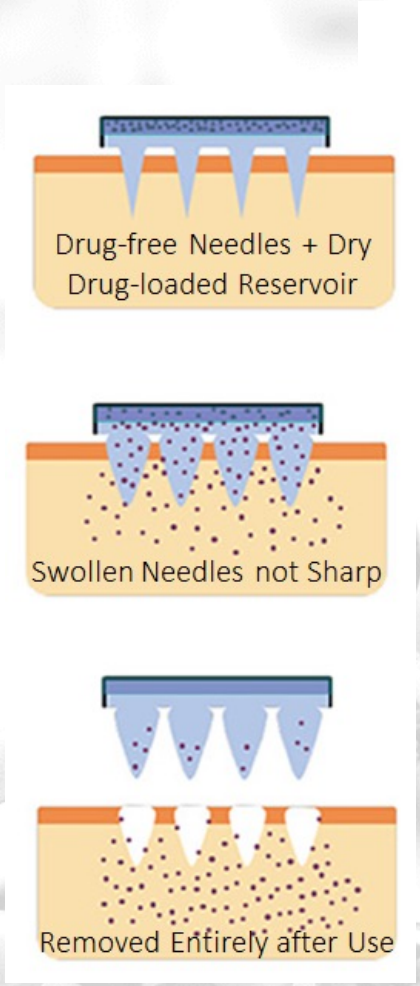
- Painless, continuous drug delivery →↑ compliance
- Zanamivir (Relenza®) →MAP is 5-day flu treatment

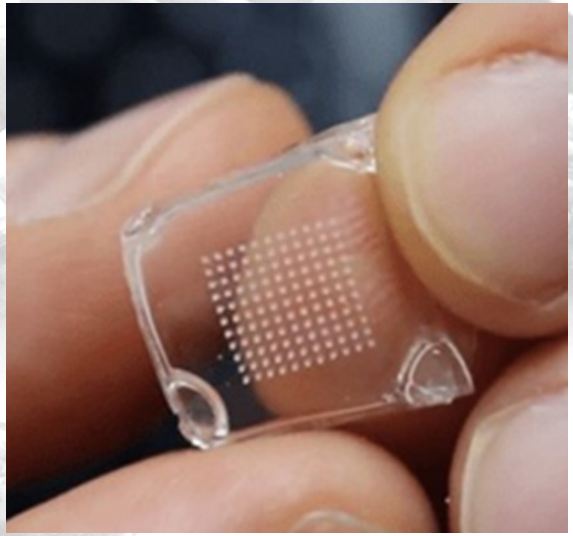
Management: Strong Scientific, R&D, & Management Background

- E. Lipka, PhD, MBA (CEO) → >25 years scientific and business leadership; Multiple execs→ >100 years R&D experience

Stage: Early (Pre-clinical), Moving to FIH with a 505(b)2 Strategy

Interactions: Establishing Strategic Partner Relations and Secured SBIRs





CEO= Chief Executive Officer; MAP= Microarray Patch; R&D= Research and Development; SBIR= Small Business Innovation Research

Assessment: While Early, SBIR Success and R&D Collaborations Can Move MPRx, Inc. Along

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

	Positives	Negatives	Uncertain
Opportunity	• UMN→ adherence and consistent drug levels in special pops	• Still early (not in humans)	• Markets: Flu therapeutics→$1.7B (2026, Global), 3.37% CAGR[1] MAP→ $639M (2028, Global), 6.1% CAGR[2]
Monetary	• Raised $7M in non-dilutive SBIR funding	• Need $3M to complete Ph 1 clinical testing, $35M to NDA	
Competitive Advantage	• MAP→ small molecules and biologics • Defined and broad IP (US) • Zanamivir PK → 5-day dosing (great for elderly) • Scientific and product development expertise • Non-dilutive SBIR funding. Alliances will enhance	• Early and no comparative clinical data	

CAGR= Compounded Annual Growth Rate; MAP= Microarray Patch; NDA= New Drug Application; POC= Proof of Concept; R&D= Research and Development; SBIR= Small Business Innovation Research; UMN= Unmet Need

Assessment: While Early, SBIR Success and R&D Collaborations Can Move MPRx, Inc. Along

	KEY POINTS FROM THE MAP
POSITIVES→	1. 505b2 play; Novel delivery system
	2. Realistic UMN
	3. Finishing preclinical; No comparisons
RED FLAGS→	4. Needs clinical & commercial POC
	5. Flu & MAP markets could be larger
RESOURCING & FINANCIAL→	6. Self supporting with multiple SBIRs → Needs alliance $s for clinicals

MAP= Microarray Patch; POC= Proof of Concept;; UMN= Unmet Need

WHAT ABOUT PRODUCT?

Defining Characteristics

Examples

Product- A Development Stage Set to Commercialize

Opportunity

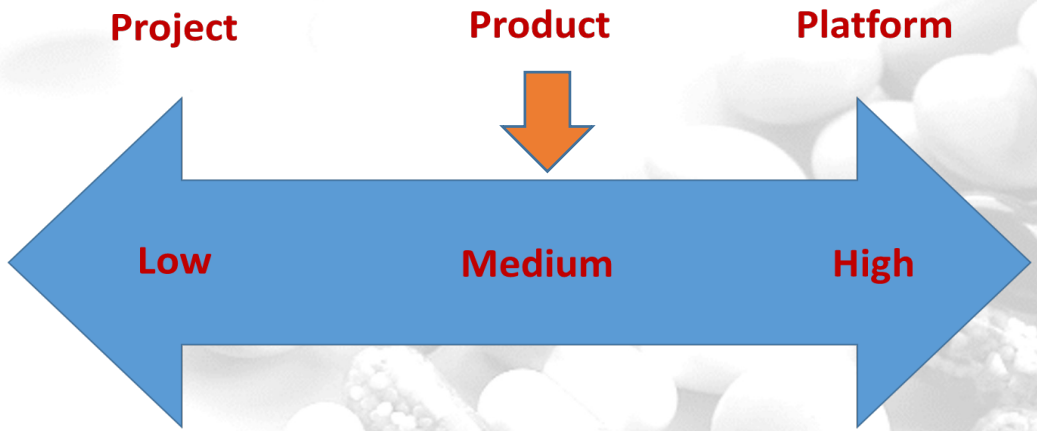
- Value
  - Interest
  - May not be compelling/significant yet

Monetary

- Investment is in
- Further development and $'s → prove significant "value"

Competitive Advantage

- In the clinic and maybe POC
- IP → more well defined
- Barriers → regulatory path and GTM



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

Boni, JCB 2019

JD Bioscience: An Emerging 5-year-Old, Clinical-Stage Firm from Korea

Institute for the Global Entrepreneur

Global Entrepreneurship Accelerator (Korea)

Technology: GM-60106 (a peripheral HTr2A inhibitor) is 1st in class

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

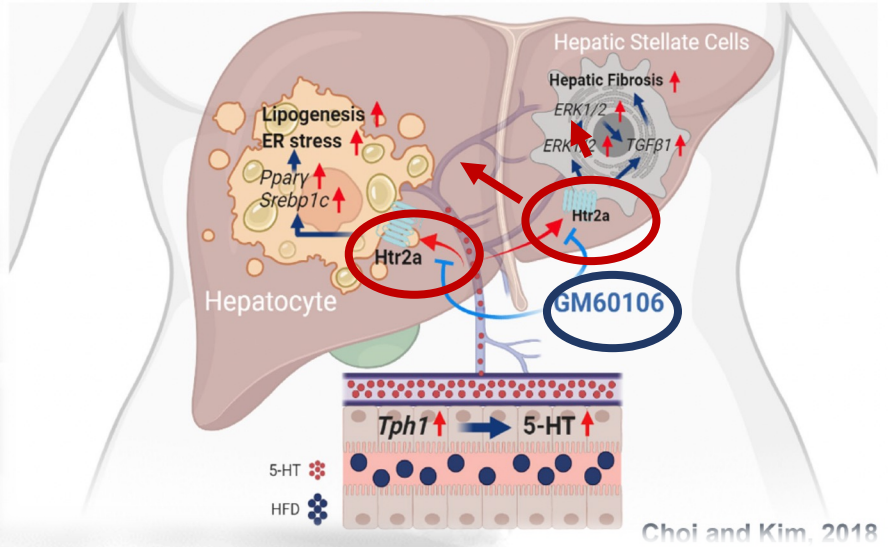
- J. Ahn, Ph.D. (CEO)→ Med Chem Prof, > 5 L/O to pharma
- D. Kim, Ph.D. (Director)→ Merck (20 years, Januvia®), Kainos (9 years, CTO)
- R. Loomba, MD (SAB) → Professor & Director, NAFLD Center, UCSD

Stage: FIH Phase 1 Q3 of 2022 in Australia for SAD and MAD

Interactions: Engaging industry partners for alliance opportunities

JD BIOSCIENCE

MOA of GM-60106 during hepatic steatosis and liver fibrosis



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

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 • Market: $144.4M→$27.2B (2019-29), 68.8% CAGR (Global)[1] • UMN→ lipid, inflammation, and fibrosis management[2,3] • Trend→ Movement to combo therapy[2] (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

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

1. Global Data, NASH, 2020
2. Loomba and Shulman, 2021
3. Albhaisi and Sanyal, *Liver* Intl, 2021

Assessment: Early-Stage Clinical Can Benefit from Alliances

POSITIVES→

RED FLAGS→

RESOURCING & FINANCIAL→

KEY POINTS FROM THE MAP

1. Large market → No approved treatments.
2. Combo therapy (Pfizer; Gilead/Novo Nordisk)
3. Starting FIH
4. Unique MOA with POC (4 animals); No H/H.
5. Complicated disease. Issues with clinicals.
6. Has funding; Needs more for Ph 2 and 3→ Alliance/licensing→ Move asset along.

FIH= First in Human; H/H= Head to Head; MOA= Mechanism of Action; Ph= Phase; UMN= Unmet Need

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

Technology: Chemical Genomics-driven and Proprietary Chemistry Approach

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

Management: Seasoned Industry Scientists

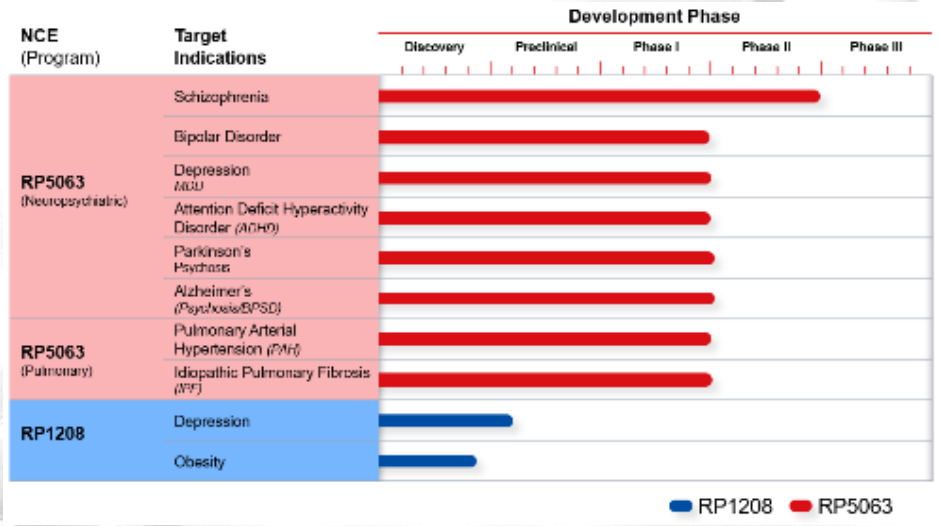
- L. Bhat, PhD- CEO, M. Cantillon, MD (CMO) (>16 yrs with co., > 20 yrs industry)

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

Interactions: SPAC (Tenzing) 2020 (Public)

•Exploring industry options for development and commercialization

Reviva PHARMACEUTICALS



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

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

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

	Positives	Negatives
Opportunity	• Schizophrenia → $7.8B →$9.3B, 3.68% CAGR, (2020-26).[1] • UMN→ Broad efficacy, ↑ safety and clean PK (B → Ph 3) • PAH→$7B, 5.2% CAGR (2021)[2] IPF→ $3.1B→$6.16B, 7% CAGR (2020-30) • UMN→ Dz modification → ↓ M&M (B → 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

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= Pharmacokinetics; POC= Proof of Concept; SPAC= Special Purposes Acquisition Company; US= United States

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

KEY POINTS FROM THE MAP

POSITIVES→

1. Interesting markets with UMNs
2. Lead asset in Ph 3 and Ph 2 (ODD)
3. SPAC with Tenzing (public)

RED FLAGS→

4. Need $ for Ph 2 ODDs & GTM for schizophrenia

RESOURCING & FINANCIAL→

5. Would benefit from alliance to commercialize lead indication

GTM= Go to Market; ODD= Orphan Drug Designation; Ph= Phase; SPAC= Special Purposes Acquisition Company

WHAT ABOUT PLATFORM?

Defining Characteristics

Examples

Platform- Built to Last with Multiple Products and Management Team to Carry Products Further

Opportunity	• Large market • Significant need • Compelling solution
Monetary	• Passed the clin/reg inflection points • ↑ profits and margins possible • ↑ROI potential for investors
Competitive Advantage	• Unique, differentiable solution • Strong IP (or can be established) • ↑ with a partnership

Boni, JCB 2019

Clin: Clinical; IP= Intellectual Property; Reg= Regulatory; ROI= Return on Investment

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

Technology: mRNA Platform **DESIGN STUDIO → speed, scale, & flexibility**

- Immuno-oncology, cardiovascular, autoimmune, and rare diseases

Management: Seasoned Business and Scientific Leadership

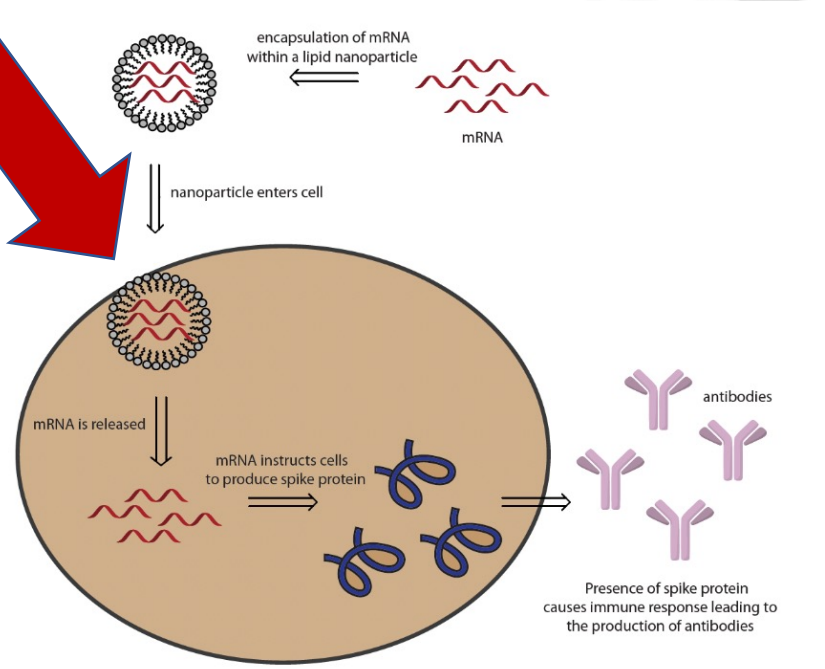
- S. Bancel- CEO (>27 years pharma, Indigo board), S. Hoge, MD- President (>12 yrs pharma, Axcella Health board), 3000+ experienced personnel

Stage: In-market and Active Clinical Program

- COVID-19 vaccine, 25 ongoing trials (Ph 2 [Zika] and Ph 3 [Adult RSV, CMV])

Interactions: Alliances and Projects with Different Partners. **? M&A**

moderna
messenger therapeutics



Public Citizen, 2020

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

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

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

	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	• **Revenue**→ $803.4M→$18.5B (2020-21)[4] • **Market cap**→$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

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.

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

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

KEY POINTS FROM THE MAP

POSITIVES→

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

RED FLAG→

6. $ left on the table?

RESOURCING & FINANCIAL→

7. Benefit from alliance. Maybe M&A (BioNTech-Pfizer → $37B vs. Moderna → $18.5 B in 2021)

B= Billion; ID= Infectious Disease; IO= Immuno-Oncology; UMN= Unmet Needs

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

Kite: Cell Therapy Pioneer within an Established Pharma

Technology: Gene Editing and Cell Therapy →
Chimeric Antigen Receptor T-Cell Receptor (CAR-T)

Management: Experienced, Strategic and Research-Focused

- Gilead: D. O'Day (CEO); M. Parsey, MD, PhD (CMO); T. Yang, PhD (Exec. VP, Pharma Dev. and Manufacturing); Kite: C. Shaw (CEO) (Eli Lilly), C. Calderaro (Global Head, Technical Ops) (30 years, Genentech, J&J)[2]

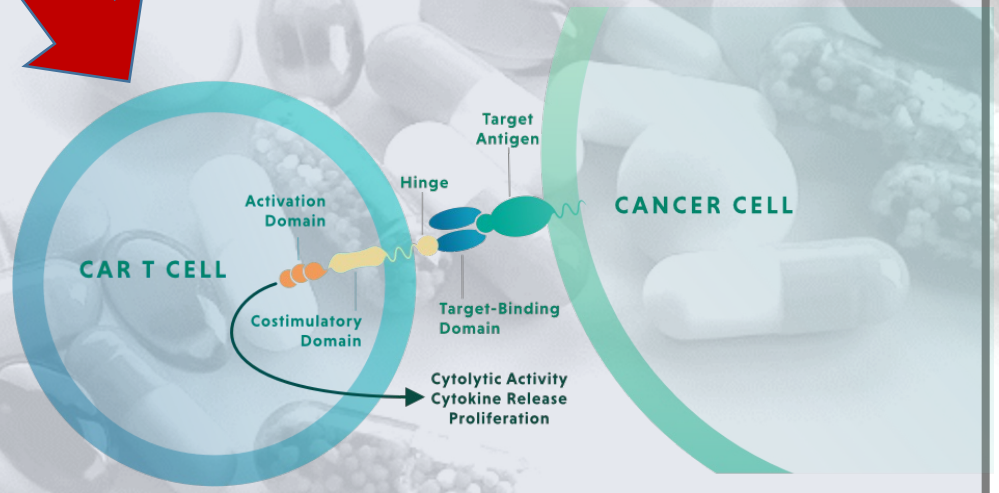
Stage: In-market and Pipeline (Products and Indications)

- In-market products, axi-cel (Yescarta®) and brexucel (Tecartus®)[1]
- Pipeline→ HM and ST

Interactions: Acquired by Gilead (2017). Functions as its own unit. Alliances with HiFiBio Therapeutics and Appia Bio.[1]

Kite
A GILEAD Company

Arie Belldegrun, MD
(Founder)



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

1. Kite Pharma, 2022
2. 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
Opportunity	• **Market:** CAR-T→1.96B→ $20.56B(2021-29), 31.6% CAGR[1] • **UMN**:↓ chemo and treatment time, needs in solid tumors, and ↑ survival and cures	• **Competition:** G1 Tx, BioNTech, Amgen, Novartis, J&J, & BMS/Juno[1]
Monetary	• 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: $80B[4] • Room to grow	
Competitive Advantage	• 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	

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

1.Polaris Market Research, 2022
2.CraftCo, 2022
3.GILEAD, 2021
4.Yahoo Finance, 2022
5.Kite Pharma, 2022
6.Kite, 2021 10K

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

KEY POINTS FROM THE MAP

POSITIVES→

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)

RED FLAG→

5. Evolving competitive space

RESOURCING & FINANCIAL→

6. Already a great marriage. Could benefit from alliance to fully tap pipeline.

HM= Hematologic Malignancy; Ph= Phase; UMN= Unmet Needs

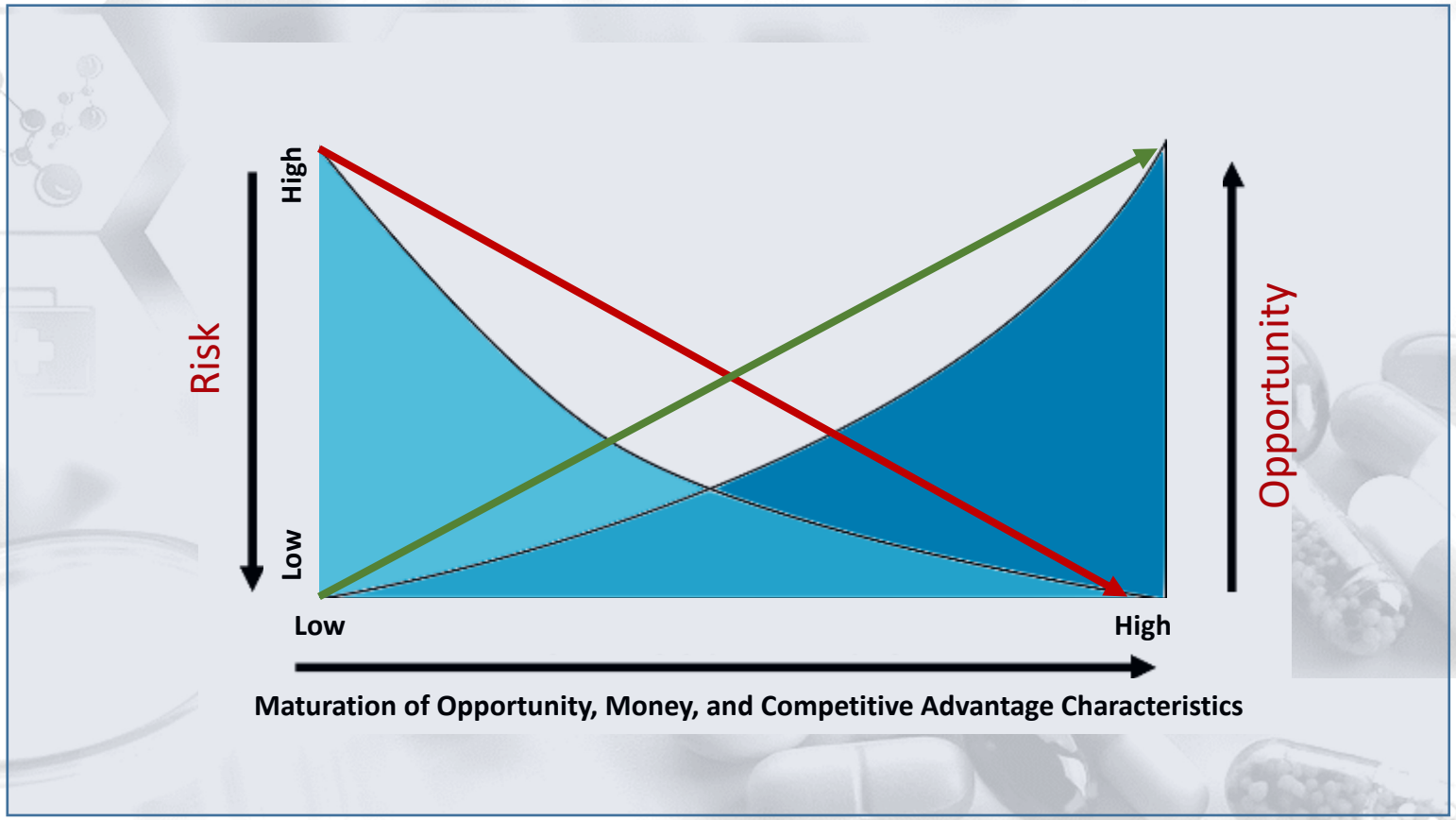
1.Polaris Market Research, 2022
2.CraftCo, 2022
3.GILEAD, 2021
4.Yahoo Finance, 2022
5.Kite Pharma, 2022
6.Kite, 2021 10K

TAKE HOME CONSIDERATIONS

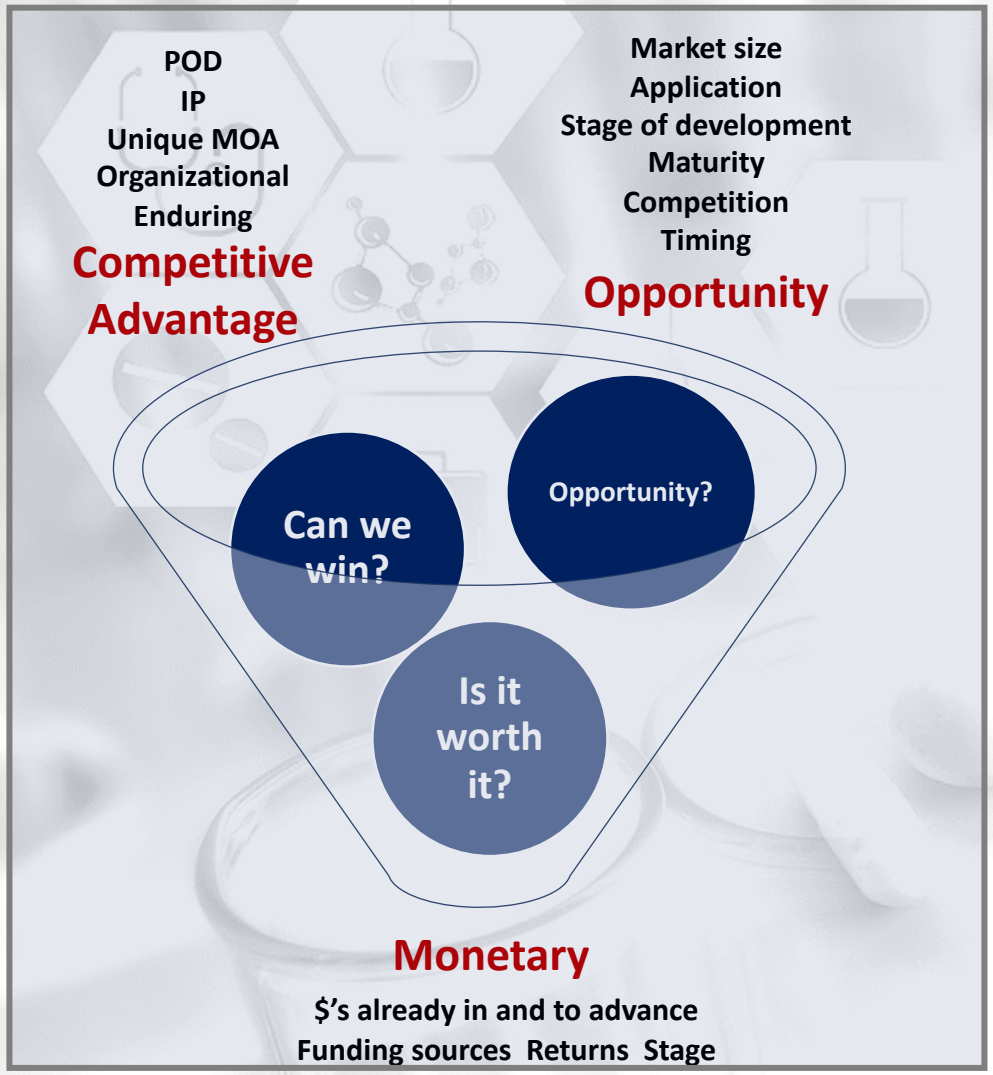
3 Key Learnings

Learning 1: Maturity→

↓ Risk → ↑ Opportunity Development



Learning 2: Quick Screen → Useful Lens for Sensemaking



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

Learning 3: Different Engagement Strategies Exist

Project $s	Product $s	Platform $s
• Collaborations • License (@ low value) • Corporate VC (@ low value) • Government	• License & alliance (@ low-to-mid value) • M&A, with complementary firms and offerings →further value → bigger target	• Sustainable (multiple products) and fundable team for IPO or acquisition • Leverage success → alliances or M&A → more growth

Maturity

Nascent → **WIP** → **Developed**

Boni, JCB 2019 IPO= Initial Public Offering; Mergers & Acquisition; WIP= Work in Progress.

And Finally: Many Thanks to Our Collaborative Team

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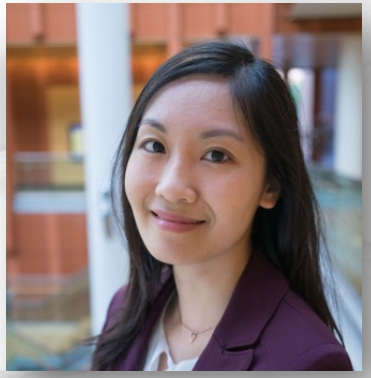

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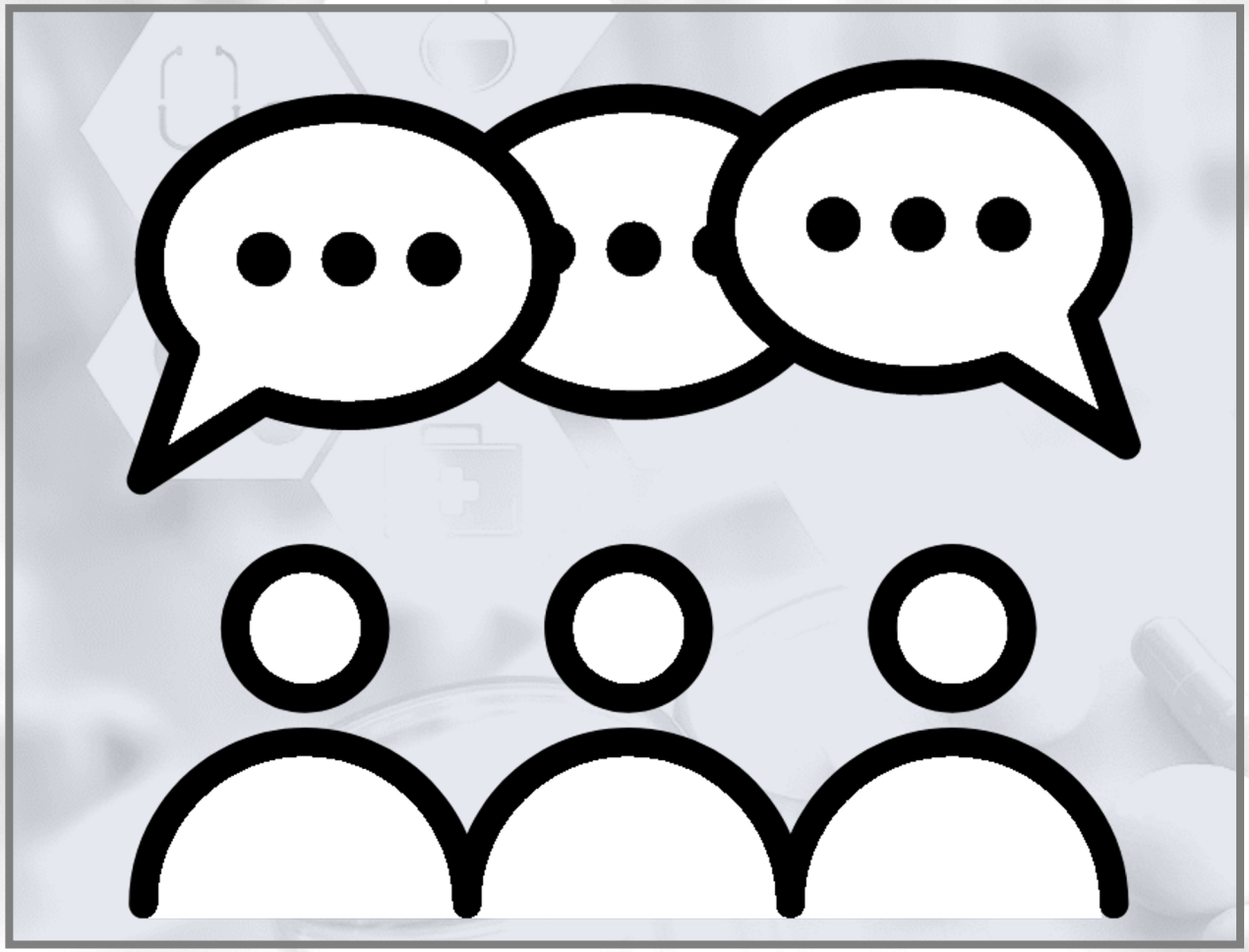


To Access Slides (PDF)

To access Boni *JCB* Article (PDF)

Back Up Project Cases

MyoTecSci (MTS): Early, Early-Stage, Korean Startup Focused on Sarcopenia

Technology: Diverse Assets with IP (Korea and US)

Management: **Strong Academic Science, Limited business**

- HS Kim, MD, PhD, (CEO) → Prof. & Vice Dean at Korea University College of Medicine; YS Ahn, PhD (BD) (Sanofi)

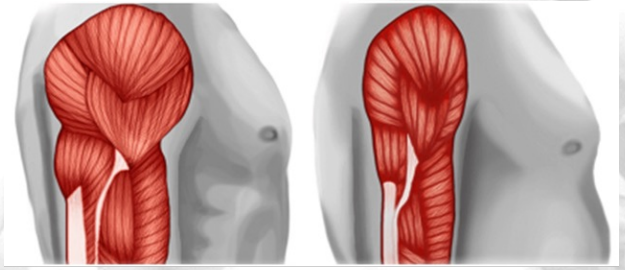
Stage: Preclinical and Working on POC

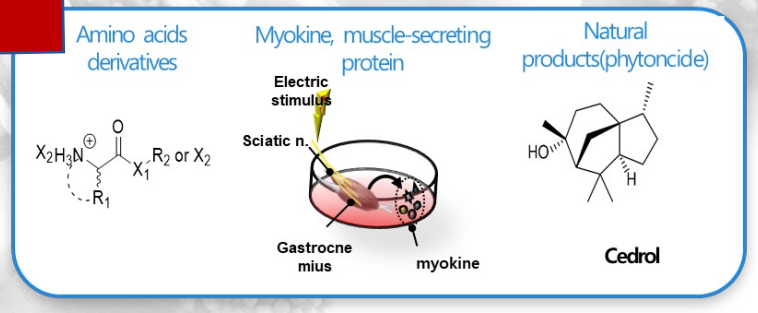
Interactions: Korean and Israeli collaborations for med chem assets

Institute for the Global Entrepreneur

Global Entrepreneurship Accelerator (Korea)

science Myo-Tec-Sci Technology





BD= Business Development; CEO= Chief Executive Officer; POC= Proof of Concept

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

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

	Positives	Negatives	Uncertain
Opportunity	• Market:$2.75B-$3.7B (2020-27), 5.12% CAGR[1] • UMN: No approved therapies • Applications: AML, DMD, geriatric, cancer, and health/wellness[2]	• Regulatory: Potential ODD, but no clear path • History: Past failures in the clinic • Assets very early	
Monetary	• Korean government grants	• Need significant $ for POC and FIH	• Funding <$1M
Competitive Advantage	• IP: Patents (Korea, US) • Novel MOAs and approaches • corporate collaborations → joint scientific projects and licensing compounds	• Very early, Inexperienced management	• Some preclinical POC data

KEY POINTS FROM THE MAP

1. Diverse assets with IP
2. Realistic UMN
3. Very early, despite some POC
4. Regulatory track not clear
5. Limited industry experience; Focus
6. Marginal sized market
7. Some $'s in, grants & licensing $s from collaborators→ More to advance

ALS= Amyotrophic lateral sclerosis; DMD= Duchenne's Muscular Dystrophy; IP= Intellectual Property; M= Million; MOA= Mechanism of Action; ODD= Orphan Drug Designation POC= Proof of Concept; UMN=Unmet Need

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

Technology: Novel electrochemistry + metallic nanoparticles →signaling with diagnostic immunoassays

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

Stage: Preclinical

Interactions: Contract Work (Primary) and Own Assays

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

AgPlus Diagnostics

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

Assessment: Build Out Collaborative Alliances and Contract Development Projects

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

	Positives	Negatives	Uncertain
Opportunity	• PoC dx: $32.9→$73.3 B (2020-20), CAGR 8.3%	• Early stages of implementing multiple assays	• Offering assay development and manufacturing
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	
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

KEY POINTS FROM THE MAP

1. PoC diagnostics attractive market;
2. Potentially faster regulatory route
3. Early→ Needs preclinical validation
4. Technology not the industry standard
5. IP as trade secret
6. Service $s from partners → Need more for a regulatory-approved product

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