ARTICLE

The Quick Screen in Action: Project, Product, or Platform Case Examples

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ABSTRACT

Assessing innovative technologies and venture opportunities in the biopharma-life science space involves a complicated effort. However, should it be? This question is especially relevant when screening new opportunities. This paper addresses how established firms can quickly and efficiently assess new biomedical-life science ventures of different maturity (development and commercial) levels. Boni's (2012, 2019) "quick screen" and metaphorical "3 Ps" (project, product, platform) provide a practical framework to examine new

biopharma-life science ventures (assets). Boni's works (2012, 2019) frame these elements. They intend to provide a framework to complement case studies for use separately in a workshop or "boot camp" format. Our present effort includes multiple case studies to provide practical guidance for the framework's use. Accordingly, this paper extends Boni's work by examining eight practical cases gathered via a purposeful sample to illustrate the use of the "quick screen" relative to each metaphorical category: project (4), product (2), and platform (2). Data sources included company and market information from company documents, firm websites, peer-review sources, market reports, and business portals. Data were mapped against "quick screen" criteria and categorized as positives, negatives, or uncertainties. Evaluation of the mapped data led to low to medium to high ratings relative to opportunity, monetary, and competitive advantage criteria. Descriptions provide qualitative insights to situate each case example relative to its specific "3 P" category, with six cases subclassified (e.g., moderate-low, low-moderate, high-moderate) when graded. This paper provides four practical contributions: 1) multiple "real world" cases to illustrate the framework, 2) a risk-opportunity-maturity relationship model, 3) scenarios of when or when not to use the "quick screen", and 4) engagement strategies based on "P" classification as practice contributions. It concludes that Boni's (2012, 2019) construct provides a useful and efficient tool for examining new biopharma- life science ventures (assets) at differing maturities. Future work should build on these case examples, findings, and contributions while embracing a more-structured case study evaluation methodology to further practice and theory contributions.

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INTRODUCTION

A story tracing back to a great scientist-scholar illustrates the importance of practical vs. scholarly knowledge. His university sets him on a speaking tour with a chauffeur.[1,2] After a year, the pair decided to trade places as the chauffeur had memorized the lecture. In the next lecture, the chauffeur poses as the professor and gives a perfect rendition since he has watched the professor hundreds of times. During the question-and-answer period, an audience member poses a complicated question. Rather than stressing over it, the chauffeur pivots by responding that the question is so simple that even his chauffeur in the back could answer it. This story frames the paper's focus on screening and evaluating biopharma-life science opportunities. Generally, assessing innovative technologies and venture opportunities in this space is complicated. Managers, investors, and entrepreneurs engage in highly involved business analyses and cases. These professionals delve deep into the scientific, technological, and clinical aspects. They examine the market size, competition, and growth rates. Their analyses include 1) Porter's 5-forces (customers, suppliers, rivals, new entrants, substitutes) [3], 2) SWOT (strengths, weaknesses, opportunities, threats) [4], 3) financial returns, and 4) risk and mitigation. Interestingly, while acquiring a biopharma-life science asset is a serious endeavor, should such decisions need detailed analysis and review at the outset. However, one might query whether reviewing such opportunities, especially when screening prospects, should require such a complicated effort, at least at the outset. Such consideration leads to a relevant question to guide this paper- how can established firms quickly and efficiently assess biomedical-life science startups of different maturity (development and commercial) levels?

Art Boni, Ph.D.- Carnegie Mellon professor emeritus, *Journal Commercial Biotechnology* editor emeritus, and past serial entrepreneur- begins to tackle such questions.[5,6] He proposes a simple, structured screening methodology for identifying and evaluating potential commercialization opportunities coined the "quick screen" and distinct metaphors for opportunities- project, product, and platform. While useful, Boni's works [5,6] leave readers desiring something more concrete. Of particular interest is the need for practical cases. Such examples can help fortify Boni's 2019 construct [5] and offer practical insights to aid managers, investors, and entrepreneurs in implementing this approach. Accordingly, this paper addresses the overarching question and provides case examples from a purposeful sample to extend Boni's work [5,6] and illustrate the framework in action. This work does not use structured case study methods, such as those of Eisenhardt, [7,8] Gioia, [9] Langley, [10] or Yin, [11] to build theory. It also does not delve into considerations beyond Boni's (2012, 2019) construct, such as individual and social cognitive factors, organizational

learning considerations (e.g., absorptive capacity), quantitative analyses or metrics (e.g., risk/reward ratios), differential weighing of variables, or "know unknowns." Rather, it describes multiple cases using the "quick screen" elements and evaluating data culled from multiple sources. This work's contributions provide 1) practical "real world" case examples and evidence, 2) a risk-opportunity-maturity relationship model, 2) scenarios of when or when not to use the "quick screen," 3) engagement strategies based on the "P" classification, and 4) considerations for future works to extend this construct. Such efforts offer a platform for more structured research to advance additional practice and theoretical contributions. This paper charts a course that defines the "quick screen" and metaphorical "3 Ps," provides multiple cases, and discusses practical insights and limitations.

Characterizing Quick Screen and the Three "Ps"

Setting the Basis

To establish the "quick screen's" basis, one needs to examine two critical facets belying new ventures that investors or partners evaluate closely. These are the elements of opportunity and risk, the "Yin and Yang" of considerations that influence engagement with such ventures when significant ambiguity is present. Accordingly, one must ask, what are some of the critical considerations that define opportunity and risk? For opportunity, the most common pieces include market size, growth rate, competitive mix, and unmet needs. [12] Adding to these are the opportunity's timing and maturity stage considerations. For risk, the most common considerations for life science products and firms start with technologic (e.g., scientific basis), clinical, legal (e.g., intellectual property), and regulatory (e.g., Food and Drug Administration path and status). [12-15] Beyond these four core pieces are those involving the business aspects such as market risk (e.g., direction, segmentation, competition) and financial (e.g., investment in, resources still needed, returns). [12-15] The final risk pieces center on the ability to deliver on the promise. These involve the leadership, the team, and their ability to implement the plan to de-risk the opportunity and reach a relevant inflection point.

Business development executives consider such facets when they build a business case for management investment into a new asset or company to acquire of license. Figure 1 highlights the essential components. This case considers external considerations. These include the market (size and growth), customers (primary and secondary), unmet needs, and competition (established, future, substitutes). Also, this assessment might include a PESTLE analysis [16] to consider the political, economic, social, technological, legal, and environmental factors that might influence market trends to enhance or diminish the attractiveness of an opportunity. Next, the case engages the internal facets of the investment specific to the product or technology and the firm being examined. Such elements consider product profile, company, management team, leadership, and record of accomplishment. This analysis shall include a SWOT, target/market fit assessment, differentiating claims for the product or technology, and a SWOT for the firm. [17,18] The final piece engages financial and risk assessment pieces. Financial analyses can include a 5-year proforma, revenue projections, cost analysis for development, net present value, and internal rate of return. [17,18] Risk and mitigation consider the previously discussed risk factors and mitigation strategies. [17,18] This effort is extensive, involved, and comprehensive.

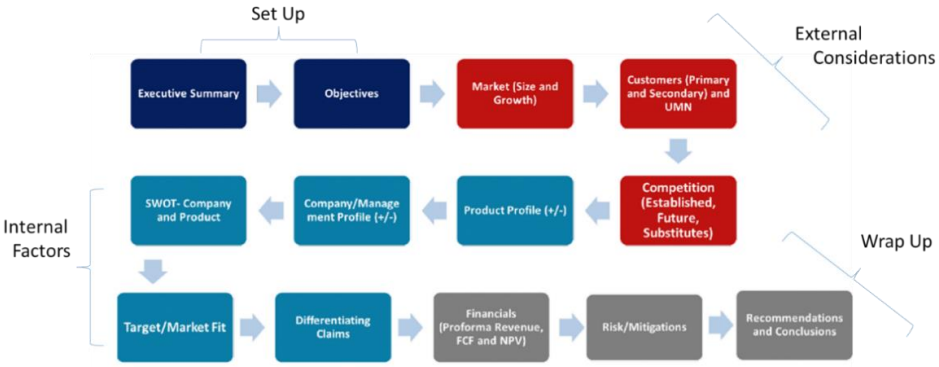

Figure 1. Business case elements.[17, 18]

However, executives and investors might be examining hundreds of opportunities each month. These individuals might not have the time for such extensive evaluation. They need to assess new ventures and assets efficiently. These individuals do not necessarily have the time for extensive evaluations until they have decided to take a more serious look at the prospect.

The "Quick Screen"

Enter the "quick screen" as an alternative lens for these individuals to assess. Boni[5] describes such an approach (Figure 2). So, what is the "quick screen" and some of its critical elements? The "quick screen" centers on three core questions: 1) "What is the opportunity?", 2) "Can we win?", and 3) "Is it worth it?" Interestingly, Kevin Sherer and Bob Bradway of Amgen used similar queries in their assessment of the biosimilar business. [19] Boni [5] continues to expand each screening question with anchors to define a good opportunity. Anchors for the "what is the opportunity?" query considers significant value creation and compelling market need(s). The "can we win?" (competitive advantage) question delves into points of differentiation and sustainability of the company, product, and technology advantages. Finally, whether it is "worth it" (monetary), there is the consideration of profit and return potential and good fit and timing. To be viable, Boni [5] (2019) puts forth that the professional performing the screen should be able to answer yes to all three. Such elements allow individuals to characterize opportunities quickly and rate them as low, medium, or high based on the opportunities such prospects offer and their associated risks.

Figure 2. The "quick screen" addresses three questions and considers the five anchors of a good opportunity. (Adapted [5])

The "3 P's": Different Levels of Opportunity Maturity

Boni [5] adds to the "quick screen" by describing three metaphors to characterize prospective ventures or assets- project, product, or platform- based on their levels of maturity- early or preclinical, developing or in clinical development, and emerging or going-to-market or in-market (Figure 3). These fit with the developing life science or biopharma value chain (Figure 4). Projects are early opportunities. They exist in the preclinical space, at either the base technology, pre-animal, or animal stages of development. They offer incremental improvement opportunities, represent lower-value development, and involve a few years (two to three) in the maturity timeline.[13, 20] They commonly represent opportunities for collaboration (e.g., joint science projects), grants, or to fit into another scientific or manufacturing value chain. [5] Sometimes, such prospects may garner a licensing opportunity or early-stage seed investment from Private Equity, Angels Investors, or corporate venture capital. [5,21]

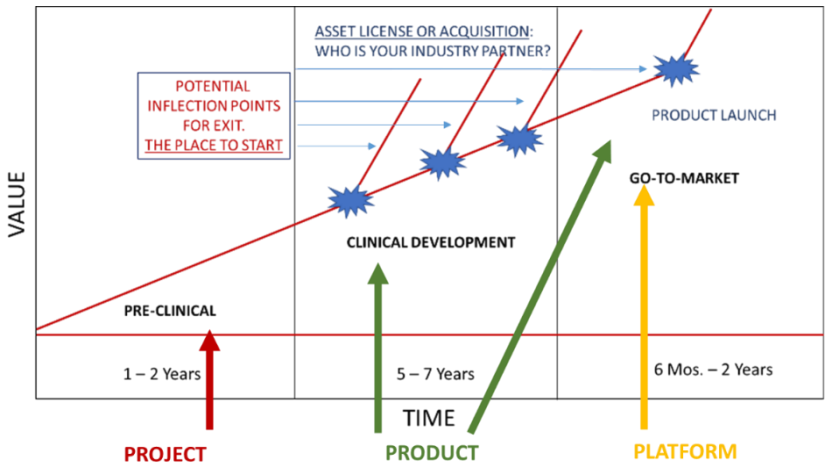

Figure 3. The three "Ps" reflect enhanced maturity levels and value inflection points.[20]

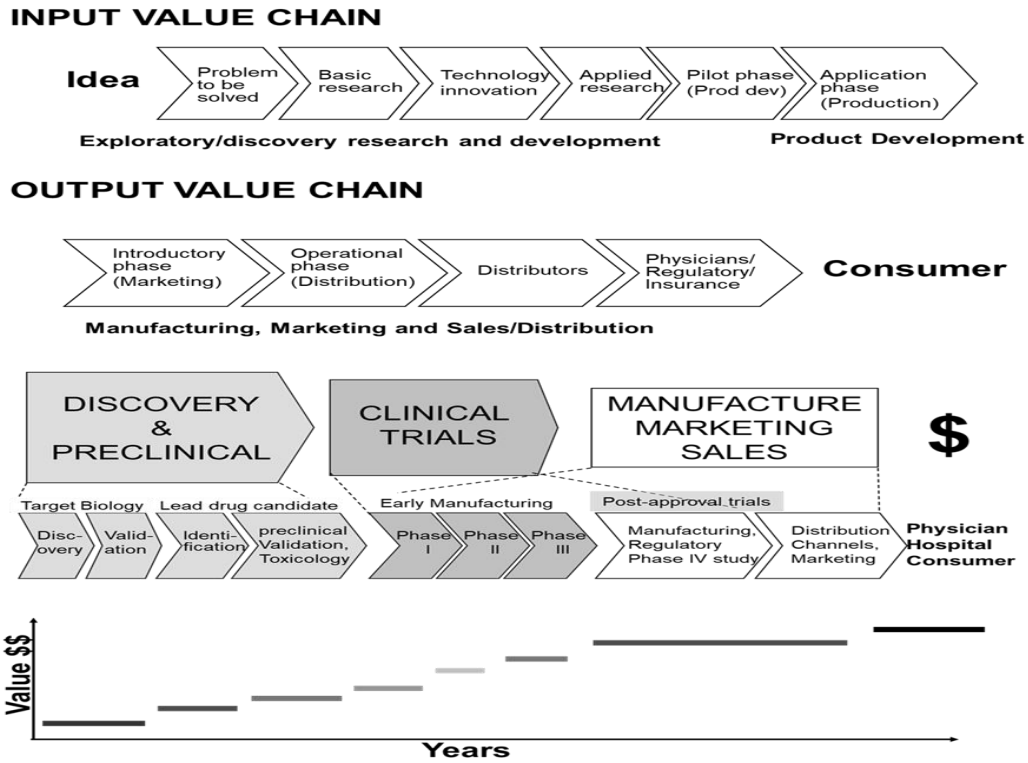

Figure 4. The life science value chain and its ties to clinical development and commercialization. (Adapted [13])

Products define those prospects where there may be more significant benefits and generate more value.[13] They are at a development stage set to commercialize. They exist within clinical development or just entering the market. This phase can involve more time (five to ten years) to create value. [13] These opportunities might do well with licensing deals or alliances. [5]Finally, a platform represents a continuous stream of products on the market. It can represent either a platform technology to generate multiple products (e.g., bispecific monoclonal antibodies [22]) or a product that grows with multiple indications (e.g., Humira®[23]). It is built to last with multiple products and a management team to carry products further. [5] As the prospect matures from project to platform, the product value grows significantly and avails multiple potential inflection points (e.g., licensing or acquisition) for an exit. [13, 20,24,25]

The Quick Screen and the "3 Ps"

Utilizing the "quick screen" can characterize each prospective opportunity level. Projects will rate low relative to opportunity, money, and competitive advantage criteria. The opportunity is low because the asset is early, the product is not fully defined, and the value is not yet compelling or significant. [5] Money is low since the existing market dollars for the stage of the opportunity are low, yet significant investment is needed to decrease technological, clinical, and regulatory risk. [5] Competitive advantage is low since there are other potential competitive options, limited intellectual property (and freedom to operate), and the point-of-differentiation is not fully defined as the asset and company still is very early. [5]

A product situates a medium rating. In this case, the opportunity is of interest and value but might not be compelling or significant due to clinical de-risking. [5] Money reflects the current investment (which can be substantial); however, it reflects the significant amount needed for further clinical development, regulatory approval, manufacturing, and going-to-market activities. [5] Finally, for competitive advantage, while the product is in the clinic, it might show clinical proof-of-concept, and the intellectual property is more well-defined. [5] Nevertheless, regulatory and going-to-market barriers still exist.[5] Finally, a platform garners high scores for each criterion. The opportunity reflects the characteristics of a large market with significant needs and a compelling solution. [5] Money reflects the passing of essential clinical-regulatory inflection points. [5] It also offers potentially high profits, margins, and return on investment. [5] Finally, the competitive advantages are significant. Such is due to a unique, differentiable solution, strong intellectual property (or to be established), experienced management, and the potential to be enhanced with partnerships. [5]

Methods

This work employs a systematic approach using the "quick screen" elements and evaluating data culled from multiple sources. It did not employ structured case study methods, such as those of Eisenhardt, [7, 8] Gioia, [9] Langley, [10], or Yin, [11] to build theory. This project involved identifying and classifying case examples of biomedical-life sciences new ventures within the metaphorical "3 Ps" categories based on their fit relative to previously described "quick screen" criteria and considerations. This effort engaged in choosing cases in a purposeful sampling manner and by the availability of data from each venture selected. This action led to culling data to provide background around the venture, technology, current stage, leadership, alliance activity, market size and growth, competition, investment in and needed, intellectual property, and points of differentiation. These elements allowed for the assessment of the case examples utilizing the "quick screen" and the "3 Ps." Data sources varied. They ranged from peer-review literature to grey literature (periodicals, news) to industry reports and web sources to the companies' websites, 10-Ks, and non-public sources (e.g., investor presentations). This effort did not evaluate source or data quality. Since this project's objective was to provide case descriptions to illustrate fit within the construct, this analysis did not go beyond Boni's (2012, 2019) construct.

It did not consider individual and social cognitive factors, organizational learning considerations (e.g., absorptive capacity), quantitative analyses or metrics (e.g., risk/reward ratios), differential weighing of variables, or "know unknowns." While these elements were not part of this analysis's scope, they offer interesting areas for further work to extend Boni's (2012,2019) work. Instead, this effort focuses on describing multiple cases using the "quick screen" elements and evaluating data culled from multiple sources.Review led to the classification of the data as positive, negative, or reflecting uncertainty. Analysis of the multiple factors led to a low rating of the project, product, or platform. These included a mix of positive vs. negative or uncertain elements, the stage of development, investment culled and resources needed to advance the next inflection point, maturity of differentiation points, technology, clinical-regulatory stage, intellectual property, management experience, and alliances. Based on the data and maturity of the venture, this effort rated some firms in the low and moderate case groupings into separate groups based upon maturation with the individual "3 P" stage. For low, it was low or moderate-low. For moderate, it was low-moderate or high-moderate.

Case Examples

Introduction

Four cases offer insight into using the "quick screen" and the "3 Ps." Figure 5 highlights where these cases fit relative to maturity and rating (low, medium, high). Each case discussion involves mapping positives, negatives, and uncertainty considerations. Ratings consider these factors, and the ventures fit relative to the specific project, product, and platform characteristics described previously.

Project Cases

The project's category includes four relevant cases to characterize early ventures and the use of the "quick screen." In all these cases, they have not entered human testing. They range from exceedingly early to pre-investigational new drug applications (IND). Two cases include preclinical animal testing. Others involve a device, a drug delivery system, and an early peptide development system.

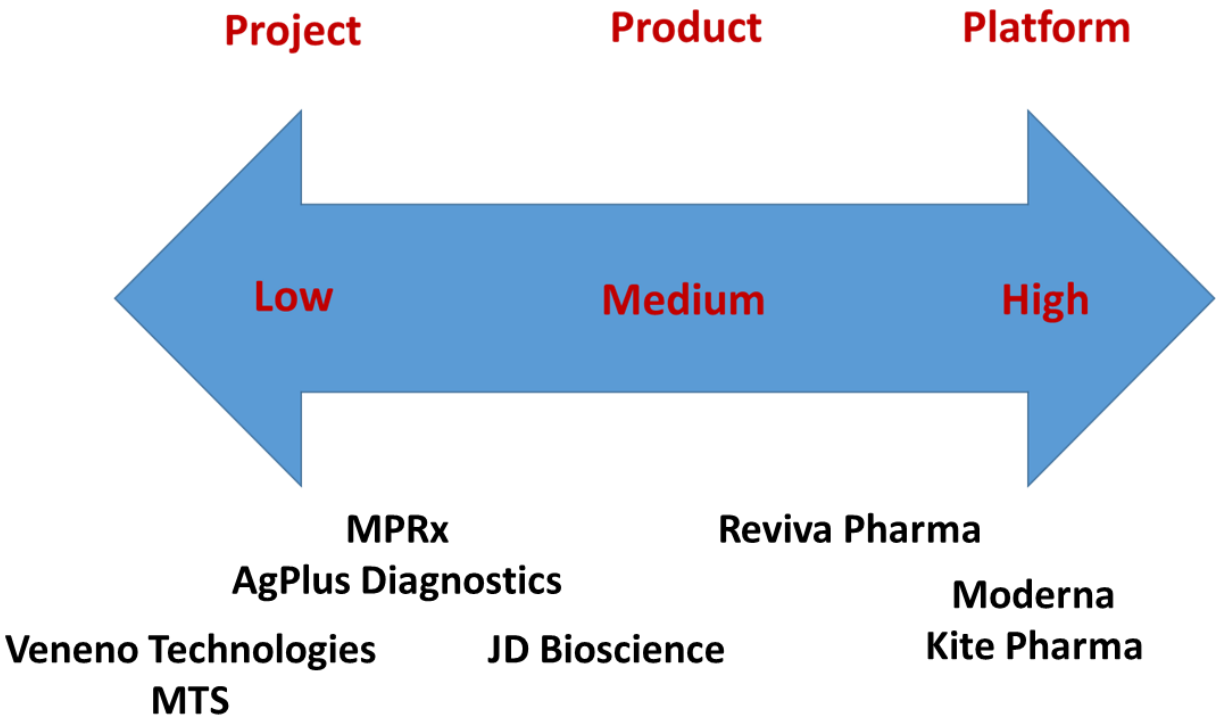

Figure 5. Case examples situate from low to medium to high ratings based on the "quick screen" criteria of opportunity, monetary, and competitive advantage, along with the project, product, and platform continuum.

Veneno Technologies

The earliest case describes a two-year-old Japanese firm called Veneno Technologies.[26] This startup is pioneering a disulfide-rich peptide discovery (DRP) suite.[27] Its technological process involves five steps- 1) DRP space (a genetic library for on-demand design), 2) PERISS (affinity screening to identify DRP sequence), 3) Anchor (a DRP functional, cell-based assay), 4) Super-Secret (a low-cost mass production involving DRP secretion into the culture medium) and 5) DRP characterization (via cell-based and cell-free assays). [27] Veneno (venom in English [28]) fashions its DRP scaffolding mimicking the structure of venoms from various animal and insect species. Its value proposition involves accelerating and enhancing the DRP drug discovery process, leading to increased output and decreased timing than traditional methods. This early-stage company's (pre-animal) management brings strong scientific background, with many of its key executives possessing over ten years of biopharma research and development experience. [26] Its current business model involves building collaborative biopharma scientific project partnerships, resulting in multiple scientific collaboration agreements with large biotech and pharmaceutical companies. [29] A map of key considerations for Veneno Technologies (Table 1) reflects the use of the "quick screen" for the early-stage cases. Positive aspects of the Veneno opportunity include attractive markets (peptide and drug discovery services), significant unmet needs for screening/library production and developing sustainable oral peptides, and several productivity advantages with the suite.

However, the opportunity (and company) is quite early. While Veneno has raised $2 million, [26,29] this venture needs significantly more capital to prove its

technology and move a lead peptide into animals. Additionally, the drug discovery marketplace is highly competitive, with many players. [30] This consideration raises questions about the durability of a tool/service business model. Also, the firm will need multiple successful projects, alliances, and/or licensing deals to generate non-dilutive revenue to reinvest to develop a lead peptide further to achieve animal proof of concept and enter clinical testing. Thus, this early prospect rates as low when

considering the screening criteria. Nonetheless, while early, the company can benefit from its current research and development collaboration strategy to gain further non-dilutive revenue and critical relationships and allow for future development of a lead asset.

MyoTecSci (MTS)

The next early-stage case involves MTS, a Korean startup focused on sarcopenia (muscle wasting) [31, 32] and sarcopenia-like presenting diseases. [33, 34] This firm brings three early-stage technology assets: amino acid derivatives, myokine (muscle-secreting protein), and cedrol (a natural product, phytoncide) (Figure 6). [31,32] Only the first asset has progressed into animal testing and realized positive results in a few rats to support proof-of-concept.[31,32] The company's management brings strong academic science experience (over 20 years) and some industry background in business development and commercialization.[31] The company sustains itself based on non-dilutive Korean government grants and Korean and Israeli collaborations for medicinal chemistry assets.[31]

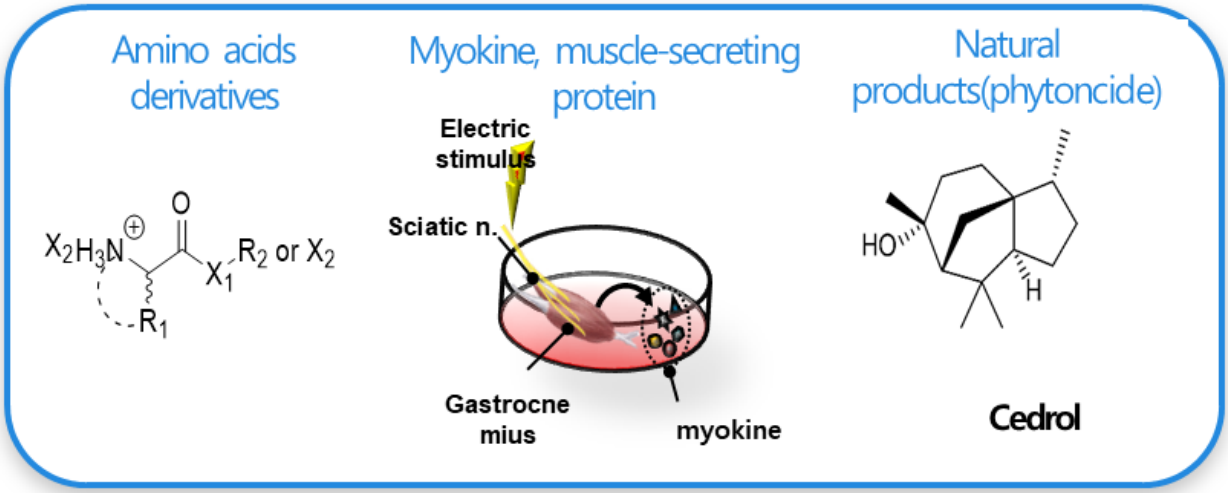

Figure 6. MTS early-stage assets[31]

The MTS map (Table 1) reveals a mixture of positive, negative, and uncertain considerations. Positive elements include diverse assets with intellectual property and multiple unmet needs. The company brings in revenue from grants and medicinal chemistry collaboration.[31] However, this firm is still extremely early, despite some proof-of-concept in limited animal work.

Furthermore, the sarcopenia regulatory track is unclear, and this indication represents a marginal-sized market opportunity.[31],[35,36]

MTS' management is science-focused and experienced, with limited industry research, development, regulatory, or commercialization background. [31,32] It also needs to focus its opportunities and resources on the three assets and five different indications. Finally, this firm will require more resourcing to advance its assets through preclinical and first-in-human testing. Like Veneno, MTS's rating is low when viewed through the "quick screen" for these diverse reasons. While this company is early, it could benefit from further research and development collaborations.

Table 1. Mapping of early-stage project ventures using the "quick screen."

Veneno Technologies (Japan)				
	Positive	**Negative**	**Uncertain**	**Rating**
Opportunity	Markets: Peptide: $28.6 B (2020, Global); 9.66% CAGR [37] Drug discovery: $58.3B (2021, Global); 8.21% CAGR [30]	↑ competition, especially in the drug discovery service space Suite→ early → service vs. product→ lower value (incomplete)	NA	Low
Money	Raised $2M seed (2021) [26, 29]	Significant capital to mature into a product and a significant inflection	NA	Low
Competitive Advantage	Productivity benefits Multiple patents Scientific expertise	Tool/service business may be questionable for a durable point of differentiation	Beginning biopharma collaborations	Low
MyoTecSci				
	Positive	**Negative**	**Uncertain**	
Opportunity	Market: Sarcopenia $2.75B-$3.7B (2022-27), 5.12% CAGR [35] UMN: No approved therapies [35, 36] Applications: ALS, DMD, geriatric, cancer, and health and wellness [31, 32]	Regulatory: Potential orphan drug designation, but no clear path History: Past failures in the clinic[38-43] Assets are exceedingly early	NA	Low
Money	Korean government grants[31]	Need significant $ for proof-of-concept and first-in-human	Funding less than $1 million[31]	Low
Competitive Advantage	IP: Patents (Korea, US)[31] Novel mechanism of action and approaches to health and wellness [31, 32]	Exceedingly early Inexperienced management	Some preclinical proof-of-concept data [31, 32] Corporate collaborations → joint scientific projects and licensing compounds[31]	Low

ALS: amyotrophic lateral sclerosis; B: Billion; CAGR: Compounded annual growth rate; DMD: Duchene's muscular dystrophy; IP: Intellectual property; NA: Not applicable; OOD: Orphan drug designation; UMN: Unmet need; US: United States; $: Dollars

AgPlus Diagnostics

Though it exists in the preclinical stage, this United Kingdom point-of-care diagnostic venture is more advanced than the prior project cases. This firm positions itself to deliver personalized health using individual biomarker profiles. [44] Its technology combines novel electrochemistry and metallic nanoparticle signaling with diagnostic immunoassays. [44] The firm's management brings over 100 years of experience in diverse areas, including clinical research, collaborative research and development, project delivery, and manufacturing in the device space. [44, 45] This venture seeks to create revenue via its assays for licensing and integration into its partners' products.[45,46] While it has not emerged in the clinic, it has generated a revenue stream by fitting into other firms' value chains through contract development projects to create new diagnostics and develop new assays.[45,46]

The AgPlus map (Table 2) shows the firm's "quick fix" profile. Its positives include the point of contact diagnostics market, faster regulatory route, and some service revenue. It also has garnered an investment of £1.5 million.[45,46] However, it is early and needs preclinical validation. The technology is not the

industry standard, and the patent position around intellectual property needs to be firmed up to shore up the current position with trade secrets.[46]

Finally, while deriving revenue from partners, the company still needs a regulatory-approved product. Nevertheless, this venture still garners a moderate-low rating.

MicroPatchRx, Inc. (MPRx, Inc.)

This Ann Arbor-based accelerator (TSRL) portfolio company. [47,48] This hydrogel microarray patch (MAP) platform utilizes a reservoir technology approach (Figure 7).[39]

Such offers a painless, continuous drug delivery system, which will aid adherence. Its lead asset using this system is zanamivir (Relenza®), which repurposes a respiratory-delivered antiviral for continuous five day flu treatment.[39] Interestingly, using this delivery system with this treatment lends to a 505(b)2 strategy, leading to a faster regulatory track and lower development costs. Leadership brings an extremely strong scientific, research and development background with 25 years of scientific and business experience.[39] While the company is working to establish industry alliances, MPRx, Inc.'s primary support source is four small business innovation research (SBIR) grant awards totaling $7 million in funding.[39]

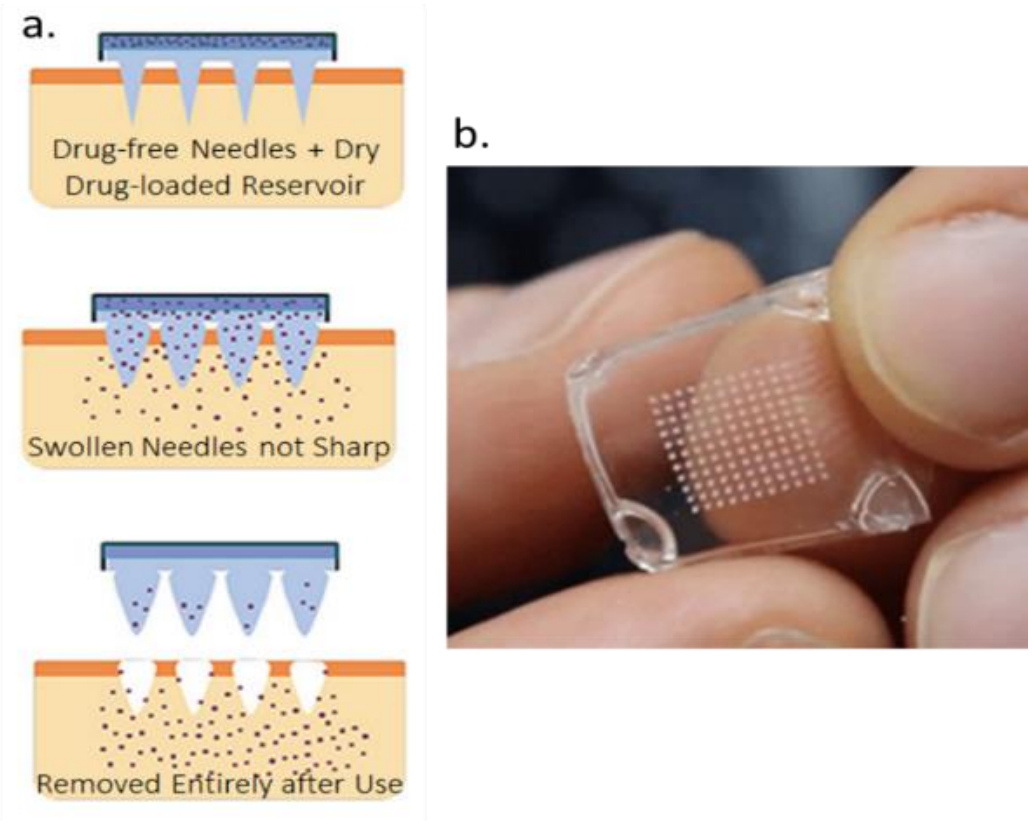

Figure 7. MPRx, Inc. novel delivery system- a) action and b) relative size.[39]

Mapping the elements of the critical screen (Table 2) provides some notable considerations. MPRx, Inc.'s positives include its novel delivery system, regulatory path, and realistic unmet need in managing flu, especially in populations such as the elderly.[39]The company is self-supporting with multiple SBIRs. An appropriate alliance will avail the needed resources for completing clinical development and commercialization to help move MPRx, Inc. to demonstrate proof of concept with its microneedle platform. However, several red flags exist. This product is just finishing preclinical, lacks comparative data, and needs clinical and commercial proof-of-concept. The flu and MAP markets are not as large as expected, with the former feeling the influence of generic intrusion. While the financial needs for

development with a 505(b)2 is smaller than with drugs undergoing the traditional route, the firm still needs approximately $50 million to support the required phase 1 and 3 clinical studies. Also, this category's lead product, Tamiflu® (oseltamivir), maintains a dominant market share. Considering these factors, this firm net a moderate-low rating for each of the three "quick screen" criteria.

Table 2. Mapping of late early-stage project ventures using the "quick screen," achieving a moderate-low rating.

AgPlus Diagnostics				
	Positive	**Negative**	**Uncertain**	**Rating**
Opportunity	Market: Point-of-care diagnostics: $32.9→$73.3 B (2020-20), CAGR 8.3% [49]	Preliminary stages of implementing multiple assays	Offering assay development and manufacturing	Medium-Low
Money	Service revenue offsets Grants and angel investments → £1.5M [45, 46] Planning to raise £ 5M for customer validation [45, 46]	Still have significant investment for development	NA	Medium-Low
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), knowledge and trade secrets [45]	Technology is not the industry standard It is early-stage	Medium-Low
MicroPatchRx, Inc.				
	Positive	**Negative**	**Uncertain**	
Opportunity	UMN→ adherence and consistent drug levels in special populations [48]	Still early (not in humans)	Markets: Flu therapeutics→ $1.7B (2026, Global), 3.37% CAGR [50, 51] MAP → $639M (2028, Global), 6.1% CAGR[48]	Medium-Low
Money	Raised $7M in non-dilutive SBIR funding[48]	Need $3M to complete Ph 1 clinical testing, $35M to NDA[48]	NA	Medium-Low
Competitive Advantage	MAP→ Small molecules and biologics Defined and broad IP (US) [48] Zanamivir PK → 5-day dosing (great for elderly patients) [48]Scientific and product development expertise [48]Non-dilutive SBIR funding [48] Alliances will enhance	Early and no comparative clinical data	NA	Medium-Low

B: Billion; CAGR: Compounded annual growth rate; EU: European Union; IP: Intellectual property; M: Million; MAP: Micropatch; NA: Not applicable; NDA: New Drug Application; SBIR: Small business innovation research; UK: United Kingdom; UMN: Unmet needs; US: United States; £: British Pounds.

Product Cases

Two cases illustrate ventures that fit within the product categorization. Both have products in clinical development. These represent polar examples as one is going into first-in-human, and the other is amid phase 3 evaluation.

JD Bioscience

With its lead asset, this 5-year-old clinical-stage Korean firm will enter first-in-human trials during the third quarter of 2022. [52,53] This medicinal chemistry-drug targeting firm, focusing on inflammatory and metabolic diseases, has its lead

asset (GM-60106) headed into single-and multiple-dose studies conducted in Australia in individuals with borderline nonalcoholic fatty liver disease (NAFLD).[54] Thus, it is an early product company. Their asset offers a novel, first-in-class treatment for nonalcoholic steatohepatitis (NASH). A peripheral serotonin 2A inhibitor provides a bimodal action by targeting the hepatocyte to limit lipogenesis and hepatic stellate cells to influence inflammation and fibrosis (Figure 8). [52,54,55]

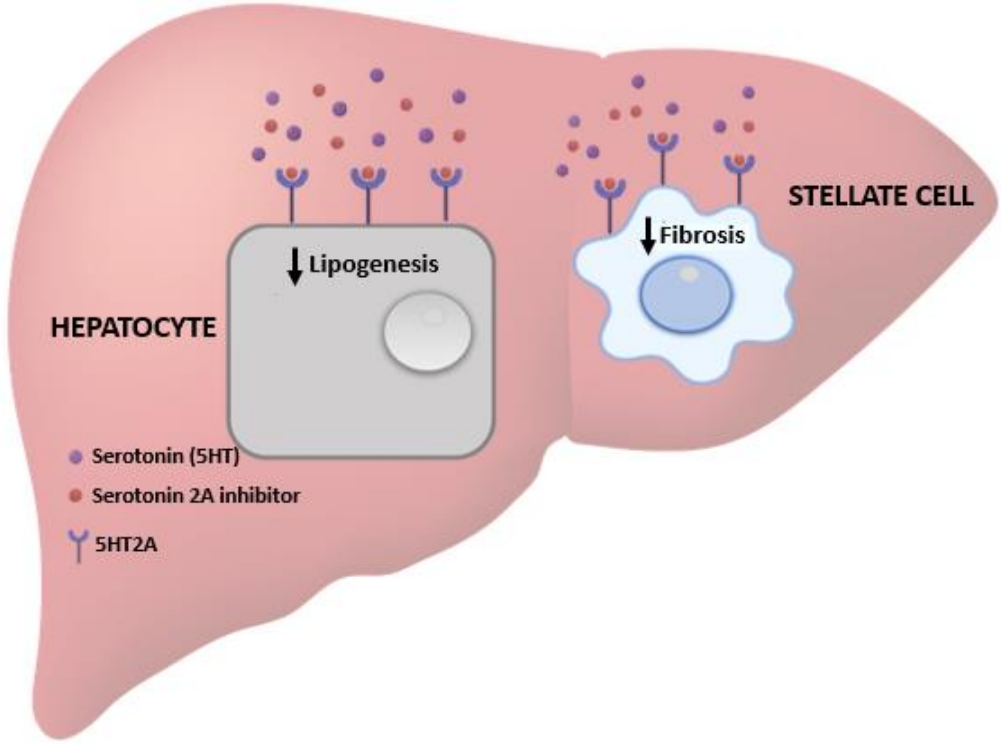

Figure 8. Bimodal actions of JD Bioscience's peripheral serotonin 2A inhibitor on lipogenesis and hepatic stellate cell

The company's management is a strong science-oriented team with a record of accomplishment and expertise. Its chief executive has already set five licensing opportunities. [55] The co-founder brings twenty years at Merck and the development of Januvia® and nine years as a chief technology officer. [55] On its scientific advisory board is one of the leading hepatologists for NASH. [55],[54]

The firm has solid financial backing. It has received $6 million in series A and $20 million from series B. [55] It already enjoys a revenue stream of approximately $750 thousand annually from collaborative projects or out-licensed medicinal chemistry assets. [55]

A map using the "critical screen" elements reveals a strong positive picture and some issues to consider (Table 3). The most noteworthy positives are a large potential population (Figure 9), a forecasted market of $28 billion globally by the decade's end, and no Food and Drug Administration-approved treatment available. [56-59] The asset brings a novel approach targeting two critical NASH pathologic features. [54] Preclinical animal work is pristine, with proof of concept in four common NASH animal models.[54] The asset is now headed into clinical trials. If these studies proceed well, the company should move into phase 2a in 2023 with an FDA "fast track" designation.[54,60,61]

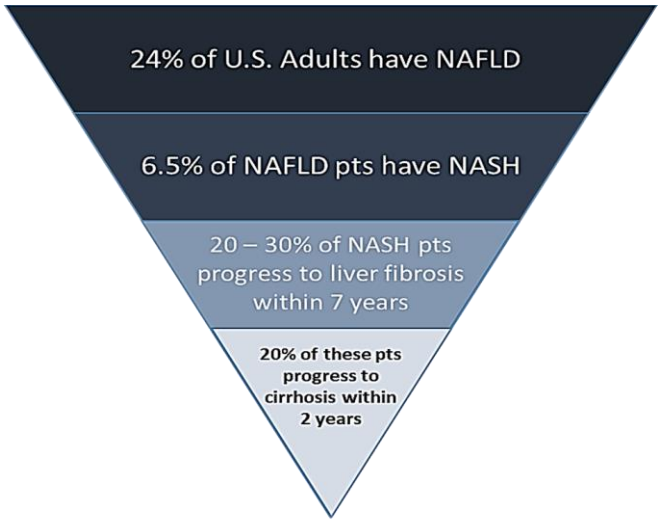

Figure 9. Breakdown of NAFLD and NASH in the United States[56-59]

However, NASH is a complicated disease, and issues exist with assets falling short of regulatory success in their later clinical trial stages (e.g., Intercept's obeticholic acid and Gilead's selonsertib). [56-59] While the company possesses some initial comparative data in animals vs. obeticholic acid, it lacks any head-to-head vs. or combination with NASH treatment data in the clinic. Such clinical data would help position and select an appropriate clinical trial path as other companies (e.g., Pfizer, Gilead, and Novo Nordisk) are pursuing combination strategies with FDA "fast track" designations.[62] [63,64]

Accordingly, this firm garners a low-moderate rating on the screen. This assessment is due to the opportunity in NASH, the company's current progress, and its lead asset in the clinic. It also recognizes the financial and clinical challenges in advancing the asset through the clinic in this complex disease. The company is exploring partnerships as a licensing opportunity or an alliance with a larger, more experience NASH-oriented company that will help move the asset along clinically and commercialize this product.

Reviva Pharmaceuticals

This late-stage drug development company represents the other end of the product spectrum. Reviva Pharmaceuticals utilizes a chemical/genomics-driven and proprietary chemistry approach. [65] This scientific strategy led to its lead asset, brilaroxazine (RP5063), a multimodal dopamine-serotonin agonist/antagonist that acts centrally and peripherally.[66] This asset has realized proof of concept in animals for schizophrenia, pulmonary arterial hypertension (PAH), and idiopathic pulmonary fibrosis (IPF) and in humans for schizophrenia. [65, 67,71] Brilaroxazine is in phase 3 for schizophrenia and will enter phase 2 for PAH and IPF. [72,73] It also possesses other assets and indications in its pipeline. [66] The firm is quite lean as it uses a virtual model. Its management brings extensive industry experience of over twenty years for its chief executive and chief medical officers. [65] It has gained financial stability by entering into a special purpose acquisition company (SPAC) arrangement with Tenzing. [74] This arrangement allows the company to access capital in the public markets starting in late 2020. [74] The "critical screen" map reflects a strong picture with a few considerations (Table 3). Brilaroxazine is engaging three interesting and nicely sized billion-dollar markets with multiple unmet needs.[75-77] It is in phase 3 and will enter phase 2 in two orphan indications.[72,73] The orphan indication areas can offer a streamlined regulatory path and other development incentives.[76-79] Furthermore, its SPAC with Tenzing makes Reviva a public company and able to gain capital from public markets.[74]
Nevertheless, the firm still will need financing to support the orphan drug development programs and go to market with schizophrenia. While the firm has multiple "shots on goal," financing, past success, and clear regulatory paths, it would benefit from alliances. Still, this venture achieves a high-moderate rating due to its considerable progress in the three assessment areas.

Table 3. Mapping of product ventures using the "quick screen."

JD Bioscience			
	Positive	**Negative**	**Rating**
Opportunity	Moving into Ph 1 a, b, and c Market: $144.4M→$27.2B (2019-29), 68.8% CAGR (Global) [56, 57] UMN→ lipid, inflammation, and fibrosis management [56, 57] Trend→ Movement to combo therapy (Pfizer fast track) [62, 64]	Uncomfortable investors and business development individuals regarding NASH and drug failures [56]	Low-Moderate
Money	Series A and B Funding (~$26M, Lead, Mirae Asset Capital)[54]	Funding needed for Ph 2 and 3	Low-Moderate
Competitive Advantage	1st-in-class peripheral 5HT2A antagonist [54]Defined IP (Korea, US) [54] ↓ fibrosis, inflammation, and lipids (4 animal models) [54]No blood-brain-barrier crossing[54] Alliance/licensing → enhance development position	No head-to-headcomparative studies with other assets through clinical development	Low-Moderate
Reviva Pharmaceuticals			
	Positive	**Negative**	
Opportunity	Market: Schizophrenia → $7.8B → $9.3B, 3.68% CAGR, (2020-26) [75] UMN→ Broad efficacy, ↑ safety and clean PK (B → Ph 3) [75] PAH→$7B, 5.2% CAGR (2021) [77] IPF→ $3.1B→$6.16B, 7% CAGR (2020-30) [76] UMN→ Disease modification → ↓ M&M (B → Ph 2) [65, 76, 77]	NA	High-moderate
Money	Reverse merger (SPAC) 2020→ Tenzing (Public) [65, 74]	Financing for Ph 3, but still needs for Ph 2s	High-moderate
Competitive Advantage	Strong IP→ multiple layers (US, EU) [65] Simple PK, attractive safety, and strong proof of concept[67-69, 80, 81] Later stage, the Public company[74] Lean management and business model[74] Would benefit from an alliance	Still needs Ph 2 and Ph 3 data and commercialization plans	High-moderate

B: Billion; CAGR: Compounded annual growth rate; EU: European Union; IP: Intellectual property; MN: Million; M&M: Morbidity and mortality; NA: Not applicable; NDA: New Drug Application; Ph: Phase; PK: Pharmacokinetics; SBIR: Small business innovation research; UK: United Kingdom; UMN: Unmet needs; US: United States; 5HT: Serotonin.

Platform

Two cases describe ventures that fit within the platform profile. Both have products on the market and others based on the technology platform in clinical development. These represent unique examples as one is an independent firm, and the other is a subsidiary of a larger venture due to its acquisition in 2017.

Moderna

Moderna represents a tremendous success story with its mRNA platform coronavirus-19 (COVID-19) vaccine, Spikevax®.[82, 83] The mRNA platform's core technology (Figure 10) and Moderna's design studio capabilities offer speed, scale, and flexibility.[84] The mRNA platform provides applications beyond infectious diseases, including immune-

oncology,cardiovascular, autoimmune, and rare diseases. [83-87] Its current marketed COVID product earned $17.7 billion in revenues, only second to Humira® and BioNTech-Pfizer's vaccine. [82,88] The company currently has an active clinical program with twenty-five ongoing trials, including phase 2 studies involving the Zika virus and phase 3 studies in adult respiratory syncytial and cytomegalovirus. [83-87]

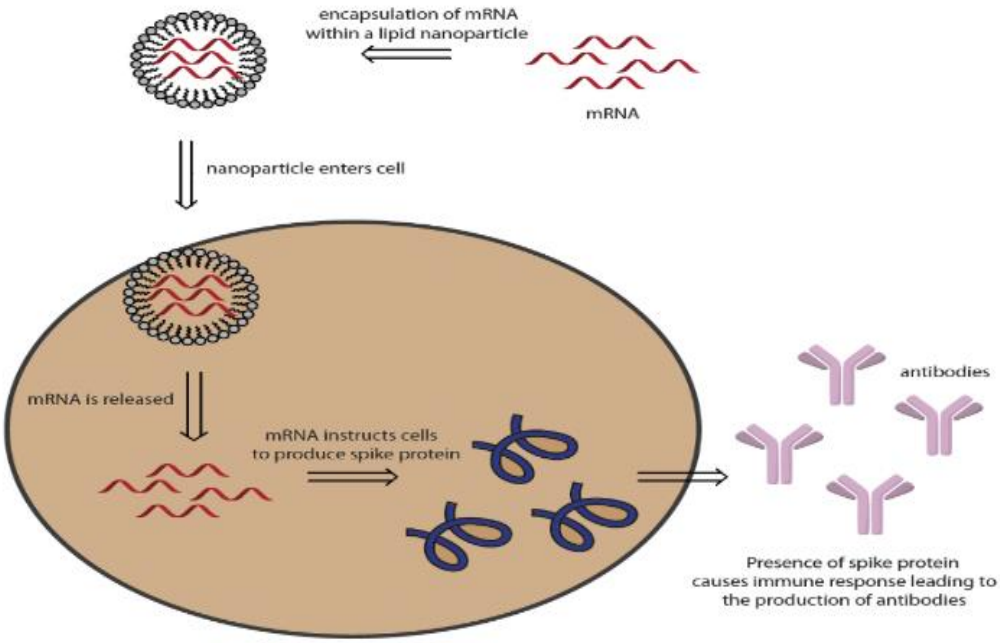

Figure 10. mRNA cellular interactions lead to immune response and the production of antibodies.[89]

Moderna's leadership brings extensive pharma experience, with its chief executive having over 27 years in the business and its president with 12 years in the industry. [83-85] The company includes over 3000 experience professionals covering diverse areas from research and development to regulatory to sales and marketing expertise. [83-85]

A "quick screen" review reflects an extremely positive picture (Table 4). Strengths include 1) large and growing markets for vaccines, [90, 91] COVID, [92] and mRNA,[93] 2) a defined, effective platform with commercial success, [84, 88] 3) a robust pipeline with infectious disease and immune-oncology applications, [86, 87] 4) seasoned management, 5) a large, talented organization, [84, 85] 6) attractive opportunities with unmet needs, [84,85,90,92,93] and 7) strong initial revenue with its COVID 19 product, Spikevax®, with some growth still available in this space. [83, 88, 94]

Two noteworthy issues, however, exist. The first involves the potential flattening of COVID-19 vaccine use and revenues. [92,95] The second is whether the company missed achieving full revenue potential. This point considers the performance of the Pfizer and BioNTech partnership with Comirnaty®, resulting in $37 billion in sales (twice that of Moderna's revenue). [82]

Overall, Moderna receives a high rating relative to the three major criteria. A significant question relates to future growth- can strategic alliances or mergers and acquisitions (of another company or by a large pharmaceutical firm) facilitate further growth? Such consideration is essential to address a future revenue decline from its COVID-19 vaccine, Spikevax®, once herd immunity occurs or emerging variants are clinically insignificant.

Kite Pharma

Kite Pharma is a Gilead company founded by serial entrepreneur Arie Belldegrun, MD.[96] It pioneered gene editing and cell therapy, leading to two FDA-approved chimeric antigen t-cell receptor (CAR-T) treatments. [97-99] The company drew on technology from the National Institute of Health in 2012 and quickly developed the opportunity leading to products in the hematology-oncology space within a decade. [98-100]

This approach (Figure 11) facilitates the immune system to kill cancer cells by utilizing the patients' T cells, programmed to engage with specific tumor antigens.[97,101,102] Such a treatment strategy leads to rapid, long-term, durable responses. [97,101,103]

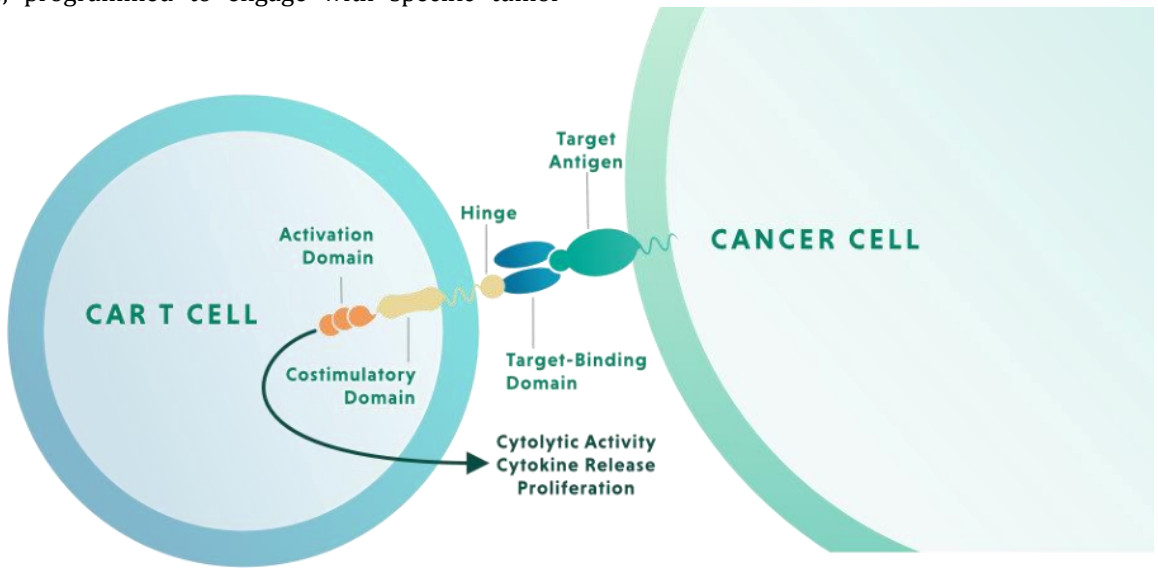

Figure 11. CAR-T cell therapy targeting and therapeutic interaction in destroying cancer cells. [97]

Its two in-market products, Yescarta® (axi-cel) and Tecartus® (brexucel), are respectively for the hematologic indications, non-Hodgkin's lymphoma [104,105] and mantle cell lymphoma. [106,107] Both products account for $871 million (up 43% due to the Tecartis® launch).[108] Also, the company has a rich pipeline with eight products in the clinic, [109] including programs focused on solid tumors, [110,113]representing over 90% of cancers.[114,115]

Acquired in 2017 by Gilead, Kite is based in Santa Monica, CA, as a subsidiary. [98, 116] The acquisition added capital and organizational capabilities to enhance the company's position. Leadership for both companies possesses deep biotech and pharma experience. [117,118] Further, the company has alliances with HiFiBio Therapeutics, [119] Appia Bio, [120] and Oxford Biotherapeutics.[110]

Considering the "quick screen," it is unsurprising that Kite brings many positives (Table 4). Its CAR-T program brings a defined, effective platform with commercial success, revenue, and growth. It focuses on the cancer space, representing a significant growth opportunity. The CAR-T space is poised to grow significantly, with a 31.6% compounded annual growth rate leading to a projection of $21 billion markets globally by the end of the decade. [121,122]

The company is pursuing multiple unmet need opportunities in hematologic malignancies and solid tumors. [109,123] Its current pipeline consists of eight active programs, three in phase 3, four in phase 2, and two in phase 1. [109] Current performance reflects a solid Kite/Gilead relationship. The current market and pipeline indicate room for additional growth. [109, 121]

However, two points of uncertainty exist. The first is that the cell therapy space is becoming more crowded. Multiple competitors, including several large players, are entering this space, such as Amgen, BioNTech, bluebird bio, Bristol Myers Squibb (by acquiring Celgene, which previously bought Juno), G1 Therapeutics, Johnson and Johnson, and Novartis. [121,122] Second is the payer landscape, which is developing restricted-use guidelines and novel reimbursement programs such as shared risk agreements)[124,127].Kite's performance and structure justify a high rating when using a "quick screen." It exemplifies the mix of market opportunities being fulfilled by technology, finances, fit, and multiple competitive advantages. Engagement of additional alliances can add to its pipeline capabilities and enhance its overall competitive position, especially as the company moves into the solid tumor space. [109-113]

Table 3. Mapping of platform ventures using the "quick screen."

Moderna			
	Positive	**Uncertainty**	**Rating**
Opportunity	Market: Vaccines: $67Bà149B (2001-27), CAGR 10.2%[90] COVID-19: $65Bà$157B (2020 -25) CAGR 19.29% [92] mRNA: $47B à $101B (2021-26) [93] UMN: HIV, RSV, CMV, Zika and cancer assets in the pipeline[86, 87]	Future COVID market[92, 95, 128]	High
Money	Revenue: $803.4Mà$18.5 B (2020-21)[88, 94] Market cap: $54.19 B (May 2022) [129] Room for growth	Revenues from COVID vaccine [92, 128]	High
Competitive Advantage	A unique platform, strong COVID-19 experience, and strong IP [83-87, 89] Ph 1 assets: HIV vaccine (mRNA-1644 and mRNA-1574) and Immuno-oncology (IL-12, MEDI 1191)[86, 87] Multiple alliances (e.g., AstraZeneca, DARPA, Merck, Vertex) [130]	NA	High
Kite Pharma			
	Positive	**Uncertainty**	
Opportunity	Market: CAR-T→1.96B→ $20.56B (2021-29), 31.6% CAGR [121, 122] UMN: ↓ chemo and treatment time, needs in solid tumors, and ↑ survival and cures [97-99, 102, 103]	Competition: G1Tx, bluebird bio, BioNTech, Amgen, Novartis, and Juno [121, 122, 131]	High
Money	Potential high revenue, profits, and margins Revenues (Gilead total): $27.3 B (2021)[132] CAR-T: $871 M (up 43% due to Tecartus® launch) [132] Market Cap: $78 B [133] Room to grow		High
Competitive Advantage	Pioneer, with well-established IP [100, 108, 132] In-market products bringing strong efficacy and safety [104-106, 132, 134] Gilead. Experienced leadership. ↑ resources and capabilities[117, 118, 132, 134] Broad HM and ST pipeline, [109]. A platform for continued innovation, especially allogenic for ST. [101, 110, 112, 113, 123, 135]		High

B: Billion; CAGR: Compounded annual growth rate; CAR-T: chimeric antigen t-cell receptor; CMV: Cytomegaly virus; COVID: Coronavirus; IP: Intellectual property; HIV: Human immunodeficiency virus; HM: Hematologic malignancy; M: Million; mRNA: Messenger RNA; RSV: Respiratory syncytial virus; NA: Not applicable; ST: Solid tumor; UMN: Unmet needs.

Discussion

This paper addresses how established firms can quickly and efficiently assess biomedical-life science startups of different maturity (development and commercial) levels. Multiple cases address this question by providing examples to address Boni's "quick screen" of biopharma and life science ventures and metaphorical categorizations through the "3 Ps." [5] This framework embraces the essential questions of opportunity, money, and competitive advantage. This work also highlights how ventures fall into one of three metaphorical categories coined the "3 Ps"- project, product, and process. This contribution offers the first paper that provides "real world" examples to

illustrate these concepts, contextualize how each case fits by mapping evidence specific to positives, negatives, and uncertainty considerations, and determine where such ventures fit on the low-to-high continuum. This mapping of case examples provides this paper's first significant contribution.

Learnings

It is important to put this work into perspective relative to practice. This work provides three learnings offering three additional contributions for those interested in using this screen and framework.

1) Risk and opportunity relationships with venture (asset) maturity:

This paper introduces the elements of risk and opportunity, their roles relative to business cases, and frames the "quick screen." Entrepreneurs, investors, and managers will weigh these factors. The quick screen" and the "3 Ps" embraces such considerations. Mapping the positives, negatives, and uncertainties within these cases allows for considering these elements to assess where a particular venture (asset) fits. The "3 Ps" exists on a maturity continuum. This consideration of risk and opportunity relative to the "quick screen" and maturation of the venture (asset) allows for proposing of a model that connects maturation, risk, and opportunity. This construct (Figure 12), this paper's second contribution, illustrates this relationship. It considers the maturation of the venture (asset) profile relative to the "quick screen" elements. This model reflects that with maturation, risk falls (i.e., de-risking of the venture or asset) and opportunity climbs, but more exponentially. This illustration reflects the significant increase in value that occurs as the venture de-risks the asset. This model allows further research to ground this construct and test these relationships.

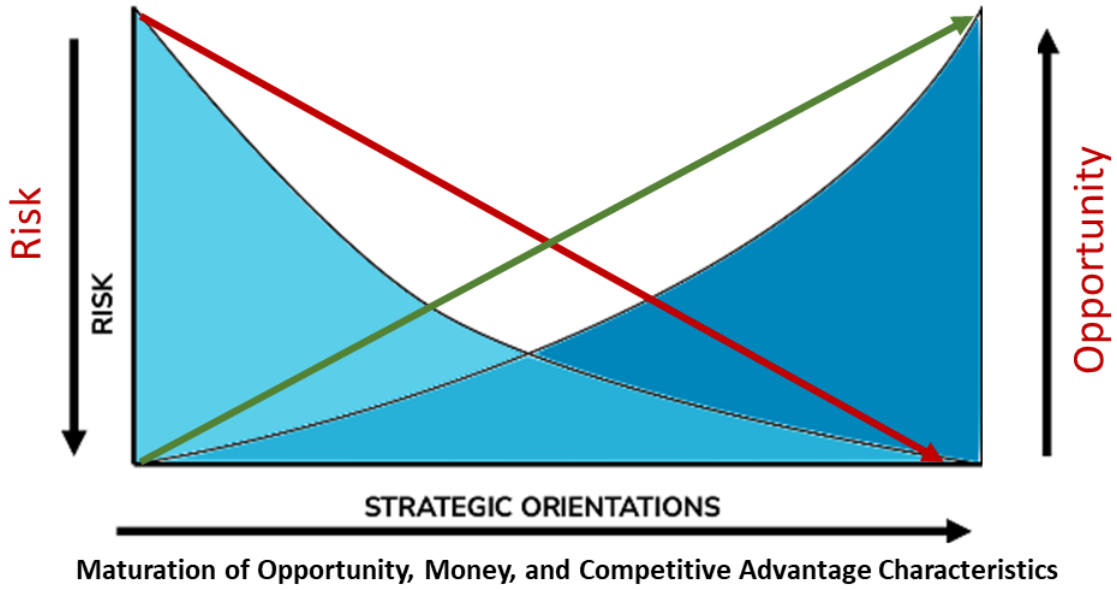

Figure 12. Modeling the relationship of life science venture (asset) maturation relative to the "quick screen" elements and changes in risk and opportunity. (Adapted [136])

2) "Quick screen" represents a useful sensemaking lens:

The concept of sensemaking is critical for individual stakeholders to reconcile diverse and substantial data pieces, facts, and relationships. The "quick screen"- focusing on opportunity, money, and competitive advantage- provides a useful lens for this evaluation and decision-making process. Figure 13 ties in the core pieces in the "quick screen" with critical elements that a stakeholder should consider when answering the questions related to each criterion. Opportunity ties in with the elements previously discussed. The elements related to the development stage and maturity are important to the opportunity. Such

pieces help consider under which of the "3 Ps" the venture (asset) situates. For monetary, the firm stage emerges as well as current investment, future needs to advance, sources, and returns as critical elements. Finally, for competitive advantage,noteworthy is not only the assets' advantages (e.g., point of differentiation, mechanism of action, intellectual property) but also the organizational advantages such as leadership experience, alliances, and firm capacity. Most notable is that such advantages are not fleeting but are sustainable over time to support long-term growth, especially in competitive markets. Like the model from the previous learning, this model offers an opportunity for further exploration for theoretical grounding and later testing. Interestingly, this construct does not incorporate cognitive considerations, which can add to the sensemaking process. The first relates to absorptive capacity, a concept that relates to an individual's or firm's ability to learn and apply information and concepts more efficiently due to prior experiences, education, access to outside expertise or customer input, and diverse perspectives. [137-139] Hence, data are only as useful as the experience of the people interpreting it and their lenses (e.g., scientific, clinical, regulatory, commercial). This consideration is an important variable in advancing Boni's framework and represents an area for future research. For example, while several junior researchers were participating in data collection and analysis in this project, the data evaluation by the three senior authors with over 100 years of industry experience (including scientific, clinical, commercial, entrepreneurship, and business development) allowed for appropriate and efficient categorization and interpretation. The depth of absorptive capacity of the screen's users, such as the lead and senior authors in this project's case, allowed for educated and controlled impressions and guesses, per Gladwell's book "Blink." [140] This paper's lead and senior authors- from their past business development, commercial, and entrepreneurial experiences- have developed more logical and deliberate processes for more efficient judgments (or snap judgments or first impressions around each case firm and assets).

Per Gladwell [140] and consistent with Cohen and Levinthal[137], individuals can teach themselves to make fast judgments or educated guesses; thus, such individual and firm-based absorptive capacity capabilities can lend to more effective use of the "quick screen." This cognitive (and organizational learning) consideration offers a nice platform for future case study research. Another cognitive consideration that can influence sensemaking involves normative bias. [141,142] This unconscious cognitive bias is about having an idea of how things or a person should be, which affects one's ability to see the positives of things outside of these definitions. [143] It involves assumptions about and preferences for traditional paths, such as commercialization and development, in this project. [143] The reliance on current definitions around concepts like opportunity, financial viability, and competitiveness maturity might limit the ability to see the full potential of some projects. [143] Countervailing or mitigating such a bias can include broadening one's educational and experience base to consider other realities and to bring diverse backgrounds and perspectives into the review process. [143] Leatherbee and Katila [139] highlight the advantage of diverse professional disciplines, thus adding further absorptive capacity in utilizing the customer discovery method and achieving consensus around business models and ideas as part of the National Science Foundation's Innovation CORPS™ program. Additionally, Reuzel and colleagues [142] offer insight into reducing such bias in health technology assessment through procedures that consider interactive evaluation and casuistry to incorporate different perspectives, define what is the matter, and broaden the space for explication and consensus building. Such observations around this cognitive consideration avails further insight into the use of the "quick screen" as part the decision making process. They also offer an additional path for exploration in future efforts examining the "quick screen."

Figure 13. "Quick screen" as a useful lens for sensemaking engages multiple considerations for each major criterion for stakeholders to weigh when assessing a venture (asset). (Adapted [5])

IP: Intellectual property; MOA: Mechanism of action; POD: Point of differentiation; $: Dollar

3) Timing appropriate use:

One major consideration exists regarding when (and not) to use the "quick screen." Just based on its label, the framework lends to efficient decision-making. Considering this point, one needs to evaluate this framework relative to Systems 1 vs. 2 (Fast vs. Slow) thinking. [144] The former, System 1, involves fast, unconscious, and automatic thinking that individuals use daily. [144] Unfortunately, such thinking can be error-prone [144] and subject to differences in absorptive capacity and lenses.[137,140]

Interestingly, per Gladwell, such processes for quick thinking and educated guesses can be developed and controlled. [140] Alternatively, System 2 embodies slow, conscious, effortful thinking needed for complex decisions. [144] This effort leads to more reliable decision-making. [144] Thus, this lens is not a heuristic. Rather, it is a tool to aid stakeholders in making decisions efficiently to determine "go/no go" or what next step relationship should be explored with the startup. This insight offers this paper's third contribution. Interestingly, if stakeholders within a venture embed this framework through continued use over time, it could emerge as a more routine, not heuristically, practice due to organizational learning. [145-147]

Such consideration reinforces the prior sensemaking points relative to sensemaking, absorptive capacity, individual experiences, lenses, and educated guesses. Still, it does not replace the need for detailed "due diligence" and the building of a reasoned business case for management or investors, especially when the value of such ventures (or assets) may reach hundreds of millions to billions of dollars. Rather, it provides a complementary tool to more engaged processes, such as the business case. These insights for testing avail the opportunity to explore via structure casework to refine this characterization and screening construct with these internal criteria.

4) Different engagement strategies exist for each maturity stage:

Each stage of maturity (project, product, platform) offers new ventures and established firms different strategies to engage, create value, and develop revenue or resource opportunities. Startups do not necessarily need to be locked into the traditional mindset of just having to raise monies from investors.

The following insights offer an opportunity for further exploration to characterize the extent of such relationships fully.

Figure 14 illustrates such diverse strategies depending on maturity. This presentation offers this paper's fourth contribution. For projects, these entities can engage with industry through three avenues. The Veneno, MTS, and AgBio cases exemplify that these ventures can partner through project collaborations via research, fitting their asset(s)

within another firm's value chain via out-licensing intellectual property or basic assets (e.g., chemical compounds for screening). They also may have the opportunity to license the asset or gain early-stage corporate venture capital, but such agreements would be extremely low valuation. As the MPRx, Inc. case illustrates, some firms can sustain themselves via government grants (e.g., SBIRs). For products, licensing and alliances fit as a nice strategy as JD Bioscience illustrates in pursuing partnerships but also shows that it can generate non-dilutive revenues of $1 million annually through out-licensing of medicinal chemistry assets early in the process. In contrast to projects, such licensing deals will involve more significant valuations and commitments depending on where in the asset's product stage, such as early or late development or pre-or post-proof of concept. Also, with products, there may be merger and acquisition opportunities with complementary firms and offerings to create further value and a bigger target or avail public market funding sources.

The Reviva Pharmaceuticals SPAC with Tenzing provides a nice example of this strategy. Platforms represent more mature entities with technology, product, leadership, and personnel to grow. The Kite Pharma-Gilead relationship reflects such engagement that led to the acquisition of the former to avail greater resources and capabilities to commercialize the cell therapy platform. Moderna, in contrast, chose to remain independent and gain public market access and value through an initial public offering. Moderna realized great commercial success with its vaccine through the emergence of a pandemic. While the company reached approximately $18.5 billion in sales globally ($17.7 with Spikevax®), it was half of the BioNTech-Pfizer relationship. [82, 88] The COVID-19 vaccine business in the future may not be certain. They will also need to prepare for launching multiple products. Thus, such entities might consider other alliances and relationships, including mergers and acquisitions options.

Figure 14. Diverse engagement options are available for new ventures depending on their stage of maturity for projects, products, or platform entities.

@: at; IPO: Initial public offering; M&A: Mergers and acquisition; SBIR: Small business innovation research; VC: Venture capital; WIP: Work in progress.

Limitations

As with all research work, limitations exist. It is important to recognize that the cases might not neatly map when using the "quick screen." For example, case ratings are broken out as low and medium-low for the project classification and low- and high-moderate for the product category. This consideration is important when pulling, categorizing, and interpreting data. Such occurrences might require contextualization or interpretation to define the best rating and classification. Examination of the data provided a clear picture based on the extent of positives vs. negatives or uncertainties. Project cases contain more negatives and uncertainties than in the other two classifications.

Platform cases have few, if any, negatives or uncertainties. Also, mapping can be more complicated when making a qualitative assessment. It is important to refer to prior discussed criteria for each screen element. Critical points for classification involve the degree of maturity, the extent of current financing, the amount of future resourcing to hit inflection points, and the degree of intellectual property protection, differentiation, management experience (research and development, and commercial) and alliances.

Second, this paper provides an exploratory effort using case examples via purposeful selection due to availability and fit for the framework. It does employ any structured methodology such as proposed by Eisenhardt, [7, 8] Gioia, [9] Langley, [10], or Yin, [11]. They help illustrate the points but might not reflect the diverse scenarios for a particular "P" classification.

This effort is purely to provide illustrative contextualization of the framework relative to multiple real firms as case examples. The third consideration relates to data, along with its sourcing and weighing. Market, competitive, and unmet need data come from private, third-party reports from market research firms with "bottom-up" and "top-down" methods. Financial limitations to purchasing the full reports lead to selecting those easily accessible through the web or university library portals. Limited data are from peer-review data, and some reports provide different estimates based on years, data sources, and geography. Other data come from unpublished investor presentations or company websites. Such raises potential questions about the strength of the data.

Also, some important variables might be undervalued, such as Food and Drug Administration regulatory practices or professional society guidelines. While this analysis did not use such inputs equivocally, it and future analyses can help evaluate the opportunity and money parts of the screen. Interestingly, part of the MTS evaluation and classification as low did consider that the FDA did not have defined guidance around sarcopenia. The analysis does not consider "unknown unknowns" and "known unknowns."[148] The former might be challenging, as it is hard to predict when the next pandemic, such as COVID-19, will emerge. However, multiple examples of the latter do exist. Such scenarios can include the Centers for Medicare and Medicaid's view of the Food and Drug Administration breakthrough designation review,

evolving regulatory guidance in diseases such as Nonalcoholic SteatoHepatitis, or changing clinical standards of practice in certain cancers, as defined by the National Comprehensive Cancer Network guidelines. Incorporating such payer, regulatory, clinical, and professional considerations could be valuable data to aid in classifying Mid to High ventures or assets, particularly related to the opportunity and financial considerations. Such points would lend to further analysis in the future.

However, for this exercise as a "screen," the goal is to gain a relative feel for the market opportunity based on size and growth estimates. Accordingly, these sources fulfilled the needs of the "quick screen" approach. Still, a more detailed analysis would be needed for due diligence and a business case. Future research should include a broader sample of such estimates, consider some weighing of some variables, and incorporate "unknown unknowns" and "know unknowns" to provide a more detailed view of current and future market size, growth, needs, and influences.

The fourth limitation relates to the previously discussed cognitive considerations. These include absorptive capacity considerations relative to experience, perspective, diversity, and normative bias and management. Finally, this analysis does not use quantitative assessments. It did not score or weigh the different influences. It only categorized the data based on positives, negatives, and uncertainties, based on the expert judgment of the lead and senior authors. Such scoring would lend to more of a positivist view and provide a more concrete weighing and assessment of the evidence within each category.

Quantifying would require clear definitions around weighing and scoring evidence to mitigate the subjectiveness that can creep into such evaluation. Ultimately, it would lend to creating quick ratios seen in the accounting and finance disciplines. One example could be a "risk vs. reward" ratio to provide a number to characterize the assessment and maturity numerically. However, such an effort moves beyond the initial spirit of the "quick screen" and this particular effort. This consideration is aspirational and should be part of the agenda for future research and work in extending the knowledge and utility of the "quick screen." Thus, one should consider the issues relative to internal and external validity or generalizability.

Such considerations would be needed for theory development, which was not this effort's purpose. Building on this initial work, such considerations would be extremely helpful for future efforts to investigate such entities as structured cases under a set methodology to develop and ground a theoretical foundation around the framework and the decision-making process from the data collected.

Conclusions

This practical paper addresses the overarching question regarding how established firms can quickly and efficiently assess biomedical startups of different maturity (development and commercial) levels. Boni's

"quick screen" and metaphorical "3 Ps" offers such a framework.[5, 6] Practical case examples provide an extremely useful mechanism for evidence that characterizes how individuals can utilize this framework to map relevant data and categorize where a new venture (asset) situates on the project-product-platform continuum. Therefore, this effort extends Boni's work. [5,6] This paper concludes that Boni's "critical screen" and "3 Ps" construct provides a useful and efficient tool for examining new biopharma and life science ventures (assets) at differing maturities.[5] In addition to providing multiple examples involving "real world" cases to illustrate the framework in action, this paper offers a risk-opportunity-maturity relationship model, scenarios of when or when not to use the "quick screen", and engagement strategies based on "P" classification as practice contributions. These efforts, along with the considerations around case data mapping and enhanced case study design, avail the opportunity for further investigation for further practice and theory contributions. Such future work can engage considerations beyond the scope of this initial characterization work, such as cognitive influences, data variable weights, "unknown knowns," and quantitative scoring and ratios.

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