

Lessons from Emerging Biopharma Companies Commercializing Their First Asset: *An Executive Panel Discussion*

*Insights from executives
who have led first asset
commercialization efforts*

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Moderator:

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Vice President, Global &
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Scott Megaffin,
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The number of emerging biopharma companies that independently commercialized their first asset increased nearly five-fold from 2015 to 2018—a trend we expect to continue in 2019 based on recent NDA submissions. Clarion has observed firsthand many of the common challenges and success drivers these companies face having supported more than 20 emerging biopharma companies in the last five years as they prepared to commercialize their first asset.

Clarion recently assembled a panel of executives at the 3rd New Product Planning Summit in Boston (December 2018) to share their learnings from navigating the transition from a development-focused to a fully commercial company. The panel highlighted **four key themes** around preparing for successful first asset commercialization, which complemented findings from a prior Clarion survey of executives with experiences launching a first asset. Here are the panelist insights:

1. Understand the Market at Fundamental Level

Emerging companies are often launching products that address rare conditions and niche unmet needs while also facing increasing payer scrutiny and influence. The panelists emphasized the importance of fundamentally understanding the patient experience, stakeholder behaviors and priorities, and other dynamics that factor into the opportunity for and potential adoption of the product. They also shared a common perspective that patients should be central to all commercialization planning and keeping this focus helps to align an organization around shared goals. One panelist shared that it was an invaluable experience to shadow a physician treating patients who would be candidates for the company's therapy.

“The most valuable thing we did before defining our launch strategy was take time to understand the market at a really fundamental level, especially the patient experience. These insights and the empathy they created were vital to how we oriented the entire launch”

2. Throw out the Old Commercialization Playbook

The old commercial playbook is obsolete. Order of entry, share of voice, sales force scale, magnitude of A&P spend, and volume-based contracts with payers are no longer the most critical factors. Commercialization success today and in the future requires more sophistication with an emphasis on personalized medicine and biomarkers, real world evidence, market development investment, patient finding and engagement, data-driven investments, and innovative contracts and access programs.

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“**You need people to be receptive to the idea that while there are a lot of great things about the commercialization models they know, there are opportunities to innovate and, in fact, you have to for success in today's and future markets**”

The panelists highlighted the need to recognize these evolving success drivers and challenge launch teams to consider novel approaches; they also urged that success requires support at the leadership level.

3. Start Early...Like Yesterday

First asset commercialization often resembles the adage, “building the plane while flying it.” In addition to preparing the product for launch, an emerging biopharma also needs to scale the organization and establish capabilities and infrastructure. In the panelists’ experience, the time to scale and prepare the company is often underestimated. As a result, key planning efforts and launch initiatives are initiated too late or never at all, impacting the launch timing, quality, or overall success.

The panelists also emphasized that in an emerging company, each launch

“**Launch planning for an emerging company takes longer than you think – hiring the right people, building infrastructure, designing new processes – expect to initiate efforts 24-36 mos. before launch.**”

readiness decision and activity takes longer than at established companies; in particular, there is overhead to align stakeholders who have different norms from past experience or no launch experience at all. Multiple panelists said they wished they started commercialization and scale-up planning at least 12 months earlier than they did.

4. Navigate the Transition from an R&D to a Commercial Company

All too often R&D-oriented Executive Teams, who have been hyper focused on clinical development and registration, do not fully appreciate the resources, capabilities, and timelines required for commercial scale-up. The panelists discussed a variety of approaches to educate the team, including conducting company-wide information sharing meetings, engaging R&D executives in scale-up planning workshops and brand plan reviews, and ongoing communication, among others. All panelists agreed that educating on commercialization requirements is an important key success factor.

“**There can be a blind spot to what it actually takes to commercialize – you need to educate leadership and the entire organization on the time and investment required. Evolving the company culture to focus on what will drive success in the future while retaining its core values is often a key step.**”

Contact Clarion for additional insights from the panel discussion and our New Enterprise Commercialization Survey, or information on our commercialization support offerings: blombardi@clarionhealthcare.com

Clarion's unique value proposition in first product commercialization

Experience

Clarion has worked on 40+ engagements helping companies commercialize their first asset

Proprietary Data

Clarion has proprietary survey data that identifies key commercialization challenges, success drivers and timing requirements

We also have a comprehensive database of launch activities, financial requirements and organizational capability needs by quarter through launch

Strategic Insights

Ability to develop and pressure-test strategic underpinnings of brand and future portfolio strategy

Unique Expertise

With extensive commercial experience and deep scientific expertise, we translate complex science into commercial success

Products & Markets

Broad therapeutic area experience including primary care, specialty, oncology, rare and ultra-rare diseases



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