



Pre-Launch Survey Highlights Importance of Updating BioPharma Go-To-Market Launch Model

How and When to Resource your Launch in the
New Healthcare Market.

Introduction: “It is Time to do things Differently”

We are all standing in quicksand - the world is literally changing under our feet and unless the biopharma industry adapts and evolves outside the comfort zone of legacy launch models, we are headed to missed opportunities and more poorly executed product launches going forward. Over the next four years, it is expected that biopharmaceutical companies will launch 54 new products per year. R&D investment continues to focus on areas of high unmet need in rare disease, orphan and oncology products, with nearly two thirds of launches expected to be from specialty drugs. **New modalities, like cell and gene therapies, are expected to drive a significant number of new launches over the next decade and FDA has shown a willingness to work with industry to shorten development times underscoring the need to begin launch preparations as early as Phase 1.**

Capturing full value from every product launch is critical. But with only about a third of launches meeting or exceeding analysts' sales expectations, the challenge is considerable, and only getting more difficult as the old model of reach, frequency, and scale no longer apply. Physician, payer, and pharmacy decision makers are changing the rules of the game, increasing hurdles to access, raising the bar on value definition and demonstration of real-world clinical application via Real World Evidence (RWE) development.

At the same time, launches are becoming smaller, more targeted in well-defined patient populations, and more competitive (many therapeutic options, many generic). In a world of mounting pressure on margins, growing market complexity, and more targeted launches, companies face the questions: (1) How can we deliver on sales expectations at launch? and (2) How can we ensure that patients have access to potentially curative new medicines?

Our experience and research emphasize that **upcoming product launches will need more impactful value propositions and marketing claims supported by RWE**. We recently analyzed a sample of 16 recent product launches according to two criteria: the product's perceived level of differentiation from existing treatments and the impact of the product's value story at launch. **Our analysis revealed that just 25 percent of upcoming launches in the sample showed significant differentiation while more than 50 percent showed moderate or no differentiation and will need to find a positioning edge to drive both willingness to prescribe and willingness to pay.**

Given today's health care market complexities, **how do you position your company and your new product launch to win at launch?** The purpose of this pre-launch survey is to help biotech and pharmaceutical executives answer this question and identify how and when to invest in their product launch.

We hope you find the results and conclusions in this pre-launch survey helpful, and we look forward to working with you to help you successfully prepare for your product launch in the future.

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Boulder Biotech Launch Specialists, LLC

Companies only have one chance to Launch Successfully

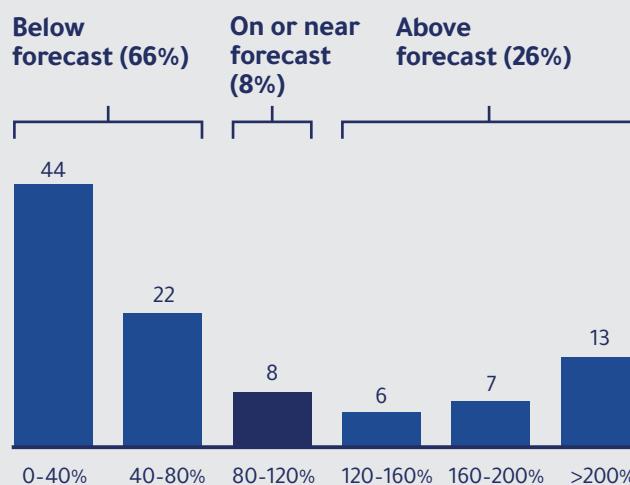
However, many product launches do not meet sales expectations

A recent analysis by McKinsey shows that two-thirds of a sample of 210 launches failed to meet pre-launch consensus sales expectations for their first year on the market in addition, they were likely to continue to under-deliver in the next two years (Figure 1). Conversely, launches that managed to exceed year 1 analyst expectations had a strong likelihood of continuing to outperform expectations for the next two years.

Figure 1: How launches perform against expectations

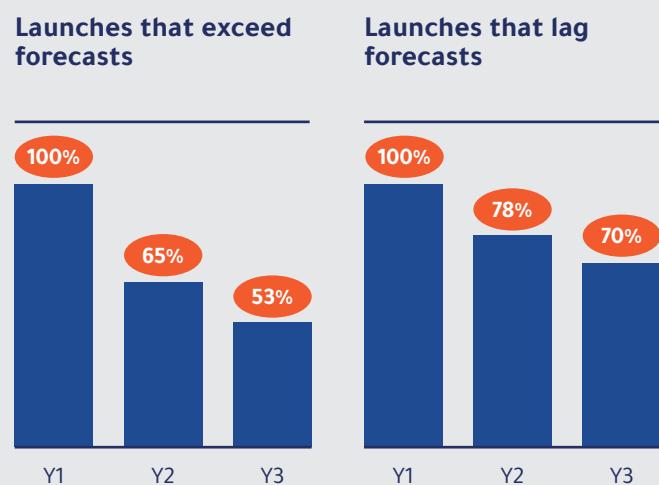
Ratio of actual sales at year of launch to forecast sales one year prior to launch¹

% of launches



Launches that exceed or lag consensus forecasts in year 1 are likely to continue doing so²

% of launches

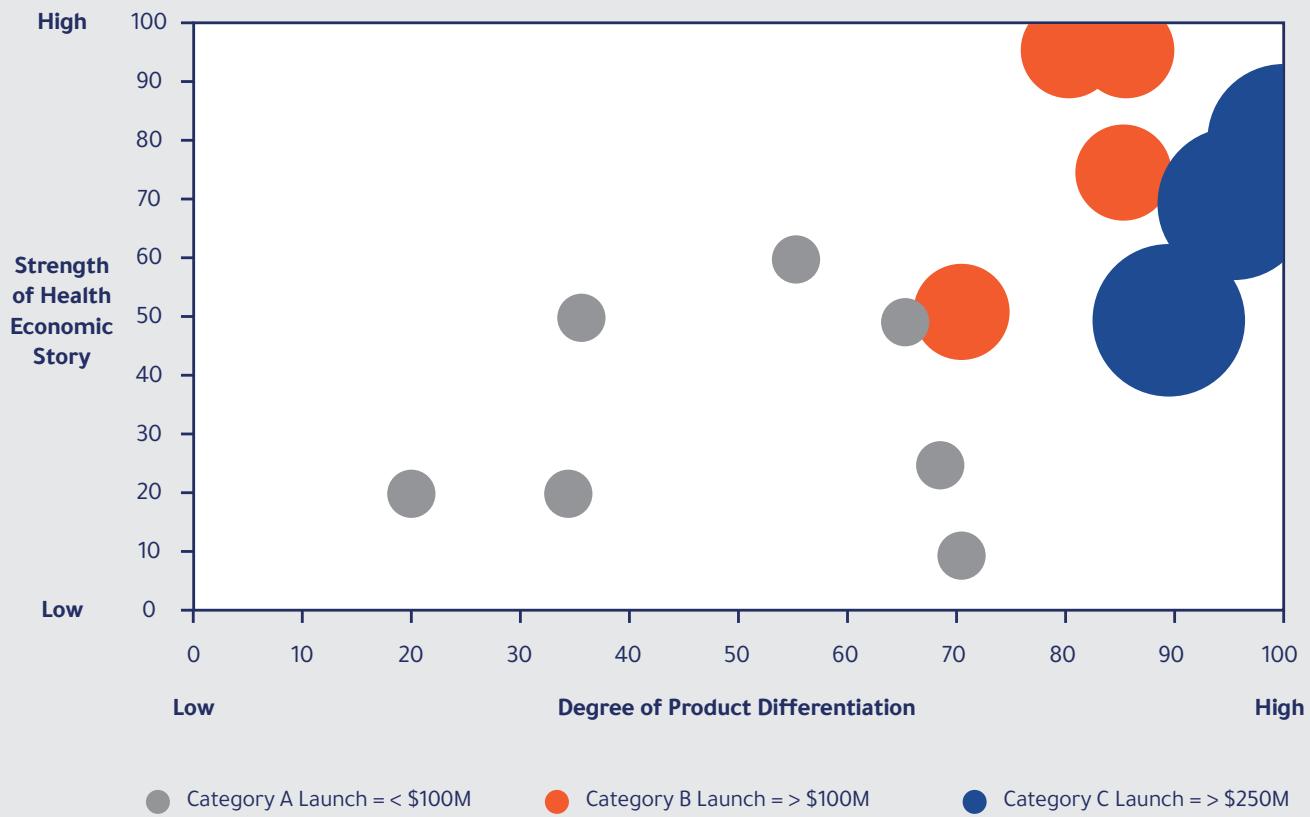


- ◆ The sample comprises 210 new molecular entities first launched between 2003 and 2009 for which Evaluate consensus forecasts were available one year prior to launch
- ◆ We took the launches whose actual sales exceeded (or lagged) forecast in year 1 and calculated the share that continued to exceed (or lag) forecast in year 2, and repeated the calculation for year 3
- ◆ Represents 30% of launches in the sample (26% of launches with 120% or more of forecast sales from the chart on the left, plus 4% from the "on or near forecast" group)
- ◆ Represents 70% of launches in the sample (66% of launches with 80% or less of forecast sales from the chart on the left, plus 4% from the "on or near forecast" group)

Source: Evaluate; McKinsey analysis

In a survey of 16 distinct biopharma launches conducted in December 2019 by Boulder Biotech Launch Specialists, we identified large differences in sales success in the first year after approval, as shown in Figure 2 below. We segmented results based on three sales buckets (size of bubble), and plotted sales achievement against strength of health economic story and degree of product differentiation. Our analysis showed that the most successful product launches had not only higher degrees of product differentiation (efficacy and safety) but also stronger value propositions supported by health economic data at launch.

Figure 2: Companies That Achieved Sales Success in First 12 Months on the Market Had Stronger Brand Differentiation Supported by Clear Value Proposition At Launch



The importance of getting launch right the first time and the difficulty of recovering from a slow start suggest that there is a need to evolve the go-to-market approach to ensure launch success. Successfully bringing a product to market has been increasingly difficult as the U.S. Healthcare Market has evolved since implementation of the Affordable Care Act. Pricing has become more controlled - and value based - as healthcare costs have increased to an unsustainable level. Customers realize there is little product differentiation and the traditional Field Sales representative based go-to-market models are struggling to effectively communicate the value proposition to more demanding and informed customers and stakeholders. **Clearly, for a launch to be successful today, a different approach from legacy launch frameworks is required.**

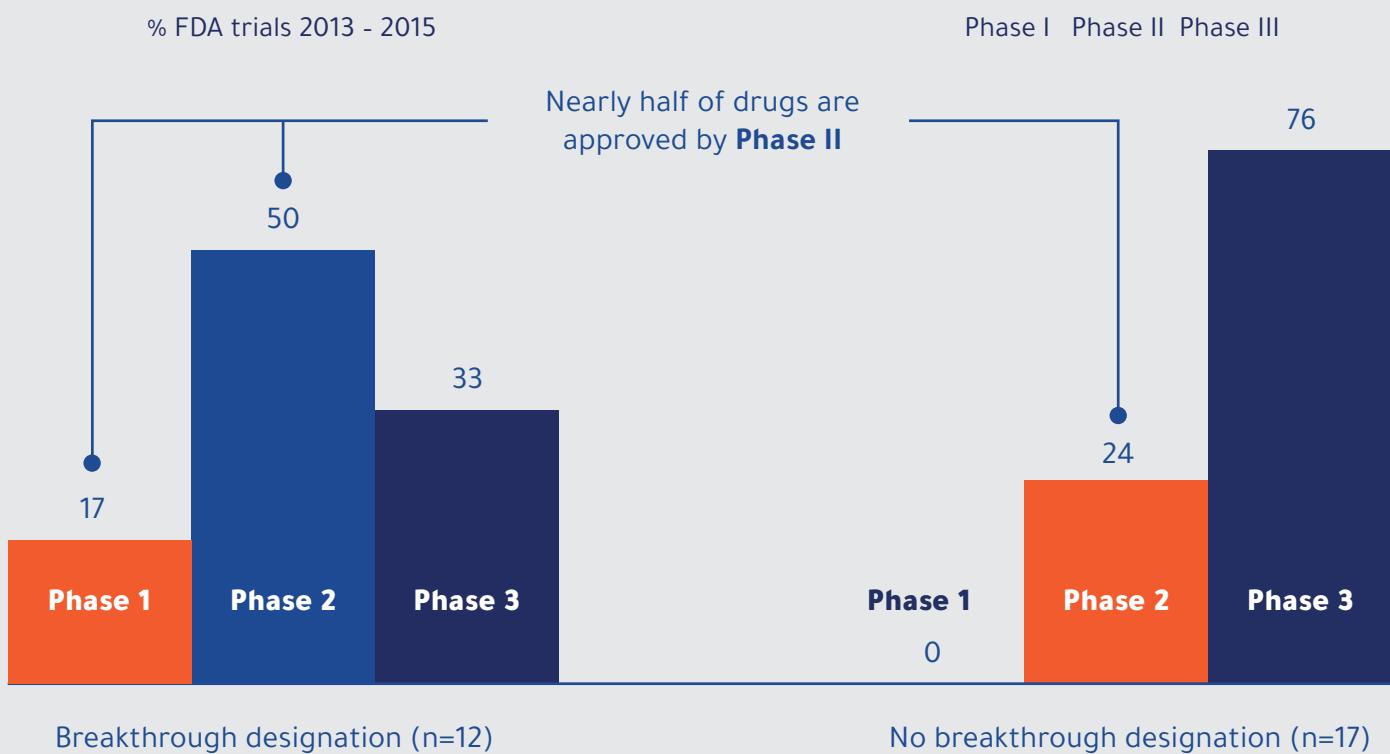
Requirements for a Successful Launch Today

Biopharma companies need to invest more resources for commercialization during pre-launch phase and as early as Phase 2

In our experience, many biotech companies wait too long to prepare for launch and lack commercial launch expertise. In an analysis of FDA clinical trials and approvals from 2013 through 2015, nearly half of new drug approvals were granted with Phase 1 or 2 data as shown in Figure 3 below.

Figure 3: Launch planning and pre-commercialization activities should begin as early as Phase 1

Nearly half of drugs are approved by Phase II given the high number with breakthrough designation.



In fact, **this data is supported by our survey respondents** who mentioned many reasons for lack of preparation at launch, as summarized in the word cloud in Figure 4.



Our pre-launch survey showed that:

- 50% of Field Teams were hired less than 6 months before approval
 - One in three respondents mentioned lack of time to prepare and lack of sales training was mentioned as a key issue impacting launch readiness
 - Lack of clear market access or channel strategy was cited by Group C respondents (lagging product launches)
 - Patient support services were often not in place at time of FDA approval due to lack of internal focus and prioritization on HCP tactics.



Time to change go-to-market launch frameworks

Digital technologies enable more agile and cost-efficient targeted promotional medical education

Respondents in our survey recommended several new areas of focus based on their launch experiences. What would survey respondents do differently? Insights are summarized in the word cloud in Figure 4.



Respondents in our pre-launch survey suggested that companies:

- ◆ Focus on more thought leader (KOL) and payer engagement prior to launch
- ◆ Invest in more digital and omnichannel promotion to HCP customers
- ◆ Develop more evidence-based data (RWE) to support their pivotal trial
- ◆ Provide deeper engagement with channel partners, including trade, distribution and GPO's
- ◆ More Field Force training - not only on own product - but expanded therapeutic area and competitor education (go beyond package insert training)

To be successful today, a different approach from legacy launch frameworks is required. The table below outlines at a high level how product launches need to evolve now and in the future.

Product Launch in the Past

Product Launch Now and in Future



Sales Force Focus



Customers demand more Field
Market Access and Medical expertise



Reach and Frequency focus
exclusively on Physicians



More need for deeper and broader
digital omnichannel communications
to more decision makers



AMCP dossier focus; HEOR data
an afterthought



More engagement of payers and
thought leaders beyond product
efficacy and safety



Little to no consideration for
positioning on guidelines
and pathways



Compelling need to demonstrate
product positioning within formularies
and clinical guidelines and pathways

We expect successful future product launches to benefit from substantial investments between phase 2 and FDA approval supported by a cross-functional approach to strengthening evidence generation in order to demonstrate outcomes which are relevant to the key stakeholders (patients, physicians and payers). Launch teams require a deep understanding of HCP and payer customers to define a more focused commercial and medical strategy, including more targeted Field Force training (not just Sales Team), identification of the most relevant key opinion leaders, as well as building Hub services for patients, physicians and payers to accelerate product adoption post launch.

Pre-launch activities need to have a strong focus, including early engagement with thought leaders to co-develop the product value proposition (aligning R&D, Medical Affairs and Commercial functions) while capturing insights to inform the commercialization and access strategy. Pre-launch market development should focus on creating awareness of the disease and adequately communicating why a new or different treatment could have significant benefits over existing treatments and where it should be positioned in the guidelines or clinical pathway.

Launching a customer-centric and digitally-enabled go-to-market model is essential. It means lowering operating costs and risks (lean approach), focusing on new channels that can deliver a better return and greater flexibility.

Three Key Pre-Launch Survey Take-Aways

Biopharma companies should consider investing more resources during the pre-launch phase within a customer centric approach. Based on our pre-launch survey, the following key actions should be adopted by biopharma companies launching products in the future:

- 1 Allocate resources to finance essential pre-launch activities.** Prioritize pre-launch investment and adopt a more agile, customer centric and digitally enabled go-to-market model. Investing more in pre-launch insights and activities prevents reactive actions post-launch that are typically very costly and have a limited impact on sales uptake.
- 2 Evolve the current go-to-market model.** New technology has put more power in the hands of companies today. Expensive ad agency models are being replaced by more nimble virtual workers that are capable of developing and deploying omnichannel digital brand content much more cost-efficiently than ever before to reach HCP customers and to improve the patient experience.
- 3 Build organizational capabilities early.** Most companies are unlikely to have or keep enough launch talent in the organization, making capability building a prerequisite for success. In a setting where only one out of 10 members of a typical launch team has ever launched a product, companies need to find different ways to develop the capabilities teams need for a successful launch and embed them in the organization. **Companies should employ alternative contract workforce structures, similar to CRO's, to deploy virtual commercial teams long before a pivotal study has commenced.** Irrespective of the approach chosen, planning and operational execution needs to be kicked off at least 18 to 24 months before the first pivotal launch.

Boulder Biotech Launch Specialists is your ideal partner. As mentioned earlier, BioPharma companies need to invest resources earlier in the drug development cycle - long before a pivotal trial read out. Most companies still wait too long to finance commercialization and hire staff which compromises their launch. To address this need, **we have developed a monthly subscription model wherein we can deploy a virtual or live team of market access, marketing, medical, regulatory and other functional area expertise to your company earlier in your clinical development program.**



Here are a few examples that illustrate how our model is different and can help your organization prepare for launch and minimize commercial execution risk:

- ◆ **We all have launch experience** - we are not 'academic' consultants - so we can share real world experience of what works as well as what does not work.
- ◆ We have in-house creative and **experienced digital marketers** to help build your brand and prepare the market for your launch.
- ◆ We can deliver commercialization services **cost efficiently through a vast network of experienced biopharma talent** and alternative workforce arrangements operating under one P&L.

Contact us so we can help Accelerate your Launch Readiness!

To learn more about how Boulder Biotech Launch Specialists can support your upcoming launch or to schedule an introductory meeting, please contact the author directly at
chris@boulderbiotechlaunchspecialists.com

