Developing a Go-To-Market Strategy for Your Lead Asset

Are you prepared?

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Launching a new therapy is a complex endeavor. There are no second chances. A biotech company must be aware of the challenges, prepare meticulously, and execute across the full spectrum of critical planning activities necessary to make that launch a success. In this paper we will review the various activities, from core market access and commercial/marketing to patient outreach, manufacturing and supply chain, pharmacovigilance, regulatory, and medical affairs that are key to successful drug launches.

This white paper is the fourth in our "Growing Up Biotech" series. The three previous papers ("Taking the Long View: Translating Science and Technology into Commercial Opportunity," "To Partner or Not to Partner: Determining Your Commercialization Plan," and "Opportunity Assessment Through the In-Licensor's Lens") discussed the technical and transactional assessments required to identify the right type of partnership for a biotech's asset or platform and overall business needs, as well as how a biotech can take an outside-in perspective to ensure it is best positioned for the partnership process.

But in the right circumstances, an independent biotech may find that going to market on its own is the best path toward maximizing the opportunity. A do-it-yourself approach to commercializing an asset allows a biotech to maintain the largest possible stake in its own drug's commercial success. Moreover, it places commercial control of the asset in the hands of the people who ostensibly know it best. Here we explore companies with sufficient internal capabilities – or the ability to acquire, manage, hire, or build those capabilities – that may not require the services and infrastructure of an established development and commercialization partner.

Biotechs hoping to launch on their own will have to independently finance a strong late-stage clinical development and commercial strategy. These capabilities may be easier to assemble in rare diseases or other conditions with high unmet medical needs, where the disease community and commercial touchpoints are more heavily concentrated. Likewise, innovative therapeutic modalities such as cell or gene therapy, where administrative capabilities need to be created and are likely to be limited to a small number of centers of excellence, may lend themselves to successful independent launches.

Indeed, for select cutting-edge therapeutics, commercial trails have yet to be blazed. Regardless of these dynamics, markets must be developed and physicians must be educated and informed in order to maximize a new asset's commercial opportunities. Biotechs must consider whether they have the financial and operational wherewithal to tackle these challenges alone. Not that any partnership is a launch panacea; successful drug launches can elude even industry behemoths.

"Launching medicines now requires understanding a pretty complex environment, with greater insights than we ever did before," Novartis CEO Vas Narasimhan remarked during the Forbes Healthcare Summit in December 2017. "The days where we just launched a medicine and it's just going to take up through a standard curve are gone. Every one of these launches is a puzzle that we need really bright minds to think through," he said. Narasimhan pointed to both the excellent launch of Novartis' auto-immune therapy Cosentyx and the difficult launch of its Entresto treatment for heart failure to illustrate that no two of these puzzles are the same. Solving them "requires different talents and skill sets than what we had in the past," he said.

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There are many reasons a company may struggle when launching its first drug, or any new drug, and each of these reasons can undermine that launch and hinder a product's long-term value. When launching a drug, momentum is precious. Planning should begin as many as five years prior to a drug's regulatory approval. Sapping momentum with poor planning or with sub-par execution can be a fatal blow. Poor launches nearly always hobble a drug's future commercial performance.

A Journey from Candidate to Product

Laying the foundation – four to five years pre-launch

From the moment a biotech has a strong sense of the product it plans to deliver to the marketplace, it should seek to understand the demand for that product in both a qualitative and quantitative manner. Companies must have clear perspectives on a number of key questions:

- What unmet need is the product addressing?
- Which patient segments would benefit most?
- Why would physicians want to prescribe it?
- Which physician segments are likely to utilize the agent?

To generate these perspectives, companies should develop and then test the anticipated product profile, which will inform subsequent workstreams and help to design and shape a drug candidate's pivotal studies. These insights are essential to ensuring the clinical development plan maximize a program's value, and should be conducted as many as five years prior to drug launch.

In parallel, insights from this research may illuminate the needs and limitations of managed care and national payer organizations and the future competitive landscape for the therapy will inform pricing strategies on a global basis. Access will be easier to achieve in select markets, and may impact launch planning efforts, both in terms of identifying launch markets and sequencing geographic market entries.

Finally, early forecasting of global product revenues will generate a baseline for developing and prioritizing commercial and market access strategies. This will also provide a strong sense of the product's potential value, which can inform conversations with external stakeholders including partners and investors.

Building out a plan – two to four years pre-launch

Identification of future prescribers, both at the expert and community levels, is essential to ensuring that a launch strategy can maximize early commercial performance. These exercises elucidate the clinical landscape from the ground up and inform both expert engagement and physician targeting heading into launch.

Depending on whether a company is entering an established market or building out a nascent one, there could be a need to devote resources to understanding an existing patient journey or partnering with the patient community to reveal critical details to understanding how patients will present and potentially be prescribed the therapy. These efforts will inform market-building activities and generate key messages that could feature in commercial efforts.

As a product nears registration, a more detailed effort to understand the competitive landscape it will enter is critical. Testing a refined, more granular product profile helps understand target development trade-offs and the impact on perceived value.

These insights will collectively inform launch planning, ensuring that commercial strategy is supported by robust understanding of how existing agents and future drugs will compete in the marketplace. They will further refine target markets and inform segmentation messaging to key stakeholders including patients and physicians.

Detail and execution – less than two years to launch

It's time to determine which markets to tackle and in what sequence, and make sure resources are secured to execute the strategy. Building out this global brand strategy will ultimately set the vision for execution.

- **Positioning and Messaging.** As a company embarks on the go-to-market plan the regulatory dialogue has advanced such that there's an understanding of specific label language for the product. How will that label translate into real-world use, and how could that language be leveraged to support your drug promotionally? Is there a need to understand a detailed patient journey or complex buying process? The answers here will ultimately set messaging for a marketing organization and refine your understanding of the product's revenue potential.

STUMBLING OUT OF THE GATE

At What Price?

Cost sensitivity is a particularly tricky area for drug launches. Even first-in-class therapeutics can falter on the market when manufacturers overshoot pricing expectations at launch. Products from commercial newcomers and entrenched players alike can stumble out of the gate when pricing strategy goes awry. Take for example the case of KV Pharmaceutical's Makena, an FDA-approved formulation of the pre-term labor drug hydroxyprogesterone. KV launched the injectable Makena in early 2011 at $1,500 per dose (about $25,000 per pregnancy), following an FDA accelerated approval, despite the availability and extensive use of compounded versions of hydroxyprogesterone from pharmacies for less than $50 per dose. The public backlash was swift, and despite reductions in the drug's price, poor uptake of the drug led KV into bankruptcy in 2012. In 2014 KV emerged from bankruptcy as Lumara, and was acquired by AMAG Pharmaceuticals.

Commercial Infrastructure

Even when the price is right, smaller drug developers can struggle in the marketplace with undersized sales forces, a less-than-firm grip on disease treatment paradigms, or poorly executed marketing campaigns. The small biotech Vivus similarly lacked the resources to build out or hire a significant primary care sales force for its obesity drug Qsymia, which the FDA approved in July 2012. A search for a commercial partner proved fruitless and Vivus's U.S. Qsymia revenue has stalled out at around $50 million per year since 2014.

Competitive Pressures

Launching a drug into a competitive market or where generics have already gained a foothold may also prove treacherous to the unprepared. Somaxon Pharmaceuticals had high hopes for its insomnia therapy Silenor when the FDA approved the drug in March 2010, based on the drug's effects on sleep maintenance, a perceived unique selling point. But even the addition of co-promotion partner Procter & Gamble in August 2010 couldn't boost Silenor's fortunes in a market crowded with generics and well known incumbents like Ambien, from Sanofi. P&G and Somaxon scuttled their marketing deal in September 2011, and Somaxon was acquired by Pernix Therapeutics for only $25 million in December 2012.

The presence of an entrenched competitor can exacerbate other problems encountered during launch. Keryx Pharmaceuticals' Auryxia was approved by the FDA in September 2014 to control serum phosphorous levels in dialysis patients. Analysts at the time expected a near-blockbuster, with consensus peak estimates of $991 million. Keryx launched the drug into a market where Sanofi's Renvela had dominated and where Renvela generics were beginning to hit the market. Management has attributed the drug's slow start to patient access challenges and general conservatism among prescribers, but a three-month supply interruption due to issues at Keryx's sole contract manufacturer for Auryxia hobbled the launch as it was picking up steam in 2016. In November 2016, the FDA granted permission for a second CMO to begin producing Auryxia, which will better enable the company to ensure supply of the drug. Keryx has guided analysts to expect $66 million in 2017 Auryxia revenue, up from $27 million in 2016.

- **Customer Segmentation and Salesforce Optimization.** With markets prioritized, it's time to organize a field force. Identifying the number and geographic distribution of key prescribers and influencers will help to determine the structure and size of an efficient commercial force to tackle these markets.

- **Product Positioning.** As the product's label and profile become clear, how will it integrate into the evolving standard of care? A refined understanding of anticipated product positioning in the eyes of prescribers can help prepare a company to drive early adoption through a focus on spaces where opportunity is highest.

- **Global Pricing Strategy.** As a company prepares to engage payer groups in different geographies, it will be critical to consolidate insights and develop pharmacoeconomic dossiers that will ultimately play a central role in pricing negotiations. Geographic variance is meaningful, making region-specific strategies essential. In parallel to this effort, consider the distribution channel strategy, and determine the role of field reimbursement support in the go-to-market strategy.

- **Early Access Programs.** Patients completing pivotal studies should be enrolled in early access programs so they can continue receiving chronic therapy and eventually receive the commercial product. Geographic differences will be meaningful here, and as such a region-by-region planning effort will be required.

- **Patient Engagement.** Engaging patient groups will help inform the resources required to support patients, which may help drive future clinical trial strategies, script fulfillment, reimbursement, and long-term patient loyalty and persistence.

Successful solo launches are indeed possible, with well planned and executed commercial strategies. Companies must have detailed understandings of the competitive landscapes for their drugs, and what those landscapes might look like in the future. They must engage payers early and understand their needs and positions, build relationships with clinical audiences, and work with regulators and players in the supply chain to begin the difficult work of laying a foundation for an eventual launch.

Rewarding, Successful Launches

Smaller biopharmaceutical companies can succeed in marketing novel agents alone, in particular when these drugs target significant unmet medical needs in relatively rare therapeutic indications or underserved subpopulations of more common ailments. Vertex's cystic fibrosis franchise, beginning with Kalydeco in 2012 and continuing with Orkambi in 2015, is emblematic of the phenomenon. Each has enjoyed a successful launch, matching a groundbreaking therapy with a serious unmet medical need.

Tailwinds from an extensive copay assistance program helped lift Kalydeco to $700 million in U.S. sales by 2016. Orkambi, which treats a broader patient population than its predecessor, is priced lower than Kalydeco but is already nearing blockbuster status, with $915 million in 2016 U.S. revenue. But a drug need not be as revolutionary as Vertex's game-changing cystic fibrosis therapies in order to enjoy a successful launch.

Acorda Therapeutics's Ampyra multiple sclerosis therapy has surpassed initial expectations for peak revenue since its 2010 launch, reaching $493 million in U.S. revenue in 2016. Acorda planned diligently for the drug's launch as many as six years ahead of approval, laying the foundation for physician, payer, and patient acceptance of its novel endpoint, which quantified walking improvements in patients. Clear communication with these stakeholders in the multiple sclerosis community helped Acorda overcome concerns about the drug's efficacy and

generate more than $85 million in its first seven months on the U.S. market.

Quick launches often draw the attention of would-be acquirers. NPS Pharmaceuticals saw strong uptake of Gattex, its drug for the ultra-orphan indication short bowel syndrome, since its launch in 2013. Shire swooped in to buy the company for $4.9 billion in January 2015. Onyx's Kyprolis multiple myeloma therapy drew the attention of Amgen, which acquired Onyx for $9.2 billion in June 2013, one year after the drug's launch. And after Viropharma's Cinryze heredary angioedema (HAE) prevention product jumped out of the gates in 2009, its growth trajectory attracted Shire's $3.3 billion buyout offer in 2013.

Looking Ahead

The successful launch of a biotech's first therapy is a challenging, but not insurmountable, task. Thorough planning, diligent market assessments, and frank evaluations of a biotech's internal capabilities and resources are necessary to maximize return on investment and get a drug into the hands of patients who will benefit from its availability on the market.

Future papers in our "Growing Up Biotech" series will examine opportunities for growth beyond the launch of a company's first asset, which requires life-cycle management strategies, including understanding how best to triage potential new indications for an existing therapy. We'll also discuss how biotechs can build a portfolio of pipeline assets to support a lead product, ensuring a strong follow up to a first successful commercial endeavor.

KEY FACTORS FOR A SUCCESSFUL LAUNCH

Commercial & Marketing

A successful launch will rely on a company's ability to target the right physicians and patients for its therapy. Understanding the natural history of the disease a drug is treating, the physician/patient interaction at the point of care, the target patient population and a patient's treatment journey are critical factors. A successful commercial strategy relies on a company's ability to understand the nature of the opportunity its new drug presents as much as it relies on the competence of a motivated sales force to drive utilization of a drug to meet that opportunity.

Reimbursement & Market Access

A full understanding of the payer landscape and a well formulated pricing strategy are essential. Engagement with payers begins well before a company begins negotiating for reimbursement and formulary placement, and may include incorporation of specific payer-relevant endpoints into clinical trials, for example. Payers may need to be proactively educated about a particular disease or subset of underserved patients. Market access must be assured, through field reimbursement support, early access programs, and patient assistance. Companies should work with patient advocates where possible to help develop educational materials and services to help patients better access and understand their medications. Once a product is on the market, real-world evidence can be collected to support its use, and health-economic outcomes research conducted to buttress reimbursement positions.

Medical Affairs

Clinical audiences should be engaged at multiple levels from regional influences up to guidelines authors. Medical science liaison field teams should be recruited, trained, and dispatched to the relevant scientific and medical audiences. Medical education, publication strategies, speaker programs, advisory boards, and disease awareness programs should be established. Conference symposiums can be organized to galvanize support among relevant stakeholders. These are powerful tools to ensure accurate and timely information about a new product is available to physicians. Post-marketing clinical trials may be required as well, for example as part of an accelerated approval agreement with regulators.

Manufacturing & Distribution

Decisions must be made around a drug's manufacturing and supply chain. Relationships with contract manufacturing organizations need to be established and managed, and for emerging therapeutic classes, the decision must be made whether to use a CMO in the first place, or to build out capabilities internally. Companies must also identify all the different relevant pharmacy channels that will be involved in getting their drugs to patients. This will vary depending on the type of product and by therapeutic area, as will relationships with specialty pharmacies and wholesalers.

Pharmacovilgilance

Once a drug hits the market, its use must be monitored to ensure it's working as intended, and that adverse events or safety issues that were unanticipated based on the drug's clinical trials aren't encountered. This pharmacovigilance will help inform a better understanding of a drug as it is used by greater numbers of patients and will serve to detect any manufacturing anomalies. Certain drugs will require risk evaluation and mitigation strategies (REMS), to monitor for serious and meaningful potential adverse events expected from the product's intended use. Here a biotech will need a dedicated team to negotiate with the FDA along the pathway to launch and to then execute the REMS program once the product is on the market. Specialized distribution channels may be necessary to understand how and where the product is being used, which often entails creation of tools for physicians to map and monitor their patients. Biotechs may hire a vendor for a REMS program, or choose to build out their own.

About ClearView Healthcare Partners

Founded in 2007, ClearView Healthcare Partners is a global strategy consulting firm serving the life science sector. The firm combines international industry knowledge and deep scientific expertise across a range of therapeutic areas with an extensive network of external stakeholders to deliver practical and actionable recommendations to our clients' most complex challenges. The firm's projects include cross-functional support at the corporate, franchise, and product levels for pharmaceutical, biotech, medical device, and diagnostics companies worldwide.

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