WHITE PAPER

LAUNCH COSTS—SPEND WISELY:
FIRST-IN-CLASS AND FOLLOW-ON LAUNCH COST ANALYSIS

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HEALTH ADVANCES

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Financial and resource planning for launch means balancing competing priorities. Success requires hard choices to reflect and realize strategic imperatives, and address market and competitive challenges.

Successful launch planning is a key driver associated with the commercial success of a pharmaceutical product. Previous Health Advances analysis demonstrated that 57% (see Figure 1) of drugs that exceed sales expectations at launch continue to outperform in subsequent years. Any delay or faulty execution caused by poor launch planning is likely to lead to unrecoverable loss in profits. Drug launch spending is high, as it requires the execution of many cost-intensive activities and resources across different operational areas to support pre-launch market development, launch and post-launch. Thus, an important component of launch planning is financial planning for full time employees (FTEs) and activities associated with pre- and post-launch. Accurate cost estimates enable organizations to better manage trade-offs and set expectations for investors, employees and customers.

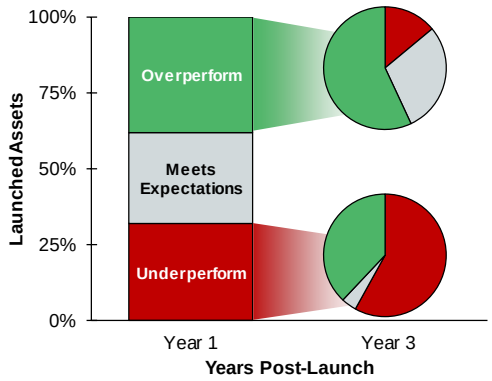

Figure 1: Importance of Launch Planning
Source: Health Advances Analysis

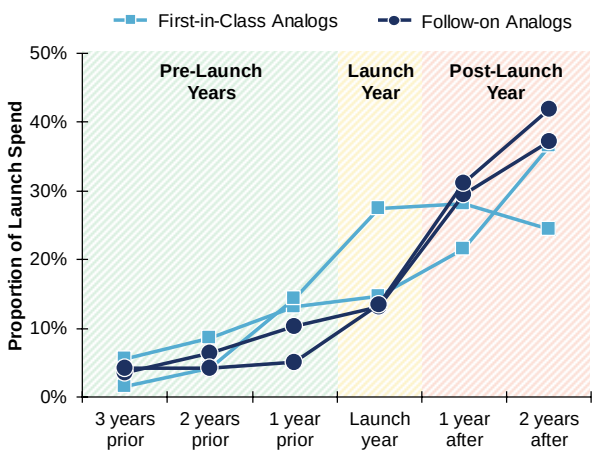

Figure 2: Distribution of Launch Spend of Analogs

Source: Health Advances interviews and analysis, analog companies' 10-Ks and materials.

Our previous study in July 2018, Launch Excellence: Once in a Life Cycle Opportunity, showed that single-product pharmaceutical companies spend an average of ~$125MM in the three years prior to launch. This underscores that launch is resource-intensive and launch planning requires appropriate financial and resource planning to ensure commercial success. In this analysis (see Figure 2), we assessed that single-product pharmaceutical companies spent between $475MM - $830MM three years prior to launch, the launch year, and two years after the launch year (total of six years). We extended the review period three years to capture and fully represent launch costs, especially in years following the product launch. The products analyzed were launched in both orphan and non-orphan disease patient populations.

We focused on analyzing the launch cost of first-in-class versus follow-on products because our hypothesis was that the order of entry significantly affects launch strategy and requirements. Of the fifteen drugs launched by single-product companies in 2012-2017, two first-in-class analogs (Drug 1 and Drug 2) and two follow-on analogs (Drug 3 and Drug 4) were selected for this case study. Both first-in-class analogs (see Figure 3) spent more upfront on market development (45%), whereas the follow-on product analogs spent only 30%. Unsurprising the post-launch spend of the first-in-class analogs is 55% of their total launch spend (from three years prior to launch to two years after launch). Follow-on product launches spent 70% on post-launch promotional activities, including large sales teams to compete in a competitive environment.

These analogs also show that competition level and callpoint type are significant determinants of launch costs and resource requirements. The commercialization costs of Drug 1 and Drug 2 (low competition indications) were ~40% of those of Drug 3 and Drug 4 (high competition indications). Salesforce size and associated support requirements are directly proportional to callpoint size, as demonstrated by the difference in both groups' expenses.

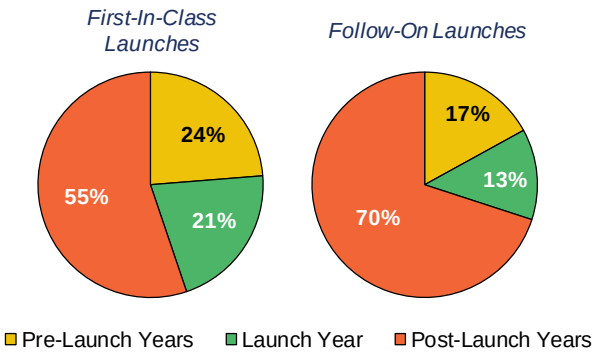

Figure 3: Average Distribution of Launch Spend

Source: Health Advances interviews and analysis, analog companies' 10-Ks and materials.

CASE STUDIES

Drug 1 is a first-in-class GI therapy. Significant investment on pre-launch activities was required to generate physician and patient enthusiasm and to ensure payer acceptance of the new therapy. Forty-eight percent of Drug 1's launch spend occurred on or before launch year, as many pre-commercial activities were conducted to develop the market. The manufacturer significantly expanded its commercial group prior to launch and has been growing the commercial group at ~20% post-launch to support potential indication expansion.

Drug 2 is a first-in-class biologic for an orphan indication. Forty-two percent of Drug 2's total launch spend is upfront because of the necessary market development for a first-in-class drug in an indication with no approved treatment. Pre-launch development included educating physicians on genetic testing, making genetic testing available and educating payers on the severity of the disease that the therapy targets. The manufacturer invested heavily in increased commercial headcount in order to support pre-launch development.

Drug 3 is a follow-on oncology drug, the second in its class. It was launched into a highly competitive space, and a third drug with the same mechanism of action was approved three months after Drug 3's launch. The success of Drug 3 was critically important for the manufacturer since the development of its lead product was halted. Sixty-seven percent of the launch cost for Drug 3 was spent in the two years after the product launch, primarily to ensure commercial success in a highly competitive space. Spending in the three years prior to launch and launch year only accounted for 20% and 13%, respectively, of the total launch spend. Finally, the company grew the salesforce aggressively from one year prior to launch to one-year post-launch.

Drug 4 is a follow-on, non-orphan, CNS modulator. It was also launched into an indication that had two similar drugs available. Similar to Drug 3, Drug 4 had less upfront investment and benefited from the increased awareness and medical education from previous competitor launches. The 3-year pre-launch spend and launch year spend each accounted for 16% of the total launch spend. In contrast, the post-launch commercialization spend for Drug 4 accounted for 68% of the total spend due to competition from other branded and generic options. Due to the broad callpoint, the company had to employ a large salesforce to target many physicians.

CONCLUSION

Launching a drug is a high-stakes and high-cost endeavor. In the years immediately preceding and proceeding launch, a company may spend $475MM - $830MM. Despite that scale of that investment, companies inevitably find that they must make hard choices and trade-offs in where and how they invest.

It is our view that good financial plans reflect strong strategies, where the trade-offs are determined by the strategic priorities. In the examples above we show how first-in-class drugs prioritized market-building activities prior to and during the launch year. These companies invested ~45% of their total launch spending on activities such as disease awareness campaigns, continuing medical education, etc. In contrast, companies with follow-on products spent more on promotional activities (70%) after drug launch. These companies tended to invest in activities that sharpened their differentiation relative to competitors including a large salesforce, post-marketing studies for label expansion, physician communication and direct-to-consumer advertising.

This analysis illustrates the importance of market and competitive circumstances in the application of launch strategy vis-à-vis financial and resource planning. Order of entry is a significant and obvious variable and it is therefore an attractive means of illustrating that broader principle. However, all launches are unique and there are other variables that will affect launch strategy and thus financial plans. In the examples here, significant differences in the approach to launch were motivated not just by order of entry, but also by the intensity of competition and the callpoint / treating physician. Thus, launch planning requires careful consideration of the market and competitive environment. That understanding will underpin a strong strategy from which a financial plan (and other decisions) should follow. That financial plan will reflect the strategy in a series of difficult trade-offs as limited resources are allocated across different activities. Launch planning is a comprehensive exercise that includes market and competitive analysis, thoughtful strategy, focused tactical plans and realistic financial and resource planning. In successful launches, like the examples here, these pieces should build on and support each other.

ANALYSIS AND METHODS

To estimate the launch cost of pharmaceutical products, we started by identifying a list of public companies that launched a single product between 2012-2017. Public single-product companies are chosen because most of their SG&A spending can be attributed to the launch of their first product and hence, the SG&A spending is a good approximation of the launch cost. The time range of 2012-2017 was selected so that there are a few years and pre- and post-launch spending data available. To ensure that our launch cost estimates are based on successful launches, we filtered the list of products to select the ones where the first two years of sales are in-line with the pre-launch analyst consensus forecast. Based on the criteria described above, we identified fifteen single-product companies and selected four successful launches between 2012-2017 for our case studies, two of which were first-in-class launches and two were follow-on launches. In each case study, we estimated the yearly launch spending based on the SG&A from three years prior to launch to two years after launch. We compared how the distribution of launch spending was influenced by the order of entry based on the four case studies.

When appropriate, we made the necessary adjustments to ensure the launch cost estimates better account for all the non-clinical development spending related to drug launch. In one example, the commercialization-related expense was classified under R&D instead of under SG&A prior to the product launch. Hence, we scaled the commercialization and personnel-related expenses and added them to the SG&A to arrive at an estimated launch spend. In a second example, the commercialization activity was managed by a separate partner. We scaled the sales and marketing spending reported in a later year by the actual sales and added the estimated sales and marketing spending to prior year's SG&A.

ABOUT HEALTH ADVANCES

Health Advances https://www.healthadvances.com is a global strategy consulting firm that focuses exclusively on the healthcare industry. We have unique capabilities to provide launch planning services founded on actionable, nuanced market insights and flexible launch planning solutions. These capabilities include:

- Deep experience turning technological insight, clinical understanding, market knowledge and competitive intelligence into compelling strategies.
  - Clients include top-five pharma as well as preclinical and clinical-stage start-ups.
  - Broad project experience in all areas related to launch (e.g., product positioning, stakeholder mapping, etc.).
- Robust primary and secondary market research capabilities to develop critical market insights.
  - Primary research experience includes in-depth interviews, focus groups, and surveys. We leverage a proprietary database of >45,000 expert contacts from all major markets.
  - Secondary research capabilities include access to a knowledge management center with research experts; numerous databases and publications; and prior work.
- Proprietary, Microsoft Excel-based customizable launch excellence toolbox to enable rapid and efficient launch planning. Our tool details activities (including interdependencies, timelines, and costs) for each function in a user-friendly interface.

ABOUT THE AUTHORS

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